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

July 2020

DZHK Item Catalogue

The DZHK aims to standardise data collection amongst its clinical studies in order to enable secondary use of the data across studies. Therefore, Standard Operating Procedures (SOPs) as well as acquisition modules for common cardiological assessment procedures are available. This Item Catalogue provides an overview of the existing DZHK-wide standardised acquisition modules. The attached secuTrial® forms contain each module's items with their respective expressions and intend to serve as a guide to study leaders and coordinators for the preparation of the eCRF. The basic data set contains 42 items, which are mandatory to be collected in every DZHK study. Other modules can be chosen depending on the study protocol. In order to maintain cross-study comparability, we recommend using as many of the harmonised items as possible. In addition, the modules can be extended by study-specific items.

Contents

Harmonised modules with corresponding SOPs

For the following harmonised modules there are SOPs that describe how to perform the examinations. The corresponding SOP for each module can be found on the DZHK website.

Anamnesis and Clinical Diagnosis (incl. Basic Data Set) (DZHK-SOP-K-02)

The module Anamnesis and Clinical Diagnosis (incl. Basic Data Set) is used to accurately record known cardiovascular risk factors, previous diagnoses and interventions. The collected findings enable a detailed assessment of a patient's cardiovascular risk.

The module contains among others the mandatory basic data set with 42 items. In the following, these items are labeled with ** (double asterisk).

The examinations ought to be performed according to DZHK-SOP-K-02.

DZHK-SOP-K-02:
- Version V1.0
- Valid as of: 01.09.2014
- https://dzhk.de/en/resources/sops/

State of the attached secuTrial® form: 13.07.2020

Anamnesis and Clinical Diagnoses (incl. Basic Data Set**) (13.07.2020 - 10:34:54 (MESZ))

General information relating to the anamnesis

I. Date of examination** ☐ tt.mm.jjjj
○ unknown ○ not assessed

II. 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. Physical Examination and Socio-demographic Data

1.1. Sex** ○ male ○ female ○ diverse ○ unknown ○ not assessed

1.2. Date of Birth** ☐ mm.jjjj

1.3. Height** ☐ cm
○ unknown ○ not assessed
○ estimated ○ measured

Hilfe: Height is measured in the standing position, without shoes and without head covering. Preferentially, measured data should be collected; only when this is not possible (e.g. in the case of bed- ridden patients) should one estimate the values or resort to information provided by the proband

1.4. Weight** ☐ kg
○ unknown ○ not assessed
○ estimated ○ measured

Hilfe: Weight is measured in normal street clothing, without a jacket and without shoes. Preferentially, measured data should be collected; only when this is not possible (e.g. in the case of bed- ridden patients) should one estimate the values or resort to information provided by the proband

1.5. Ethnicity: Caucasian** ○ yes ○ no ○ unknown ○ not assessed

Hilfe: A person's ethnic origin is defined by their ancestry in relation to a specific ethnic group. This can be determined biologically and/or geographically on the basis of membership of a certain settlement group. Accordingly, a person's skin colour can also be broadly defined. The colour spectrum can be differentiated from light to dark skin colour

1.6. Black skin colour?** ○ yes ○ no ○ unknown ○ not assessed

1.7. Family history of myocardial infarction or stroke in parents, siblings or children under the age of 65 for women or under 55 for men** ○ yes ○ no ○ unknown ○ not assessed

Hilfe: Is defined as a medically diagnosed myocardial infarction or stroke in one or both biological parents, biological siblings (including half-siblings) or biological children, provided the female relative was under age 65, or the male relative under age 55 (when the myocardial infarction/stroke occurred)

2. Cardiovascular risk factors

2.1. Diabetes mellitus** ○ yes ○ no ○ unknown ○ not assessed

Hilfe: Is defined as diabetes which has been diagnosed and/or treated by a doctor.
The American Diabetes Association criteria are:
haemoglobin A1c ≥ 6.5 % or a fasting blood glucose level of ≥ 126 mg/dl or a 2-hour blood glucose level of ≥ 200 mg/dl in the oral glucose tolerance test

2.2. Arterial hypertension** ○ yes ○ no ○ unknown ○ not assessed

Hilfe: Is defined as a current or previous diagnosis of arterial hypertension which was diagnosed and/or is being treated by a doctor. Treatment can consist of e.g. dietary changes, physical activity and/or medication. Systolic blood pressure values ≥ 140 mmHg and/or diastolic blood pressure values ≥ 90mmHg measured by a doctor on at least two separate days after a 5- minute resting phase qualify for a diagnosis of arterial hypertension

2.3. Dyslipidaemia** ○ yes ○ no ○ unknown ○ not assessed

Hilfe: Is defined as a current or previous diagnosis of dyslipidaemia which was diagnosed and/or is being treated by a doctor.
One or more of the following criteria:
total cholesterol ≥ 200 mg/dl,
LDL cholesterol ≥ 130 mg/dl,
HDL cholesterol < 40 mg/dl (men) and < 50 mg/dl (women)

2.4. Smoker** ○ yes ○ no ○ ex-smoker (stopped ≥ 6 mth. ago) ○ unknown ○ not assessed

Ex-smoker since** ☐ jjjj
○ unknown ○ not assessed

Pack years* ☐
○ unknown ○ not assessed

Hilfe: Is defined as current or previous use of cigarettes, cigars, pipes or smokeless tobacco. “Yes” for daily or occasional smoking (≥ 1x/month);
“Ex-smoker“ for abstinence of more than 6 months; ex-smoker since …; “No“ for “never smoked“.
Pack years is the product of the number of years of cigarette smoking multiplied by the average number of packs smoked per day. Example: A patient who has smoked 2 packets of cigarettes per day for 20 years has 40 pack years

2.5. Drinks per week* ☐
○ unknown ○ not assessed

Hilfe: Drinks per week is the number of alcoholic drinks consumed per week. One drink is defined as e.g. 0.25 l of beer, 0.1 l of wine or 0.02 l of spirits. Example: A patient who drinks 0.5 l beer on average two times every week has 4 drinks per week

2.6. Medically diagnosed alcoholism** ○ yes ○ no ○ unknown ○ not assessed

Hilfe: Is defined as a current or previous diagnosis of alcoholism which was diagnosed and/or is being treated by a doctor

2.7. Renal failure* ○ yes ○ no ○ unknown ○ not assessed

2.7.1. Degree of renal dysfunction*
○ 1 – eGFR 90 ml/min or higher
○ 2 – eGFR 60–89 ml/min
○ 3 – eGFR 30-59 ml/min
○ 4 – eGFR 15-29 ml/min
○ 5 – eGFR < 15 ml/min or current dialysis dependency
○ unknown
○ not assessed

Hilfe: This includes all patients who exhibit reduced renal function. If known, the degree of renal dysfunction should be quantified by the estimated Glomerular Filtration Rate (eGFR)

2.8. Current Dialysis Dependency** ○ yes ○ no ○ unknown ○ not assessed

Hilfe: Is defined as current regular, at least weekly, renal replacement therapy (including haemodialysis and peritoneal dialysis) within the last 30 days

3. Cardiac Diagnoses (Anamnesis and Previous Findings)

3.1. Coronary heart disease** ○ yes ○ no ○ unknown ○ not assessed

Hilfe: Coronary heart disease is defined as a current or previous diagnosis by a doctor with one or more of the following criteria:
- coronary artery stenosis of ≥ 50 % (diagnosed by cardiac catheterization or another direct coronary artery imaging method),
- prior coronary artery bypass operation,
- prior percutaneous coronary intervention,
- arteriosclerosis-induced myocardial infarction

3.2. Status post myocardial infarction** ○ yes ○ no ○ unknown ○ not assessed

Hilfe: Acute myocardial infarction is defined as demonstrated evidence of myocardial necrosis in a clinical setting which is consistent with myocardial infarction. One or more of the following criteria must apply:
- Evidence of an increase or decrease of a cardiac biomarker (preferably troponin) with at least one value above the 99 % percentile of the upper reference limit and, additionally, at least one of the following factors:
- symptoms of ischaemia, angina pectoris,
-ECG changes indicative of new ischaemia, e.g. ST segment elevations or a new left bundle branch block, development of pathological Q waves in the ECG,
- imaging studies show a loss of viable myocardial tissue or new regional wall motion abnormalities,
- angiographic evidence of stenosis/blood vessel blockage

3.3. Cardiomyopathy**
If the response to this question is "yes", please complete the "Cardiomyopathy Diagnostics" form.
○ yes ○ no ○ unknown ○ not assessed

Hilfe: Is defined as a diagnosis by a doctor of a primary heart muscle disease.

3.4. Heart failure**
○ yes ○ no ○ unknown ○ not assessed

3.4.1. S.p. decompensation*
○ yes ○ no ○ unknown ○ not assessed

3.4.2. Initial diagnosis of heart failure*
☐ jjjj
○ unknown ○ not assessed

3.4.3. Current NYHA class*
○ I ○ II ○ III ○ IV ○ unknown ○ not assessed

Hilfe: Is defined as a current or previous diagnosis and documentation by a doctor of heart failure, based on the following symptoms: shortness of breath with mild exertion, recurrent shortness of breath when sitting, fluid overload or pulmonary rales, distention of the neck veins, pulmonary oedema on physical examination or pulmonary oedema on chest x-rays. Documentation of reduced left ventricular function alone in the absence of clinical signs of heart failure does not meet the criteria for heart failure.

NYHA class: Classification of the patient's symptoms based on the New York Heart Association classification of heart failure:
- NYHA I: No symptoms
- NYHA II: Symptoms with heavy physical exertion
- NYHA III: Symptoms with light physical exertion
- NYHA IV: Symptoms while at rest

3.5. Atrial fibrillation/flutter**
○ yes ○ no ○ unknown ○ not assessed

Hilfe: Is defined as a current or previous diagnosis by a doctor of atrial fibrillation or atrial flutter. It is defined as an episode of atrial fibrillation or atrial flutter lasting at least 30 seconds or atrial fibrillation with evidence on the surface ECG or during pacemaker interrogation

3.6. Current or previous diagnosis by a doctor of heart valve disease**
○ yes ○ no ○ unknown ○ not assessed

Hilfe: Is defined as heart valve disease (incompetence or stenosis), which has been diagnosed and/or treated by a doctor

3.7. Diagnosis by a doctor of endocarditis*
○ yes ○ no ○ unknown ○ not assessed

Hilfe: If at any time, currently or in their previous medical history, a patient has been diagnosed by a doctor with endocarditis (heart valve inflammation), it will be documented here

3.8. Diagnosis by a doctor of a congenital heart defect**
○ yes ○ no ○ unknown ○ not assessed

Hilfe: If a patient has a known congenital heart defect, it will be coded here. Congenital heart defects include shunt defects (e.g. ASD, VSD), congenital valvular heart diseases (e.g. pulmonary stenosis) and cardiomyopathies diagnosed in the first five years of life. Patent foramen ovale does not belong to the class of congenital heart defects

4. Previous cardiovascular interventions

4.1. Interventional coronary revascularization**
○ yes ○ no ○ unknown ○ not assessed

4.1.1. If yes, date of last intervention*
☐ mm.jjjj
○ unknown ○ not assessed

Hilfe: Interventional coronary revascularization is defined as a percutaneously performed intervention on a coronary artery,

e.g. PTCA, stent implantation, rotablation et cetera. Purely diagnostic measures (intravascular ultrasound (IVUS), optical coherence tomography (OCT)) as well as functional measurements (e.g. fractional flow reserve (FFR) measurements) are not interventional coronary revascularization procedures.

4.2. Peripheral revascularization* ○ yes ○ no ○ unknown ○ not assessed

4.2.1. If yes, date of last intervention* [ ] mm.jjjj
○ unknown ○ not assessed

Hilfe: Peripheral revascularization is defined as a percutaneously performed intervention on a peripheral artery (not including coronary arteries or bypass grafts) e.g. PTA, stent implantation, rotablation et cetera

4.3. Coronary bypass operation** ○ yes ○ no ○ unknown ○ not assessed

4.3.1. If yes, date of last intervention* [ ] mm.jjjj
○ unknown ○ not assessed

Hilfe: Coronary bypass operation is defined as operative myocardial revascularization by means of a bypass graft (e.g. from the internal thoracic artery or using arterial/venous grafts). Where applicable, the date of the most recent operation should be entered

4.4. Other vascular operation* ○ yes ○ no ○ unknown ○ not assessed

4.4.1. If yes, date of last intervention* [ ] mm.jjjj
○ unknown ○ not assessed

Hilfe: Other vascular operation is defined as an operation of any kind on non-coronary blood vessels. Where applicable, the date of the most recent operation should be entered

4.5. Heart valve operation** ○ yes ○ no ○ unknown ○ not assessed

4.5.1. If yes, date of last intervention* [ ] mm.jjjj
○ unknown ○ not assessed

Hilfe: Heart valve operation is defined as a minimally invasive percutaneous (catheter-based) or open surgical procedure on a heart valve. This includes the surgical reconstruction/replacement of heart valves, valvuloplasty procedures as well as interventional treatment of heart valve diseases (e.g. dilation, implantation of protheses, heart valve repair).

4.5.2. Type of last intervention* ○ open surgery ○ catheter-based ○ unknown ○ not assessed

If open surgery* ○ replacement ○ reconstruction ○ unknown ○ not assessed

4.5.3. If more than one procedure on one valve was performed, please provide details of the last OP (= current state)*

Aortic valve* ○ native ○ reconstruction ○ mechanical prosthesis ○ bioprosthesis (open) ○ TAVI ○ unknown ○ not assessed

○ transfemoral ○ transapical ○ transaortal ○ unknown ○ not assessed

Pulmonic valve* ○ native ○ reconstruction ○ mechanical prosthesis ○ bioprosthesis (open) ○ unknown ○ not assessed

Mitral valve* ○ native ○ reconstruction ○ mechanical prosthesis ○ bioprosthesis (open) ○ clipping ○ unknown ○ not assessed

Triscuspid valve* ○ native ○ reconstruction ○ mechanical prosthesis ○ bioprosthesis (open) ○ unknown ○ not assessed

4.6. Implanted pacemaker or defibrillator?** ○ yes ○ no ○ unknown ○ not assessed

4.6.1. If yes, what was implanted?* ○ pacemaker ○ defibrillator ○ unknown ○ not assessed

4.6.2. If yes, date of last event (implantation/exchange)* [ ] mm.jjjj
○ unknown ○ not assessed

4.6.3. If pacemaker, please give pacemaker type* ○ 1-chamber pacemaker (e.g. VVI) ○ 2-chamber pacemaker (e.g. DDD) ○ biventricular pacemaker (CRT) ○ unknown ○ not assessed

Hilfe: Implantable cardiac pacemaker or defibrillator is defined as status post implantation of a cardiac pacemaker or cardio-verter defibrillator (ICD)

4.7.	**Other devices***	○ yes ○ no ○ unknown ○ not assessed
4.7.1.	**Cardiac contractility modulation (CCM)***	○ yes ○ no ○ unknown ○ not assessed
4.7.2.	**Intra-aortic balloon pump (IABP)***	○ yes ○ no ○ unknown ○ not assessed
4.7.3.	**Other devices***	

Hilfe: Other devices are defined as other implantable devices for cardiac/vascular support. This includes devices for cardiac contractility modulation, for neuromodulation (e.g. vagus nerve stimulator, baroreceptor stimulator), intra-aortic balloon pumps and left ventricular cardiac assist devices

4.8.	**S.p. myocardial biopsy***	○ yes ○ no ○ unknown ○ not assessed
4.8.1.	**Date of myocardial biopsy***	☐ mm.jjjj ○ unknown ○ not assessed
4.8.2.	**Biopsy sites***	○ left ventricle ○ right ventricle ○ left and right ventricle ○ unknown ○ not assessed

Hilfe: Status post myocardial biopsy is defined as status post bioptic removal of tissue from the heart muscle (e.g. during a right/left catheter examination or operation)

5. Current secondary diagnoses

5.1.	**PAOD****	○ yes ○ no ○ unknown ○ not assessed
5.1.1.	**Fontaine stage***	○ I ○ IIa ○ IIb ○ III ○ IV ○ unknown ○ not assessed
5.1.2.	**Acute ischaemic occlusion***	○ yes ○ no ○ unknown ○ not assessed

Hilfe: PAOD is defined as a current or previous diagnosis by a doctor of peripheral arterial occlusive disease (in the blood vessels of the pelvis and legs, or from the upper extremity of the subclavian artery to the distal extremity). Renal, coronary, cerebral and mesenteric blood vessels and aneurysms are excluded. Possible symptoms are:
- intermittent claudication,
- pain at rest,
- amputation due to severe arterial vascular insufficiency,
- vascular reconstruction, bypass operation or percutaneous revascularization,
- a positive non-invasive test (e.g. ankle-brachial index of ≤ 0.9, pathological TCPO2 measurement, evidence of 50 % or greater stenosis of a peripheral artery by Doppler/duplex sonography, CT, MRT, or angiography)

5.2.	**Stroke/TIA****	○ yes ○ no ○ unknown ○ not assessed
5.2.1.	**Date***	☐ mm.jjjj ○ unknown ○ not assessed
5.2.2.	**Aetiology***	○ ischaemic ○ haemorrhagic ○ unknown ○ not assessed
5.2.3.	**Diagnosis***	○ TIA ○ stroke ○ unknown ○ not assessed
5.2.4.	**Stroke severity***	○ minor ○ major ○ unknown ○ not assessed
5.2.5.	**Consequences of the stroke***	○ disabling ○ non-disabling ○ unknown ○ not assessed

Hilfe: Stroke/TIA is defined as a current or previous diagnosis by a doctor of:
- Ischaemic stroke: Infarction of tissue of the central nervous system, either symptomatic or silent (asymptomatic).
- Transient ischaemic attack (TIA): A transient episode of neurological dysfunction caused by focal brain, spinal cord or retinal ischaemia without acute infarction which resolves completely within 24 hours. This definition is not met by chronic (non-vascular) neurological diseases or other acute neurological diseases such as metabolic or ischaemic encephalopathy resulting from general hypoxia (e.g. in the case of respiratory insufficiency, following a cardiac/circulatory arrest).
- Haemorrhagic stroke: Neurological dysfunction caused by intra-cranial bleeding.
- Stroke where there is uncertainty as to whether the cause was haemorrhagic or ischaemic

5.3.	**Chronic lung disease****	○ yes ○ no ○ unknown ○ not assessed

Hilfe: Chronic lung disease is defined as a diagnosis by a doctor of a chronic lung disease (e.g. COPD, chronic bronchitis, pulmonary fibrosis) and/or their pharmacological treatment, for example, with inhalable or oral pharmaceuticals

5.4.	**Primary pulmonary Hypertension***	○ yes ○ no ○ unknown ○ not assessed

Hilfe: Primary pulmonary hypertension is defined as a diagnosis and/or treatment by a doctor of primary pulmonary hypertension

5.5. Depression**
If the response to this question is "yes", please complete the "Depression" form.
○ yes ○ no ○ unknown ○ not assessed

Hilfe: Depression is defined as a current or previous diagnosis by a doctor. The administration of antidepressants alone does not qualify for a diagnosis of depression

5.6. Cancer more than 5 years ago** ○ yes ○ no ○ unknown ○ not assessed

Hilfe: Cancer more than 5 years ago is defined as a current or previous diagnosis of a malignant cancer. Basal cell carcinoma is not counted as a malignancy

5.7. Cancer within the last 5 years* ○ yes ○ no ○ unknown ○ not assessed

Hilfe: Cancer within the last 5 years is defined as malignant cancer diagnosed by a doctor less than 5 years ago. Basal cell carcinoma is not counted as a malignancy

6. Blood pressure after 5 minutes at rest

6.1. Systolic**
☐ mmHg
○ unknown ○ not assessed

6.2. Diastolic**
☐ mmHg
○ unknown ○ not assessed

Hilfe: The systolic blood pressure should be measured using a blood pressure monitor that is serviced and calibrated on a regular basis. Where possible, tested devices should be used for epidemiological trials. Blood pressure measurement begins after the patient has been at rest for at least 5 minutes. Three readings are taken at intervals of 2 minutes; the average values of the second and third readings are entered into the CRF

7. Heart rate after sitting down for 5 minutes

7.1. Heart rate**
☐ per minute
○ unknown ○ not assessed

Hilfe: Measurement of the heart rate begins after the patient has been sitting down for at least 5 minutes. This should take place after measuring the blood pressure. This should be done manually by counting the radial pulse for 30 seconds; that value multiplied by two should be entered into the CRF (beats/minute)

8. Further diagnoses

8.1. Dyspnoea on exertion* ○ yes ○ no ○ unknown ○ not assessed

Hilfe: A patient who complains of shortness of breath with physical exertion within the last 14 days and/or at present

8.2. Dyspnoea at rest* ○ yes ○ no ○ unknown ○ not assessed

Hilfe: A patient who complains of shortness of breath even when at rest (e.g. when talking) within the last 14 days and/or at present

8.3. Peripheral oedema* ○ yes ○ no ○ unknown ○ not assessed

Hilfe: A patient who complains of bilateral accumulation of fluid in the extremities within the last 14 days and/or at present, whether clinically observed or perceived by the patient

8.4. Jugular venous distention* ○ yes ○ no ○ unknown ○ not assessed

Hilfe: The diagnostic test for jugular venous distention is conducted with the upper body of the patient positioned at a 45° angle

8.5. Pulmonary rales* ○ yes ○ no ○ unknown ○ not assessed

Hilfe: Pulmonary rales are defined as sounds heard over the lung during auscultation which are created by the movement of fluids and/or secretions during inspiration and expiration. They belong to the category of adventitious breath sounds overlying normal breath sounds and indicate a pathological change in the lung

9. Laboratory diagnostics (blood)

For clinically stable patients, not more than 1 week old, otherwise up to date!

9.1.	**Date blood sample was taken****	☐ tt.mm.jjjj Where applicable, give date for the latest value ○ unknown ○ not assessed
9.2.	**Haemoglobin****	☐ ○ unknown ○ not assessed
	Unit**	○ mmol/l ○ g/dl
9.3.	**Creatinine (serum, heparin plasma)****	☐ ○ unknown ○ not assessed
	Unit**	○ µmol/l=nmol/ml ○ mg/dl
9.4.	**Total cholesterol****	☐ ○ unknown ○ not assessed
	Unit**	○ mmol/l ○ mg/dl

10. The next three anamnestic questions are for women only

10.1.	**Menopause?****	○ yes ○ no ○ unknown ○ not assessed
10.1.1	**Year of menopause****	☐ jjjj ○ unknown ○ not assessed
10.2.	**Day last menstrual period began****	☐ tt.mm.jjjj ○ unknown ○ not assessed

Mögliche Angaben

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

1)

1
2
3

Biobanking Basic Set (DZHK-SOP-B-02)

The module Biobanking Basic Set is used to document the quality of samples of the Basic Set. The Basic Set consists of EDTA plasma, serum, citrate plasma, buffy coat and urine.

The processing and storage of the material ought to be performed according to DZHK-SOP-B-02.

DZHK-SOP-B-02:
- Version V1.1
- Valid as of: 15.12.2014
- https://dzhk.de/en/resources/sops/

The corresponding secuTrial® form is only available in German.
State of the attached secuTrial® form: 14.07.2020

Biomaterial-Begleitschein Basis-Set (9.6.)

1. Basis-Set (Allgemeine Informationen)

1.1.	**Biomaterial-ID Basis Abnahmeset**	☑ ☐
1.2.	**Studie**	☐
1.3.	**Einrichtungscode**	☐
1.3.	**Einrichtungscode**	☐
1.3.	**Einrichtungscode**	☐
1.3.	**Einrichtungscode**	☐
1.3.	**Einrichtungscode**	☐
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1.3.	**Einrichtungscode**	☐
1.3.	**Einrichtungscode**	☐
1.3.	**Einrichtungscode**	☐
1.3.	**Einrichtungscode**	☐

2. Blut- und Urinprobe

2.1.	**Blutentnahme durch**	☐
2.2.	**Zeitpunkt der Blutentnahme**	☐ tt.mm.jjjj hh:mm
2.3.	**Blutentnahme**	○ venös ○ arteriell ○ unbekannt ○ nicht erhoben
2.4.	**Position bei Blutentnahme**	○ sitzend ○ liegend ○ unbekannt ○ nicht erhoben
	Dauer der Position des Patienten/Probanden vor Entnahme:	☐ min. ☐ ≥ 60 min.
2.5.	**Zeitpunkt der Urinabgabe (Klinik)**	☑ ☐ tt.mm.jjjj hh:mm
2.6.	**Abstand zur letzten Nahrungsaufnahme**	○ < 8 Std. ○ >= 8 Std. ○ unbekannt ○ nicht erhoben
	Wenn bekannt, bitte die Gesamtstunden angeben	☑ ☐ Std.
2.7.	**Ernährung parenteral**	○ ja ○ nein ○ unbekannt ○ nicht erhoben
2.8.	**Menstruation bei Uringewinnung (bei Frauen)**	○ ja ○ nein ○ unbekannt ○ nicht erhoben
	Neue DZHK Basis-Sets (bestellt ab Januar 2020) enthalten nur noch je 1 Primärröhrchen.	
2.9.	**Anzahl gefüllter Primärgefäße**	

Serum	○0 ○1 x 10 ml
EDTA-Plasma	○0 ○1 ○2 (BD)
Citrat-Plasma	○0 ○1 ○2
Urin	○0 ○1

2.10. Zeitpunkt Eingang im Labor

Datum und Uhrzeit	☑ [ ] tt.mm.jjjj hh:mm
Ansprechpartner	☑ [ ]
Wenn Urin-Eingang unterschiedlich von Blut:	☑ [ ] tt.mm.jjjj hh:mm
Ansprechpartner	☑ [ ]

2.11. Ende der Zentrifugation

Datum und Uhrzeit	☑ [ ] tt.mm.jjjj hh:mm
wenn Urin-Eingang unterschiedlich von Blut, hier bitte Zeiten für Urin eintragen:	☑ [ ] tt.mm.jjjj hh:mm

2.12. Probenbeschaffenheit (Blut)

Ist die Probenbeschaffenheit unauffällig?	○ja ○nein ○unbekannt ○nicht erhoben
Ist die Probenbeschaffenheit lipämisch?	○ja ○nein ○unbekannt ○nicht erhoben
Ist die Probenbeschaffenheit ikterisch?	○ja ○nein ○unbekannt ○nicht erhoben
Ist die Probenbeschaffenheit hämolytisch?	○ja ○nein ○unbekannt ○nicht erhoben

2.13. Probenbeschaffenheit (Urin)

Ist die Probenbeschaffenheit unauffällig?	○ja ○nein ○unbekannt ○nicht erhoben
Ist die Probenbeschaffenheit trüb?	○ja ○nein ○unbekannt ○nicht erhoben
Ist die Probenbeschaffenheit blutig?	○ja ○nein ○unbekannt ○nicht erhoben

2.14. Anzahl gefüllter Aliquotgefäße

Alle 10 Serumgefäße [300µl] gefüllt?	○ja ○nein ○unbekannt ○nicht erhoben
Falls nicht, bitte spezifizieren	☑ [ ] (max 10)
Alle 10 EDTA-Gefäße [300µl] gefüllt?	○ja ○nein ○unbekannt ○nicht erhoben
Falls nicht, bitte spezifizieren	☑ [ ] (max 10)
Alle 4 Citrat-Gefäße [300µl] gefüllt?	○ja ○nein ○unbekannt ○nicht erhoben
Falls nicht, bitte spezifizieren	☑ [ ] (max 4)
Alle 8 Urin-Gefäße [300µl] gefüllt?	○ja ○nein ○unbekannt ○nicht erhoben
Falls nicht, bitte spezifizieren	☑ [ ] (max 8)
Alle 2 Buffy Coat-Gefäße [<300µl] gefüllt?	○ja ○nein ○unbekannt ○nicht erhoben
Falls nicht, bitte spezifizieren	☑ [ ] (max 2)
Kommentar	[ ]

2.15a. Zeitpunkt Einfrieren der Aliquot [ ]

(s) bei -80°C bei Zwischenlagerung am Studienzentrum

Datum und Uhrzeit ☑ tt.mm.jjjj hh:mm

Ansprechpartner ☑

2.15. Zeitpunkt Einfrieren aller Aliquots bei -80°C (Serum, EDTA-Plasma, Citrat-Plasma, Urin, Buffy Coat)

Datum und Uhrzeit ☑ tt.mm.jjjj hh:mm

Ansprechpartner ☑

3. Besonderheiten

Cardiac Catheter (DZHK-SOP-K-05)

The module Cardiac Catheter is used to document a cardiac catheter examination. This examination enables a better phenotyping of cardiomyopathies, an assessment of the degree of severity and of the prognosis.

The examinations ought to be performed according to DZHK-SOP-K-05.

DZHK-SOP-K-05:
- Version V1.0
- Valid as of: 01.09.2014
- https://dzhk.de/en/resources/sops/

State of the attached secuTrial® form: 13.07.2020

Cardiac catheter

(13.07.2020 - 10:34:54 (MESZ))

Examination details

I. 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. Right heart catheterisation

1.1. Was the right heart catheterisation performed?*

○ yes ○ no ○ unknown ○ not assessed

1.2. Date of examination*

☐ tt.mm.jjjj
○ unknown ○ not assessed

1.3. Left ventricular end-diastolic pressure (LVEDP)*

☐ mmHg
○ unknown ○ not assessed

1.4. Heart time volume*

☐ l/min
○ unknown ○ not assessed

1.5. Systolic pulmonary artery pressure*

☐ mmHg
○ unknown ○ not assessed

1.6. Diastolic pulmonary artery pressure*

☐ mmHg
○ unknown ○ not assessed

1.7. Mean pulmonary artery pressure*

☐ mmHg
○ unknown ○ not assessed

1.8. Pulmonary capillary pressure (PCWP)*

☐ mmHg
○ unknown ○ not assessed

1.9. Mean RA*

☐ mmHg
○ unknown ○ not assessed

1.10. Central venous oxygen saturation*

☐ %
○ unknown ○ not assessed

1.11. Arterial oxygen saturation*

☐ %
○ unknown ○ not assessed

1.12. Transpulmonary gradient*

☐ mmHg
○ unknown ○ not assessed

1.13. Pulmonary vascular resistance*

☐ dyn*s*cm-5
○ unknown ○ not assessed

1.14. Systemic vascular resistance (SVR)*

☐ dyn*s*cm-5
○ unknown ○ not assessed

1.15. Body height*	☐ cm ○ unknown ○ not assessed
1.16. Weight*	☐ kg ○ unknown ○ not assessed
1.17. Haemoglobin*	☐ ○ unknown ○ not assessed
Unit	☐ 2)

2. Left heart catheterisation

2.1. Was the left heart catheterisation performed?*	○ yes ○ no ○ unknown ○ not assessed
2.2. Date of recording*	☐ tt.mm.jjjj ○ unknown ○ not assessed
2.3. Coronary heart disease (CHD)*	○ none ○ 1-vessel CHD ○ 2-vessel CHD ○ 3-vessel CHD ○ unknown ○ not assessed
2.4. Pump function*	○ good ○ mildly impaired ○ moderately impaired ○ severely impaired ○ unknown ○ not assessed

3. Myocardial biopsy

3.1. Was the myocardial biopsy performed?*	○ yes ○ no ○ unknown ○ not assessed
3.1.1. Date of recording*	☐ tt.mm.jjjj ○ unknown ○ not assessed
3.1.2. Ventricle*	○ LV ○ RV ○ LV and RV ○ unknown ○ not assessed
3.1.3. Institution performing the assessment*	
3.2. Previous biopsies available*	○ yes ○ no ○ unknown ○ not assessed
3.2.1. Date of previous biopsy*	☐ tt.mm.jjjj ○ unknown ○ not assessed
3.2.2. Previous diagnosis*	
3.2.3. Number of biopsies*	☐ ○ unknown ○ not assessed
3.2.4. Ventricle*	○ LV ○ RV ○ LV and RV ○ unknown ○ not assessed
3.2.5. Institution performing the assessment*	

4. Storage diseases

4.1. Storage diseases*	○ yes ○ no ○ unknown ○ not assessed
4.2. Amyloidosis*	○ yes ○ no ○ unknown ○ not assessed
4.3. Other storage disease*	○ yes ○ no ○ unknown ○ not assessed
Please specify*	

5. Histological/immunohistological/viral findings report

5.1. Histological findings report available*	○ yes ○ no ○ unknown ○ not assessed
5.1.1. Dallas criteria positive (including cell analysis)*	○ yes ○ no ○ unknown ○ not assessed
5.1.2. Positive for fibrosis*	○ yes ○ no ○ unknown ○ not assessed
Demonstration of fibrosis*	○ biopsy ○ MRI ○ both ○ unknown ○ not assessed
Quantified (late gadolinium enhancement)*	○ yes ○ no ○ unknown ○ not assessed ☐ % ○ unknown ○ not assessed
Localisation (late gadolinium enhancement) (multiple answers are possible)*:	
left ventricular*	☐
right ventricular*	☐
septum*	☐
5.1.3. Necrosis*	○ yes ○ no ○ unknown ○ not assessed
5.1.4. Granulomas*	○ yes ○ no ○ unknown ○ not assessed
5.1.5. Giant cells*	○ yes ○ no ○ unknown ○ not assessed
5.1.6. Myocyte hypertrophy*	○ yes ○ no ○ unknown ○ not assessed
5.2. Immunohistological findings report available*	○ yes ○ no ○ unknown ○ not assessed
5.2.1. Positive for inflammation*	○ yes ○ no ○ unknown ○ not assessed
5.2.2. Positive for virus and other pathogens in the myocardium*	○ yes ○ no ○ unknown ○ not assessed
Adenovirus*	○ yes ○ no ○ unknown ○ not assessed

	Coxsackie Virus*	○ yes ○ no ○ unknown ○ not assessed
	Epstein-Barr Virus*	○ yes ○ no ○ unknown ○ not assessed
	Parvovirus B19*	○ yes ○ no ○ unknown ○ not assessed
	Herpes Simplex Virus 1/2*	○ yes ○ no ○ unknown ○ not assessed
	Humanes Herpesvirus 6*	○ yes ○ no ○ unknown ○ not assessed
	Humanes Cytomegalovirus*	○ yes ○ no ○ unknown ○ not assessed
	Influenza A und B*	○ yes ○ no ○ unknown ○ not assessed
	Hepatitis C*	○ yes ○ no ○ unknown ○ not assessed
	Other pathogens (in myocardium)*	○ yes ○ no ○ unknown ○ not assessed
	Chagas*	○ yes ○ no ○ unknown ○ not assessed
	Borrelia*	○ yes ○ no ○ unknown ○ not assessed
	Fungi*	○ yes ○ no ○ unknown ○ not assessed
	Other*	○ yes ○ no ○ unknown ○ not assessed
	Please specify*	
	Positive virus detection in the blood*	○ yes ○ no ○ unknown ○ not assessed
	Determined by*	○ plasma ○ serum ○ unknown ○ not assessed
	Please specify virus*	

6. Procedural complications

6.1.	**Procedural complications***	○ yes ○ no ○ unknown ○ not assessed
	Apoplexy*	○ yes ○ no ○ unknown ○ not assessed
	Pericardial effusion*	○ yes ○ no ○ unknown ○ not assessed
	Pericardial tamponade*	○ yes ○ no ○ unknown ○ not assessed
	Access site*	○ yes ○ no ○ unknown ○ not assessed
	Minor bleeding*	○ yes ○ no ○ unknown ○ not assessed
	Major bleeding*	○ yes ○ no ○ unknown ○ not assessed
	Death*	○ yes ○ no ○ unknown ○ not assessed
	Other*	○ yes ○ no ○ unknown ○ not assessed
	Other, please specify*	

Mögliche Angaben

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

1)

1
2
3

2)

g/dl
mmol/l

ECG (DZHK-SOP-K-03)

The module ECG (electrocardiogram) is used to document important parameters from ECG and long-term ECG measurements.

The measurements ought to be performed according to DZHK-SOP-K-03.

DZHK-SOP-K-03:
- Version V1.0
- Valid as of: 01.09.2014
- https://dzhk.de/en/resources/sops/

State of the attached secuTrial® form: 13.07.2020

Electrocardiogram

(13.07.2020 - 10:34:54 (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.	**Insufficient ECG recording quality***	○ 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*	

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.	**PR interval***	☐ ms ○ unknown ○ not assessed

Hilfe: Begins where P leaves the isoelectric line. Ends at the beginning of the Q wave. If there is no Q wave present, the measurement ends at the beginning of the R wave upstroke. Measured in Lead II, otherwise in the lead with the best representation.

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

Hilfe: Begins where Q leaves the isoelectric line. Ends where S meets the isoelectric line. If there is no Q wave present, measurement begins at the R wave upstroke. Measured in Lead II, otherwise in the lead with the best representation.

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

Hilfe: Begins where Q leaves the isoelectric line. Ends where T meets the isoelectric line. Measured in Lead II, otherwise in the lead with the best representation. The QT interval is the measured, not the corrected, QT interval.

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

Hilfe: 1st degree: PR interval > 0.20 seconds 2nd degree: Includes Type 1 (Wenckebach) and Type 2 (Mobitz) Type 1, Wenckebach: in each cycle the PR interval is prolonged until a QRS complex is blocked. Type 2, Mobitz: intermittent blocking of a QRS complex with no prior increase in the PR interval. 3rd degree: P waves appear independent of the QRS complexes, mostly with 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 of the QRS complex up to the last negative deflection in V5 or V6 or the left pre-cordial leads to ≥0.06 sec. Incomplete: QRS width ≤0.12 sec. Complete: QRS width >0.12 sec. Right bundle branch block: Prolongation of the QRS complex up to the last negative deflection in >30 sec. Incomplete: RBB morphology with a 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 anteriorer hemiblock: extreme left axis deviation in the pre-cordial leads, deep S wave in V5- V6, QRS is not widened. Left posteriorer hemiblock: right to extreme right axis deviation.

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.	**Pathological ST segments***	○ 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: Typical for infarction (measured at J point in at least 2 adjacent leads ≥0.25 mV for men≤40 years, ≥0.2 mV for men>40 years or ≥0.15 mV for women in leads V2 V3 or ≥0.1 in other leads without the presence of a left bundle branch block.

1.16.	**Q-waves as an indicator of a prior 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.	**Duration of recording***	☐ 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
SVES: supraventricular extrasystoles

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

	tachycardia*	☐ per minute ○ unknown ○ not assessed
2.12.	**SDNN***	☐ ms ○ unknown ○ not assessed

Hilfe: Standard deviation of all NN intervals of the global index of heart rate variability

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 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

Echocardiography (DZHK-SOP-K-08)

The module Echocardiography is used to document parameters of transthoracic echocardiography examinations.

These examinations ought to be performed according to DZHK-SOP-K-08.

DZHK-SOP-K-08:
- Version V1.0
- Valid as of: 01.09.2014
- https://dzhk.de/en/resources/sops/

State of the attached secuTrial® form: 13.07.2020

Echocardiography

(13.07.2020 - 10:34:54 (MESZ))

Examination details

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

II. Date of examination*
[ ] tt.mm.jjjj
○ 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. Examination

1.1. Heart rate*
[ ] /min
○ unknown ○ not assessed

1.2. Rhythm

1.2.1. Sinus rhythm*
○ yes ○ no ○ unknown ○ not assessed

1.2.2. Atrial fibrillation*
○ yes ○ no ○ unknown ○ not assessed

1.2.3 Pacemaker*
○ yes ○ no ○ unknown ○ not assessed
[ ] 2)

1.2.4 Other rhythm*
○ yes ○ no ○ unknown ○ not assessed

2. Image quality

2.1. Parasternal long axis*
○ proper axial alignment with good image quality
○ axis deviation with good image quality
○ unknown (limited possibility of assessment)
○ not assessed

2.2. Parasternal short axis*
○ proper axial alignment with good image quality
○ axis deviation with good image quality
○ unknown (limited possibility of assessment)
○ not assessed

2.3. Apical four-chamber view*
○ proper axial alignment with good image quality
○ axis deviation with good image quality
○ unknown (limited possibility of assessment)
○ not assessed

2.4. Apical three-chamber view*
○ proper axial alignment with good image quality
○ axis deviation with good image quality
○ unknown (limited possibility of assessment)
○ not assessed

2.5. Apical two-chamber view*
○ proper axial alignment with good image quality
○ axis deviation with good image quality
○ unknown (limited possibility of assessment)
○ not assessed

2.6. Subcostal*
○ proper axial alignment with good image quality
○ axis deviation with good image quality
○ unknown (limited possibility of assessment)
○ not assessed

3. Dimensions (long axis: M-mode parasternal)

3.1. M-mode measured in:*
- ○ parasternal long axis
- ○ parasternal short axis
- ○ 2D
- ○ anatomical M-mode
- ○ unknown (impossible to locate)
- ○ not assessed

3.2. Aortic root diameter (end-systolic) (AO)*
☐ mm
○ unknown ○ not assessed

3.3. Left atrium (end-systolic) (LA diam)*
☐ mm
○ unknown ○ not assessed

3.4. Interventricular septum (end-diastolic) (IVS_d)*
☐ mm
○ unknown ○ not assessed

3.5. Left ventricular end-diastolic diameter ($LVED_d$)*
☐ mm
○ unknown ○ not assessed

3.6. Left ventricular posterior wall ($LVPW_d$)*
☐ mm
○ unknown ○ not assessed

3.7. Left ventricular end-systolic diameter ($LVED_s$)*
☐ mm
○ unknown ○ not assessed

4. 2D measurements (4CH and 2CH apical, subcostal)

4.1. Left ventricular ejection fraction (LV-EF)*
☐ %
○ unknown ○ not assessed

4.2. Method*
- ○ Simpson biplane
- ○ Simpson monoplane (4CH)
- ○ visual
- ○ unknown
- ○ not assessed

4.3. Left ventricular end-diastolic volume (LVEDV)*
☐ ml
○ unknown ○ not assessed

4.4. Left ventricular end-systolic volume (LVESV)*
☐ ml
○ unknown ○ not assessed

4.5. Left atrium AP longitudinal (end-systolic) ($LA_{S\ (AP\ longitudinal)}$)*
☐ mm
○ unknown ○ not assessed

4.6. Left atrium AP transversal (end-systolic)($LA_{S\ (AP\ transversal)}$)*
☐ mm
○ unknown ○ not assessed

4.7. Left atrial area 4-chamber view (end-systolic) (LA area (4CH))*
☐ cm²
○ unknown ○ not assessed

4.8. Left atrial area 2-chamber view (end-systolic) (A2 LA area $(2CH)_s$)*
☐ cm²

	○ unknown ○ not assessed
4.9. Wall motion disorder*	○ yes ○ no ○ unknown ○ not assessed
4.10. RV dilatation (mid-ventricular)*	○ yes ○ no ○ unknown ○ not assessed
4.11. TAPSE*	☐ mm ○ unknown ○ not assessed
4.12. MAPSE lateral*	☐ mm ○ unknown ○ not assessed
4.13. MAPSE septal*	☐ mm ○ unknown ○ not assessed
4.14. Pericardial effusion*	○ yes ○ no ○ unknown ○ not assessed
4.15. Vena cava diameter*	☐ mm ○ unknown ○ not assessed
4.16. Vena cava response to breathing (> 50 % decrease on inspiration)*	○ yes ○ no ○ unknown ○ not assessed

5. Mitral valve Doppler (PW)

5.1. E-wave*	☐ m/s ○ unknown ○ not assessed
5.2. A-wave*	☐ m/s ○ unknown ○ not assessed

6. Tissue Doppler (TDI)

TDI lat cannot be measured*	☐
6.1. E´-wave (lateral)*	☐ cm/s ○ unknown ○ not assessed
6.2. A´-wave (lateral)*	☐ cm/s ○ unknown ○ not assessed
6.3. S´ (lateral)*	☐ cm/s ○ unknown ○ not assessed
TDI sep cannot be measured*	☐
6.4. E´-wave (medial)*	☐ cm/s ○ unknown ○ not assessed
6.5. A´-wave (medial)*	☐ cm/s ○ unknown ○ not assessed
6.6. S´ (medial)*	☐ cm/s ○ unknown ○ not assessed

7. Pulmonary venous flow

7.1. Pulmonary venous systolic velocity (PVsVel)*	☐ cm/s ○ unknown ○ not assessed
7.2. Pulmonary venous diastolic velocity (PVdVel)*	☐ cm/s ○ unknown ○ not assessed

8. Valves

Mitral valve

8.1.	**Mitral valve***	○ native ○ post-surgical ○ unknown ○ not assessed
	Status post mitral valve surgery*	○ mitral valve reconstruction ○ biological mitral valve replacement ○ mechanical mitral valve replacement ○ interventional reconstruction/clipping ○ unknown ○ not assessed
8.1.1.	**Mitral valve morphology***	○ normal ○ abnormal ○ unknown ○ not assessed
	Sclerosis*	○ yes ○ no ○ unknown ○ not assessed
	Mitral leaflet calcification*	○ yes ○ no ○ unknown ○ not assessed
	Mitral annular calcification*	○ yes ○ no ○ unknown ○ not assessed
	Separation disorder*	○ yes ○ no ○ unknown ○ not assessed
	Flail leaflet*	○ yes ○ no ○ unknown ○ not assessed
	Myxomatous prolapse*	○ yes ○ no ○ unknown ○ not assessed
	Prolapse due to fibroelastic deficiency*	○ yes ○ no ○ unknown ○ not assessed
	Pseudo-prolapse*	○ yes ○ no ○ unknown ○ not assessed
8.1.2.	**Mitral valve insufficiency (MI)***	○ no MI ○ mild MI ○ moderate MI ○ severe MI ○ unknown (cannot be determined) ○ not assessed
8.1.3.	**Mitral valve stenosis (MS)***	○ no MS ○ mild MS ○ moderate MS ○ severe MS ○ unknown (cannot be determined) ○ not assessed
Aortic valve		
8.2.	**Aortic valve***	○ native ○ post-surgical ○ unknown ○ not assessed
	Status post aortic valve surgery*	○ status post biological aortic valve replacement surgery ○ status post mechanical aortic valve replacement* ○ status post interventional aortic valve replacement* ○ unknown ○ not assessed
8.2.1.	**Aortic valve morphology***	○ normal ○ abnormal ○ unknown ○ not assessed
	Sclerosis*	○ yes ○ no ○ unknown ○ not assessed
	Calcification*	○ yes ○ no ○ unknown ○ not assessed
	Separation disorder*	○ yes ○ no ○ unknown ○ not assessed
	Bicuspid*	○ yes ○ no ○ unknown ○ not assessed
8.2.2.	**Aortic valve insufficiency (AI)***	○ no AI ○ mild AI ○ moderate AI ○ severe AI ○ unknown (cannot be determined) ○ not assessed

8.2.3. Aortic valve stenosis (AS)*	○ no AS ○ mild AS ○ moderate AS ○ severe AS ○ unknown (cannot be determined) ○ not assessed

Pulmonary valve

8.3. Pulmonary valve*	○ native ○ post-surgical ○ unknown ○ not assessed
8.3.1. Pulmonary valve morphology*	○ normal ○ abnormal ○ unknown ○ not assessed
Sclerosis*	○ yes ○ no ○ unknown ○ not assessed
Calcification*	○ yes ○ no ○ unknown ○ not assessed
Separation disorder*	○ yes ○ no ○ unknown ○ not assessed
8.3.2. Pulmonary valve insufficiency (PI)*	○ no PI ○ mild PI ○ moderate PI ○ severe PI ○ unknown (cannot be determined) ○ not assessed

Tricuspid valve

8.4. Tricuspid valve*	○ native ○ post-surgical ○ unknown ○ not assessed
8.4.1. Tricuspid valve morphology*	○ normal ○ abnormal ○ unknown ○ not assessed
Sclerosis*	○ yes ○ no ○ unknown ○ not assessed
Calcification*	○ yes ○ no ○ unknown ○ not assessed
Ebstein*	○ yes ○ no ○ unknown ○ not assessed
Anomaly*	○ yes ○ no ○ unknown ○ not assessed
Separation disorder*	○ yes ○ no ○ unknown ○ not assessed
8.4.2. Tricuspid valve insufficiency (TI)*	○ no TI ○ mild TI ○ moderate TI ○ severe TI ○ unknown (cannot be determined) ○ not assessed

Mögliche Angaben

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

1)

1
2
3

2)

PM+sinus rhythm
PM+atrial fibrillation
stimulation mode

MRI (DZHK-SOP-K-06)

The module MRI is used to document analyzing parameters of cardiac magnetic resonance imaging examinations.

These examinations ought to be performed according to DZHK-SOP-K-06.

DZHK-SOP-K-06:
- Version V1.0
- Valid as of: 01.09.2014
- https://dzhk.de/en/resources/sops/

State of the attached secuTrial® form: 13.07.2020

Magnetic resonance imaging

(13.07.2020 - 10:34:54 (MESZ))

Examination details

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

II. Date of examination*
[ ] tt.mm.jjjj
○ 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. Cine 4-chamber view

1.1. Diameter of the right ventricle*
[ ] mm
○ unknown ○ not assessed

1.2. Diameter of the right atrium*
[ ] mm
○ unknown ○ not assessed

1.3. MAPSE*
[ ] mm
○ unknown ○ not assessed

1.4. TAPSE*
[ ] mm
○ unknown ○ not assessed

1.5. Maximum left atrial area*
[ ] cm²
○ unknown ○ not assessed

1.6. Minimum left atrial area*
[ ] cm²
○ unknown ○ not assessed

1.7. Maximum length of the axis of the left atrium*
[ ] mm
○ unknown ○ not assessed

1.8. Minimum length of the axis of the left atrium*
[ ] mm
○ unknown ○ not assessed

2. Cine 2-chamber view

2.1. Maximum left atrial area*
[ ] cm²
○ unknown ○ not assessed

2.2. Minimum left atrial area*
[ ] cm²
○ unknown ○ not assessed

2.3. Maximum length of the axis of the left atrium*
[ ] mm
○ unknown ○ not assessed

2.4. Minimum length of the axis of the left atrium*
[ ] mm
○ unknown ○ not assessed

3. Short-axis multislice cine

3.1.	**Basal septum***	☐ mm ○ unknown ○ not assessed
3.2.	**Basal lateral wall***	☐ mm ○ unknown ○ not assessed
3.3.	**Left ventricular end-diastolic diameter (LVEDD)***	☐ mm ○ unknown ○ not assessed
3.4.	**Left ventricular end-systolic diameter (LVESD)***	☐ mm ○ unknown ○ not assessed
3.5.	**Left ventricular ejection fraction (LV-EF)***	☐ % ○ unknown ○ not assessed
3.6.	**Left ventricular end-diastolic volume index (LV-EDVI)***	☐ ml/m² ○ unknown ○ not assessed
3.7.	**Left ventricular end-systolic volume index (LV-ESVI)***	☐ ml/m² ○ unknown ○ not assessed
3.8.	**Left ventricular stroke volume index (LV-SVI)***	☐ ml/m² ○ unknown ○ not assessed
3.9.	**Indexed left ventricular mass (LV mass/body surface)***	☐ g/m² ○ unknown ○ not assessed
3.10.	**Right ventricular ejection fraction (RV-EF)***	☐ % ○ unknown ○ not assessed
3.11.	**Right ventricular end-diastolic volume index (RV-EDVI)***	☐ ml/m² ○ unknown ○ not assessed
3.12.	**Right ventricular end-systolic volume index (RV-ESVI)***	☐ ml/m² ○ unknown ○ not assessed
3.13.	**Right ventricular stroke volume index (RV-SVI)***	☐ ml/m² ○ unknown ○ not assessed

4. Examination details (Late Gadolinium Enhancement (LGE))

4.1.	**LGE in AHA 17-segment model infarction-typical***	○ yes ○ no ○ unknown ○ not assessed

Mögliche Angaben

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

1)

1
2
3

Spiroergometry (DZHK-SOP-K-07)

The module Spiroergometry is used to document spiroergometry examinations. The cardiopulmonary exercise test analyses the reactions and the interplay of the heart, circulation, breathing and metabolism during gradually increasing exercise, both in terms of qualitative and quantitative measures.

The examinations ought to be performed according to DZHK-SOP-K-07.

DZHK-SOP-K-07:
- Version V1.1
- Valid as of: 01.07.2015
- https://dzhk.de/en/resources/sops/

State of the attached secuTrial® form: 13.07.2020

Spiroergometry

(13.07.2020 - 10:34:54 (MESZ))

Examination details

I.	**Was the cardiopulmonary exercise testing performed?***	○ yes ○ no ○ unknown ○ not assessed
II.	**Date of examination***	[ ] tt.mm.jjjj ○ 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).

Examination

1.	**Pacemaker***	○ yes ○ no ○ unknown ○ not assessed
2.	**Heart rate***	○ sinus rhythm ○ atrial fibrillation ○ pacemaker rhythm ○ unknown ○ not assessed
3.	**Use of beta blockers***	○ yes ○ no ○ unknown ○ not assessed
4.	**Duration of exercise***	[ ] mm:ss ○ unknown ○ not assessed
5.	**Type of exercise*** **Treadmill*** **Bicycle***	[ ] 2) [ ] 3)
6.	**Reason for stopping***	[ ] 4)
7.	**HR (at rest)***	[ ] /min ○ unknown ○ not assessed
8.	**Maximum HR (during exercise)***	[ ] /min ○ unknown ○ not assessed
9.	**HR (1 minute after exercise)***	[ ] /min ○ unknown ○ not assessed
10.	**RRsys (at rest)***	[ ] mmHg ○ unknown ○ not assessed
11.	**RRdia (at rest)***	[ ] mmHg ○ unknown ○ not assessed
12.	**RRsys (during exercise)***	[ ] mmHg ○ unknown ○ not assessed
13.	**RRdia (during exercise)***	[ ] mmHg ○ unknown ○ not assessed
14.	**Watt (max)***	[ ] Watt ○ unknown ○ not assessed
15.	**VE/VCO2 (at rest)***	[ ]

		○ unknown ○ not assessed
16.	**VE/VCO2 (during exercise)***	☐ ○ unknown ○ not assessed
17.	**PET CO2 (at rest)***	☐ mmHg ○ unknown ○ not assessed
18.	**PET CO2 (during exercise)***	☐ mmHg ○ unknown ○ not assessed
19.	**VE/VCO2 slope***	☐ ○ unknown ○ not assessed
20.	**VO2 (at rest)***	☐ ○ unknown ○ not assessed
	Unit	☐ 5)
21.	**VO2 peak***	☐ ml/min ○ unknown ○ not assessed
22.	**VO2 Norm***	☐ ○ unknown ○ not assessed
	Unit	☐ 5)
23.	**VO2 AT***	☐ ○ unknown ○ not assessed
	Unit	☐ 5)
24.	**VE max***	☐ l/min ○ unknown ○ not assessed
25.	**BF (respiratory rate) (at rest)***	☐ l/min ○ unknown ○ not assessed
Hilfe:	BF - breathing frequency	
26.	**BF (during exercise)***	☐ l/min ○ unknown ○ not assessed
Hilfe:	BF - breathing frequency	
27.	**Maximum BF***	☐ l/min ○ unknown ○ not assessed
Hilfe:	BF - breathing frequency	
28.	**VT (at rest)***	☐ ml ○ unknown ○ not assessed
29.	**VT (during exercise)***	☐ ml ○ unknown ○ not assessed
30.	**VD/VT (at rest)***	☐ % ○ unknown ○ not assessed
31.	**VD/VT (during exercise)***	☐ % ○ unknown ○ not assessed
32.	**Saturation sO2 (at rest)***	☐ % ○ unknown ○ not assessed

33.	**Saturation sO2 (during exercise)***	☐ % ○ unknown ○ not assessed
34.	**Respiratory quotient (RQ) at rest***	☐ ○ unknown ○ not assessed
35.	**Respiratory quotient (RQ) during exercise***	☐ ○ unknown ○ not assessed
36.	**Respiratory quotient after end of exercise (RQ maxpost)***	☐ ○ unknown ○ not assessed
37.	**Used BORG scale***	○ Borg rating of perceived exertion scale (6/20) ○ Borg dyspnoea scale (0/10) ○ unknown ○ not assessed
	Borg rating of perceived exertion scale*	☐ 6)
	Borg – dyspnoea scale*	☐ 7)

Mögliche Angaben

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

1)

1
2
3

2)

Bruce protocol
modified Bruce protocol
modified Naughton protocol)
unknown
not assessed

3)

modified Jones protocol
WHO protocol
unknown
not assessed

4)

maximum exertion reached
ST segment depression (> 0.2 mV) or elevation
progressive atrial or ventricular arrhythmias or bundle branch block patterns
frequency decrease during exercise
missing BP increase or BP decrease over 2 exercise levels
maximum exhaustion (e.g. of legs)
chest pain (e.g. AP symptoms), severe dizziness
excessive dyspnoea
subject's expression of the wish to terminate the test
unknown
not assessed

5)

ml/min

l/min

6)

6 - no exertion at all
7 - extremely light
8
9 - very light
10
11 - light
12
13 - somewhat hard
14
15 - hard
16
17 - very hard
18
19 - extremely hard
20 - maximal exertion
unknown
not assessed

7)

0 - no breathing difficulty at all
0,5 - very, very slight (just noticeable)
1 - very slight
2 - slight
3 - moderate
4 - somewhat severe
5 - severe
6 - severe to very severe
7 - very severe
8 - very severe to very, very severe
9 - very, very severe (almost maximal)
10 - maximal breathing difficulty
unknown
not assessed

6-Minute Walking Test (DZHK-SOP-K-04)

The module 6-Minute Walking Test is used to document the results of the 6-minute walking test. The test evaluates the functional reserves and the degree of physical tolerance of patients with chronic heart and lung diseases in their individual daily life as well as it records the course of the disease and the success of therapeutic measures.

The examination ought to be performed according to DZHK-SOP-K-04.

DZHK-SOP-K-04:
- Version V1.0
- Valid as of: 01.09.2014
- https://dzhk.de/en/resources/sops/

State of the attached secuTrial® form: 13.07.2020

Examination details

I. **Was the 6-minute walk test performed?*** ○ yes ○ no ○ unknown ○ not assessed

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

III. **Examiner No.*** [ ]

IV. **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. Examination

1.1. **Measurement of blood pressure and heart rate after resting period*** ○ yes, on left side ○ yes, on right side ○ no ○ unknown ○ not assessed

1.1.1. **Systolic blood pressure*** [ ] mmHg
○ unknown ○ not assessed

1.1.2. **Diastolic blood pressure*** [ ] mmHg
○ unknown ○ not assessed

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

1.2. **Walk distance*** [ ] m
○ unknown ○ not assessed

2. Borg scale

BORG scale (before test start)*

2.1. **Borg – dyspnoea scale*** [ ] 2)

BORG scale (after end of test)*

2.2. **Used BORG scale (after end of test)*** ○ Borg rating of perceived exertion scale (6/20) ○ Borg – dyspnoea scale (0/10) ○ unknown ○ not assessed

Borg rating of perceived exertion scale* [ ] 3)

Borg – dyspnoea scale* [ ] 2)

3. Aids/stop criteria

3.1. **Were aids used?** ○ yes ○ no ○ unknown ○ not assessed

3.1.1. **If yes*** ○ measuring wheel ○ walking aid ○ oxygen administration ○ other ○ unknown ○ not assessed

3.1.2. **Please specify*** [ ]

3.2.	**Test was stopped prematurely***	○ yes ○ no ○ unknown ○ not assessed
3.2.1.	**In case the test was stopped prematurely: Total test time***	☐ mm:ss ○ unknown ○ not assessed
3.2.2.	**Reason for stopping***	○ angina pectoris ○ severe dyspnoea ○ dizziness ○ insecure gait/risk of falling ○ calf cramps ○ claudication ○ muscular exhaustion ○ decreased saturation ○ other ○ unknown ○ not assessed
3.2.3.	**Please specify***	
3.3.	**Other particular findings***	○ yes ○ no ○ unknown ○ not assessed
3.3.1.	**If yes***	○ walking breaks ○ examined person needs to support himself/herself ○ other ○ unknown ○ not assessed
	Please specify*	

Mögliche Angaben

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

1)

1
2
3

2)

0 - no breathing difficulty at all
0,5 - very, very slight (just noticeable)
1 - very slight
2 - slight
3 - moderate
4 - somewhat severe
5 - severe

6 - severe to very severe
7 - very severe
8 - very severe to very, very severe
9 - very, very severe (almost maximal)
10 - maximal breathing difficulty
unknown
not assessed

3)

6 - no eertion at all
7 - etremely light
8
9 - very light
10
11 - light
12
13 - somewhat hard
14
15 - hard
16
17 - very hard
18
19 - extremely hard
20 - maximal exertion
unknown
not assessed

Harmonised modules without corresponding SOPs

The following harmonised modules have no corresponding SOPs.

Cardiomyopathy Diagnostics

The module Cardiomyopathy Diagnostics is used to document analyzing parameters of cardiomyopathy examinations.

State of the attached secuTrial® form: 13.07.2020

Cardiomyopathy Diagnostics

(13.07.2020 - 10:34:54 (MESZ))

General Diagnostic Information

I.	**Were cardiomyopathy diagnostics collected?***	○ yes ○ no ○ unknown ○ not assessed
II.	**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).

Cardiomyopathy Diagnostics

1.	**Dilated cardiomyopathy***	○ yes ○ no ○ unknown ○ not assessed
	If "yes"*	○ hereditary ○ inflammatory ○ toxic ○ other ○ unknown ○ not assessed
	Please specify*	
2.	**Left ventricular non-compaction cardiomyopathy***	○ yes ○ no ○ unknown ○ not assessed
3.	**Hypertrophic cardiomyopathy***	○ yes ○ no ○ unknown ○ not assessed ○ non-obstructive ○ obstructive ○ unknown ○ not assessed ○ hereditary ○ non-familial ○ unknown ○ not assessed
3.1.	**Positive pressure gradient at rest (echocardiography)***	○ yes ○ no ○ unknown ○ not assessed [ ] mmHg ○ unknown ○ not assessed
3.2.	**Positive pressure gradient on exertion (stress echocardiography)***	○ yes ○ no ○ unknown ○ not assessed [ ] mmHg ○ unknown ○ not assessed
3.3.	**Wall thickness measured by***	○ MRI ○ echocardiography ○ unknown ○ not assessed
	Septum*	○ yes ○ no ○ unknown ○ not assessed [ ] mm ○ unknown ○ not assessed
	Lateral*	○ yes ○ no ○ unknown ○ not assessed [ ] mm ○ unknown ○ not assessed
4.	**Arrhythmogenic right ventricular cardiomyopathy***	○ yes ○ no ○ unknown ○ not assessed

4.1.	**Positive biopsy for plakoglobin***	○ yes ○ no ○ unknown ○ not assessed
5.	**Myocarditis***	○ yes ○ no ○ unknown ○ not assessed
5.1.	**Viral myocarditis***	○ yes ○ no ○ unknown ○ not assessed
5.2.	**Autoimmune myocarditis***	○ yes ○ no ○ unknown ○ not assessed
5.3	**Toxic myocarditis**	○ yes ○ no ○ unknown ○ not assessed
5.4.	**Other***	○ yes ○ no ○ unknown ○ not assessed
6.	**Toxic cardiomyopathy***	○ yes ○ no ○ unknown ○ not assessed
6.1.	**Alcohol-induced***	○ yes ○ no ○ unknown ○ not assessed
6.2.	**Status post chemotherapy***	○ yes ○ no ○ unknown ○ not assessed
7.	**Diagnosis***	○ assured ○ probable ○ possible ○ unknown ○ not assessed
8.	**Family history***	○ assured familial clustering ○ assumed familial clustering ○ no familial clustering ○ unknown ○ not assessed

Mögliche Angaben

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

1)

1
2
3

Depressions

The module Depressions is used to document different parameters in the course of a depression diagnosis.

State of the attached secuTrial® form: 13.07.2020

Depression

(13.07.2020 - 10:34:54 (MESZ))

1. *Diagnosis of Depression*

1.1. Diagnosis*

○ major depression/depressive episode ○ dysthymia ○ other ○ unknown ○ not assessed

1.2. Please specify*

Hilfe: Depression is defined as a current or previous diagnosis of depression by a doctor or psychotherapist.

2. *Whooley Screening Questions*

Please ask the patient the following questions:

2.1 During the past month, have you often been bothered by feeling down, depressed or hopeless?*

○ yes ○ no ○ unknown ○ not assessed

2.2. During the past month, have you often been bothered by little interest or pleasure in doing things?*

○ yes ○ no ○ unknown ○ not assessed

3. *Questionnaire*

3.1. Questionnaire available*

○ yes ○ no ○ unknown ○ not assessed

3.1.1. If “yes”, which one?*

3.1.2. Date*

tt.mm.jjjj

○ unknown ○ not assessed

3.1.3. Pathological*

○ yes ○ no ○ unknown ○ not assessed

Laboratory Diagnostics

The module Laboratory is used to document different measurement parameters of laboratory examinations.

State of the attached secuTrial® form: 13.07.2020

Laboratory diagnostics

(13.07.2020 - 10:34:54 (MESZ))

Date blood sample was taken** ☐ tt.mm.jjjj Where applicable, give date for the latest value
○ unknown ○ not assessed

1. EDTA (haematology + HbA1c)

1.1. Erythrocytes*
☐
○ unknown ○ not assessed
Unit ☐ 1)

1.2. Leukocytes*
☐
○ unknown ○ not assessed
Unit ☐ 2)

1.3. Platelets*
☐
○ unknown ○ not assessed
Unit ☐ 3)

1.4. Haemoglobin*
☐
○ unknown ○ not assessed
Unit ☐ 4)

1.5. Haematocrit*
☐
○ unknown ○ not assessed
Unit ☐ 5)

1.6. Free Haemoglobin*
☐
○ unknown ○ not assessed
Unit ☐ 6)

1.7. HbA_{1C}*
☐
○ unknown ○ not assessed
Unit ☐ 7)

2. Serum, heparin plasma (clinical chemistry)

2.1. Sodium*
☐ mmol/l
○ unknown ○ not assessed

2.2. Potassium*
☐ mmol/l
○ unknown ○ not assessed

2.3. Calcium*
☐ mmol/l
○ unknown ○ not assessed

2.4. Ferritin*
☐
○ unknown ○ not assessed
Unit ☐ 8)

2.5. Transferrin saturation*
☐
○ unknown ○ not assessed
Unit ☐ 9)

2.6. LDL cholesterol*
☐
○ unknown ○ not assessed
Unit ☐ 10)

2.7. HDL cholesterol*

○ unknown ○ not assessed

Unit 10)

2.8. NT-proBNP*

○ unknown ○ not assessed

Unit 11)

2.9. BNP*

○ unknown ○ not assessed

Unit 12)

2.10. hs-CRP*

○ unknown ○ not assessed

Unit 13)

2.11. Total bilirubin*

○ unknown ○ not assessed

Unit 14)

2.12. ASAT/GOT*

○ unknown ○ not assessed

Unit 15)

2.13. ALAT/GPT*

○ unknown ○ not assessed

Unit 15)

2.14. LDH*

○ unknown ○ not assessed

Unit 15)

2.15. hsTroponin T*

○ unknown ○ not assessed

Unit 16)

2.16. Troponin I*

○ unknown ○ not assessed

Unit 17)

2.17. Total creatine kinase (CK)*

○ unknown ○ not assessed

Unit 18)

2.18. Creatinine*

○ unknown ○ not assessed

Unit 19)

2.19. Urea*

○ unknown ○ not assessed

Unit 20)

2.20. MDRD*

○ unknown ○ not assessed

Unit 21)

2.21.	**Albumin***	☐ ○ unknown ○ not assessed
	Unit	☐ 22)

3. *Citrate plasma (coagulation)*

3.1.	**INR***	☐ ○ unknown ○ not assessed
3.2.	**PTT***	☐ s ○ unknown ○ not assessed
3.3.	**HIT diagnostic*** **Perfomed on**	○ positive ○ negative ○ unknown ○ not assessed ☐ tt.mm.jjjj ○ unknown ○ not assessed

4. *Urinalysis*

4.1.	**Was urinalysis assessed?****	○ yes ○ no ○ unknown ○ not assessed
4.2.	**Granulocyte esterase***	○ negative ○ + ○ ++ ○ +++ ○ unknown ○ not assessed
4.3.	**Nitrite***	○ positive ○ negative ○ unknown ○ not assessed
4.4.	**pH***	☐ ○ unknown ○ not assessed
4.5.	**Glucose***	○ positive ○ negative ○ unknown ○ not assessed
4.6.	**Ketone bodies***	○ positive ○ negative ○ unknown ○ not assessed
4.7.	**Urobilinogen***	○ positive ○ negative ○ unknown ○ not assessed
4.8.	**Bilirubin***	○ positive ○ negative ○ unknown ○ not assessed
4.9.	**Haemoglobin***	○ positive ○ negative ○ unknown ○ not assessed
4.10.	**Specific gravity***	☐ ○ unknown ○ not assessed
	Unit	☐ 23)

Mögliche Angaben

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

1)

Tpt/l (=10^12/l)
/pl
M/µl
million/µl
x10^6/nl
billion/ml
T/l

2)

Tpt/l (=10^12/l)
/nl=Gpt/l (=10^9/l)
K/µl
thousands/µl
x10^3/nl
billion/ml
G/l

3)	Tpt/l (=10^12/l)
	/nL=Gpt/l
	K/µl
	thousands/µl
	x10^3/nl
	billion/ml
	G/l
4)	g/dl
	mmol/l
5)	%
	l/l
6)	g/dl
	mg/dl
7)	%
	µmol/mol
	mmol/mol
8)	µg/l
	ng/ml
	mg/l
9)	%
	g/l
10)	mmol/l
	mg/dl
11)	µg/l
	ng/l
	pg/ml=ng/l
12)	nmol/(sl)
	pg/ml=ng/l
13)	mg/l
	mg/dl
14)	µmol/l=nmol/ml
	mg/dl
15)	U/l
	µkatal/L

16)

ng/l
pg/ml
ng/ml

17)

µg/l
ng/dl
ng/ml
g/l
ng/l

18)

U/l
µkatal/L

19)

mg/dl
µmol/l=nmol/ml

20)

mg/dl
mmol/l

21)

ml/min
ml/min/1,73m²

22)

g/l
g/dl

23)

g/ml
kg/l=g/ml
no unit

Medication

The module Medication is used to document a patient's medication intake.

State of the attached secuTrial® form: 13.07.2020

Medication

(13.07.2020 - 10:34:54 (MESZ))

Examination details

I.	**Was the medication administered?***	○ yes ○ no ○ unknown ○ not assessed
II.	**Date of medication***	☐ tt.mm.jjjj ○ unknown ○ not assessed

1. Cardiovascular medication

1.1.	**ACE inhibitor***	○ yes ○ no ○ unknown ○ not assessed
1.2.	**AT1-receptor antagonist***	○ yes ○ no ○ unknown ○ not assessed
1.3.	**Aliskiren***	○ yes ○ no ○ unknown ○ not assessed
1.4.	**Beta blocker***	○ yes ○ no ○ unknown ○ not assessed
1.5.	**Other antiarrhythmic agent*** **Please specify***	○ yes ○ no ○ unknown ○ not assessed
1.6.	**Thiazide***	○ yes ○ no ○ unknown ○ not assessed
1.7.	**Loop diuretic**	○ yes ○ no ○ unknown ○ not assessed
1.8.	**Aldosterone antagonist**	○ yes ○ no ○ unknown ○ not assessed
1.9.	**Other diuretic***	○ yes ○ no ○ unknown ○ not assessed
1.10.	**Cardiac glycoside***	○ yes ○ no ○ unknown ○ not assessed
1.11.	**Nitrate***	○ yes ○ no ○ unknown ○ not assessed
1.12.	**Ranolazine***	○ yes ○ no ○ unknown ○ not assessed
1.13.	**Ca antagonist***	○ yes ○ no ○ unknown ○ not assessed
1.14.	**Amiodarone***	○ yes ○ no ○ unknown ○ not assessed
1.15.	**Ivabradine***	○ yes ○ no ○ unknown ○ not assessed
1.16.	**Statin***	○ yes ○ no ○ unknown ○ not assessed
1.17.	**Other lipid-lowering agent***	○ yes ○ no ○ unknown ○ not assessed

2. Anticoagulation

2.1.	**ASA***	○ yes ○ no ○ unknown ○ not assessed
2.2.	**Thienopyridine (prasugrel, ticagrelor, thienopyridines (e.g. clopidogrel))***	○ yes ○ no ○ unknown ○ not assessed
2.3.	**Vitamin K antagonist***	○ yes ○ no ○ unknown ○ not assessed
2.4.	**New oral anticoagulant (NOAC)***	○ yes ○ no ○ unknown ○ not assessed

3. Antidiabetic drugs

3.1.	**Insulin***	○ yes ○ no ○ unknown ○ not assessed
3.2.	**Oral antidiabetic drug***	○ yes ○ no ○ unknown ○ not assessed

4. Other drugs

4.1.	**NSAIDs***	○ yes ○ no ○ unknown ○ not assessed
4.2.	**Anti-obstructive pulmonary disease drug***	○ yes ○ no ○ unknown ○ not assessed

4.3.	**Antidepressant***	○ yes ○ no ○ unknown ○ not assessed
4.4.	**Soporific/sedative agent***	○ yes ○ no ○ unknown ○ not assessed
4.5.	**Others***	

5. Only for women

5.1.	**Oral contraceptive***	○ yes ○ no ○ unknown ○ not assessed
5.2.	**Hormone therapy***	○ yes ○ no ○ unknown ○ not assessed