DZHK-SOP-C-05

Cardiac Catheterization

Left and right heart catheterization.

Left ventricular ventriculography.

Collection of left/right ventricular myocardial biopsies.

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This SOP is a translation from the original German SOP and valid without signatures.

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<th>Endorsed by Head of Section</th>
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<td>Ralf Bauer (Heidelberg)</td>
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## 1 INTRODUCTION

### 1.1 LIST OF ABBREVIATIONS

<table>
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<tr>
<th>Abbreviation</th>
<th>Plain text</th>
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<tbody>
<tr>
<td>A.</td>
<td>artery</td>
</tr>
<tr>
<td>ARVC</td>
<td>arrhythmogenic right ventricular cardiomyopathy</td>
</tr>
<tr>
<td>avDO2</td>
<td>arteriovenous difference of O2 content</td>
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<tr>
<td>BSA</td>
<td>body surface area</td>
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<tr>
<td>CC</td>
<td>cardiac catheterization</td>
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<tr>
<td>CFA</td>
<td>common femoral artery</td>
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<td>CI</td>
<td>cardiac index</td>
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<tr>
<td>CO</td>
<td>cardiac output</td>
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<tr>
<td>CO2art</td>
<td>arterial O2 content</td>
</tr>
<tr>
<td>CO2ven</td>
<td>central venous O2 content</td>
</tr>
<tr>
<td>CVP</td>
<td>central venous pressure = mean pressure right atrium</td>
</tr>
<tr>
<td>ECG</td>
<td>electrocardiogram</td>
</tr>
<tr>
<td>FDA</td>
<td>Food and Drug Administration</td>
</tr>
<tr>
<td>Hb</td>
<td>haemoglobin</td>
</tr>
<tr>
<td>i.S.</td>
<td>in serum</td>
</tr>
<tr>
<td>INR</td>
<td>international normalized ratio</td>
</tr>
<tr>
<td>IU</td>
<td>international units</td>
</tr>
<tr>
<td>JL</td>
<td>Judkins left catheter</td>
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<tr>
<td>JR</td>
<td>Judkins right catheter</td>
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<tr>
<td>LAO</td>
<td>left anterior oblique</td>
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<tr>
<td>LVEDP</td>
<td>left ventricular end diastolic pressure</td>
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<tr>
<td>mAP</td>
<td>mean arterial pressure</td>
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<tr>
<td>mPAP</td>
<td>mean pulmonary arterial pressure</td>
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<tr>
<td>MPC</td>
<td>multipurpose catheter</td>
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<td>mPCWP</td>
<td>mean pulmonary capillary wedge pressure</td>
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<tr>
<td>MRi</td>
<td>magnet resonance imaging</td>
</tr>
<tr>
<td>Abbreviation</td>
<td>Description</td>
</tr>
<tr>
<td>--------------</td>
<td>-------------</td>
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<tr>
<td>MVO2</td>
<td>mixed venous oxygen saturation</td>
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<tr>
<td>NaCl</td>
<td>natrium chloride</td>
</tr>
<tr>
<td>PAO2</td>
<td>pulmonary arterial oxygen content</td>
</tr>
<tr>
<td>pAOD</td>
<td>peripheral arterial occlusive disease</td>
</tr>
<tr>
<td>PCWP</td>
<td>pulmonary capillary wedge pressure</td>
</tr>
<tr>
<td>PTCA</td>
<td>percutaneous transluminal coronary angioplasty</td>
</tr>
<tr>
<td>PT</td>
<td>parameter of functional performance of the extrinsic blood coagulation pathway</td>
</tr>
<tr>
<td>PTT</td>
<td>partial thromboplastin time</td>
</tr>
<tr>
<td>Q-pulm</td>
<td>cardiac output in the pulmonary circulation</td>
</tr>
<tr>
<td>Q-syst</td>
<td>cardiac output in the systemic circulation</td>
</tr>
<tr>
<td>RA mean</td>
<td>mean right atrial pressure</td>
</tr>
<tr>
<td>RAO</td>
<td>right anterior oblique</td>
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<tr>
<td>SAO2</td>
<td>systemic arterial oxygen content</td>
</tr>
<tr>
<td>SVR</td>
<td>systemic peripheral vascular resistance</td>
</tr>
<tr>
<td>TSH</td>
<td>thyroid stimulating hormone</td>
</tr>
<tr>
<td>V.</td>
<td>Vena</td>
</tr>
<tr>
<td>venO2VCi</td>
<td>venous oxygen saturation Vena cava inferior</td>
</tr>
<tr>
<td>venO2VCS</td>
<td>venous O2 saturation Vena cava superior</td>
</tr>
<tr>
<td>vO2</td>
<td>oxygen consumption</td>
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<td>WG</td>
<td>working group</td>
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1.2 OBJECTIVE
The purpose of cardiac catheterization, which is covered in this SOP, is the imaging and hemodynamic assessment of cardiomyopathies.

Cardiac catheterization is performed for further phenotyping of cardiomyopathies, estimation of severity and prognosis.

1.3 TARGET GROUP
This SOP is intended for all invasive cardiologists who perform right and left heart catheterization diagnostics or myocardial biopsies.

1.3.1 Inclusion Criteria
An invasive cardiac assessment is indicated according to the current guidelines. In the context of the objective, these are primarily individuals with cardiomyopathy already confirmed by other imaging techniques, unclearly impaired left ventricular pump function and/or corresponding symptoms.

1.3.2 Exclusion criteria
All patients without clinical indications for diagnostic left heart catheterization/right heart catheterization, or myocardial biopsy.

1.4 APPLICATION AND TASKS
In the context of invasive cardiac diagnostics, the left ventricular pumping force (by ventriculography), relevant coronary stenoses as an expression of an ischemic genesis of the heart disease (by coronary angiography), and the hemodynamic effects of the heart disease on the systemic as well as the pulmonary arterial circulation (by right heart catheterization) should be determined in particular. In the absence of contraindications, standardized removal of myocardial biopsies from the left or right ventricle for further diagnostic specification is also of crucial importance.

Diagnostic cardiac catheterization complements non-invasive imaging methods such as echocardiography and MRI, as well as spirometry/ergometry and the 6-minute walk test. Ideally, these non-invasive preliminary examinations should be available prior to performing cardiac catheterization. To ensure that the cardiac catheter examination is carried out effectively and with few complications, preparation and education of the participant as well as the methodology, diagnosis and documentation need to be standardized. This SOP deliberately does not deal with details regarding the technical equipment of the catheterization laboratory, staff training, or adherence to radiation protection regulations since it is assumed that generally accepted standards are established at each site, and because these standards are specified by the German X-Ray Regulations and the Guidelines of the German Cardiac Society and can be consulted there (http://leitlinien.dgk.org/files/2001_Leitlinie_Einrichtung_und_Betreiben_von_Herzkatheterraume_H.pdf). Therefore, the details given essentially serve as examples.
1.5 **Correlations to Other Examinations**

Preliminary noninvasive examinations are performed in accordance with the current recommendations, clinical standards and local circumstances.

1.6 **Level of Quality**

The minimum requirements for this SOP correspond to Quality Level 1 of the DZHK.

<table>
<thead>
<tr>
<th>DZHK Quality Level</th>
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<tr>
<td>Implementation</td>
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<tr>
<td>Level 1</td>
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<tr>
<td>Level 2</td>
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<tr>
<td>Level 3</td>
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2 Examination Conditions

2.1 Equipment/Hardware

The general rules of good professional practice and asepsis must be observed.

A detailed description of the set-up of a cardiac catheterization laboratory are summarized in the guidelines of the German Cardiac Society:


The minimum complementary apparatus equipment in the cardiac catheterization laboratory should include:

- pressure transducer (pressure dome with catheter and de-aerator connection)
- contrast medium injector (high-pressure injector)
- blood gas analyzer
- pulse oximeter
- defibrillator (battery-powered)
- oxygen and compressed air connection (option of invasive ventilation)
- suction device
- emergency equipment and medications (see below) including a temporary pacemaker

2.2 Special Clinical Consumables

General requirements:

- 2500 IU unfractionated heparin/5 ml NaCl 0.9%
- 1 mg nitroglycerin/10 ml NaCl 0.9%
- 20 ml NaCl
- 2x 10 ml injections with local anaesthetic and 20-G needles
- contrast medium (ca. 120 ml Imeron®)
- 4 ECG electrodes
- pressure regulator, valve manifold with rotator with 3 successively switched 3-way valves
- 10 ml contrast medium injection syringe
• 1 sterile OP gown
• 1 pair of sterile gloves
• pressure bandage medium
• 2 plastic disposable dishes with heparinized NaCl 0.9%
• 20 sterile dressings 10x10 cm

**Right heart catheterization:**

• puncture needle (size 1.4 x 7 mm)
• plastic syringes 1 x 10 ml, 2 x 20 ml and 10 x 2 ml
• J-tip guide wire (0.035 inch, 145 cm in length)
• 7 French multipurpose diagnostic catheter
• 7 French dilatator

**Coronary angiography with LV angiography:**

• puncture cannula (size 1.4 x 7 mm)
• J-tip guide wire (0.035 inch, 145 cm in length)
• 4 French arterial sheath
• 4 French pigtail catheter (LV angiography)
• 4 French Judkins left catheter (100 cm) (JL) (for men taller than 170cm, use of a 5 French is preferable)
• 4 French Judkins right catheter (100 cm) (JR)
• injection piston for high-pressure injection pump
• injection tube for high-pressure injection pump
• 500 ml NaCl, infusion set and pressure bag
2.3 **REQUIRED DOCUMENTS AND INFORMATION**

- **Blood collection documentation** (potassium i.s., sodium i.s., creatinine i.s., urea i.s., small blood count, Quick, INR, PTT, TSH basal).

- **Information and consent (signature) using the standard information sheets**: Information must be provided specifically and separately for left heart catheterization, right heart catheterization and the coronary angiography as well as for the taking of myocardial biopsies. The detailed anamnesis and physical examination should take place in the same context (see DZHK-SOP-C-02-Anamnesis and clinical diagnosis).

- participating person (subject ID)
- date of birth (dd.mm.yyyy)
- sex
- height (in cm)
- weight (in kg)
- Examiner ID and registrant ID

Resting ECG (12-lead) (see DZHK-SOP-C-03-rest ecg)

2.4 **INFORMATION AND PARAMETERS TO BE DOCUMENTED**

*Right heart catheterization:*

- date of examination (dd.mm.yyyy)
- cardiac output (in l/min)
- systolic pulmonary arterial pressure (in mmHg)
- diastolic pulmonary arterial pressure (in mmHg)
- mean pulmonary arterial pressure (in mmHg)
- pulmonary capillary pressure (PCWP) (in mmHg)
- mean RA (in mmHg)
- central venous oxygen saturation (in %)
- arterial oxygen saturation (in %)
- transpulmonary gradient (in mmHg)
- pulmonary vascular resistance (in dyn*s*cm-5)
- systemic vascular resistance (in dyn*s*cm-5)
- body height (in cm)
- weight (in kg)
- hemoglobin (in g/dl or mmol/l))

**Left heart catheterization:**

- date of recording (dd.mm.yyyy)
- left ventricular end-diastolic pressure (LVEDP) (in mmHg)
- coronary heart disease (CHD)
  - none
  - coronary sclerosis
  - 1-vessel CHD
  - 2-vessel CHD
  - 3-vessel CHD
  - unknown
  - not assessed
- pump function
  - good
  - slightly limited
  - moderately limited
  - highly restricted
  - unknown
  - not assessed

**Myocardial biopsy:**

- date of recording (dd.mm.yyyy)
  - ventricle
• LV
• RV
• LV and RV
• unknown
• not assessed

• institution performing the assessment (please enter as free text)
• previous biopsies available
• date of previous biopsy (dd.mm.yyyy)
• previous diagnosis (please enter as free text)
• number of biopsies

• ventricle
  • LV
  • RV
  • LV and RV
  • unknown
  • not surveyed

• institution performing the assessment (please insert as free text)

Storage disease:
• storage disease
• amyloidosis
• other storage diseases
  • if available please comment as free text

Histological/ immunohistological/ viral findings
• histological findings available
• dallas criteria positive (incl. cell lysis)
• fibrosis positive
• necrosis
• granulomas
• giant cells
• myocytic hypertrophy
• immunohistological findings present
• inflammation positive
• virus and other pathogen detection in myocardium positive
• adenovirus
• coxsackievirus
• Epstein-Barr virus
• parvovirus B19
• herpes simplex virus ½
• human herpes virus 6
• human cytomegalovirus
• influenza A and B
• hepatitis C
• other pathogens in the myocardium
  o chagas
  o borrelia
  o fungi
  o other (Please specify as free text)
• virus detection in blood positive
• determined from
  o plasma
  o serum
  o unknown
  o not assessed
  o virus please specify as free text
Procedural complications

- apoplexy
- pericardial effusion
- pericardial tamponade
- access site
- minor bleeding
- major bleeding
- death
- other (please specify as free text)

2.5 Staff

The corresponding legal regulations apply.
3 PROCESS OF IMPLEMENTATION/WORK PROCESS/WORK STEPS

3.1 PROCESS Flow CHART

Inclusion criteria
- verified cardiomyopathy
- unclearly impaired left ventricular pump function and/or corresponding symptoms

Preparation of the workplace 3.2.1

Preparation of the participant 3.2.3

Implementation
- local anaesthesia 3.3.1
- right heart catheter 3.3.2
  1. determination of venous step oximetry
  2. determination of right cardiac/pulmonary arterial hemodynamics
- arterial puncture and airlock insertion 3.3.3
- probing of the left ventricle and ventriculography 3.3.4
- coronary angiography 3.3.5

Follow-up of the examination
- aftercare 3.4.1
- preservation/shipping/processing 3.4.2

sampling biopsy
- Left ventricular endomyocardial biopsy 3.3.6
- right ventricular myocardial biopsy 3.3.7
- number of biopsies 3.3.8

3.2 PREPARATIONS FOR THE EXAMINATION

The relevant legal regulations apply. Deviations in accordance with local standards and conditions (e.g. French gauges, closure systems, contrast medium assist pumps) are possible.

3.2.1 Preparation of the Work Space
- 2 disposable plastic dishes with heparinized NaCl 0.9%
3.2.2 Preparation of the Equipment

The cardiac catheterization monitoring station and the examination room are prepared according to local standards.

3.2.3 Principles of Preparing the Patient for Examination

The patient is prepared for examination according to established local standards. First an indwelling catheter is inserted into a peripheral vein, ideally in the proximal left arm (crook of elbow). The person must lie flat on the back on the examination table, fully undressed. Then the person is connected to a monitoring (3-lead) ECG and a pulse oximeter. After palpating the pulse, the puncture site is shaved thoroughly with a disposable razor. Disinfectant is then applied extensively to the puncture site and the person is covered completely with sterile drapes. The materials required for the examination are provided on a sterile covered table.

- 5 ml syringe with 2500 IU unfractionated heparin in NaCl 0.9%
- 10 ml disposable plastic syringes with 1 mg nitroglycerine in NaCl 0.9%
- 2 x 10 ml disposable syringes with lidocaine (1%) and 27-G injection needles
- 2 x 20 G injection needles
- puncture cannulas (size 1.4 x 7 mm)
- 10 x 2 ml disposable plastic syringes
- j-tip guide wire (0.035 inch, 145 cm in length),
- 7 french multipurpose diagnostic catheter
- 7 french dilatator
- 4 french arterial sheath
- 4 french pigtail catheter (LV angiography)
- 4 french Judkins left catheter (100 cm) (JL) (for men taller than 170cm, use of a 5 French is preferable)
- 4 french Judkins right catheter (100 cm) (JR)
- 8 french arterial sheath
- 7 french MB1 Guiding Launcher (Medtronic®),
- biopsy forceps (e.g. Endo-Flex long®).
3.3 Performing the Examination

Because of the performance of coronary angiography with LV angiography in conjunction with right ear catheterization and left ventricular myocardial biopsy sampling, the preferred approach is via the right common femoral artery (CFA) (Judkins technique) and the right femoral vein, if possible. Depending on the study protocol in, a different approach may be appropriate (e.g. the radial artery). In principle, left and right ventricular myocardial biopsy is possible. Specific requirements regarding the biopsy site should be individually determined in the respective study protocol. Accordingly, different venous (e.g. femoral vein, jugular vein) and arterial (femoral artery) access routes exist.

3.3.1 Local Anesthesia

After palpating the artery, a local anesthesia is applied with e.g. 2x10 ml lidocaine (1%) by superficial infiltration of the skin and the subcutaneous tissue in the area of the subsequent puncture channel to the CFA and the femoral vein using a 25 G needle. The local anesthetic takes approx. 3 minutes to take effect.

3.3.2 Right Heart Catheterization

Right heart catheterization is performed in accordance with the relevant standards and the respective study protocol. Puncture of the right femoral vein is performed under aspiration approx. 2 cm medial to the arterial puncture site. The guide wire is introduced through the indwelling catheter into the cranial vein until the tip reaches the inferior vena cava. To dilate the puncture channel, the 7 French dilator is fully inserted and subsequently exchanged for the 7F multipurpose catheter (MPC). The MPC is positioned above the guide wire in the upper part of the superior vena cava.

After removal of the guide wire, the venous oxygen saturation levels are taken.

1) Determination of venous saturation oximetry (also for shunt diagnostics):

Following aspiration of approx. 5 ml of blood, venous blood is collected for determination of the venous oxygen saturation levels from the following locations (collection in 2 ml disposable plastic syringes):

- cranial superior vena cava
- caudal superior vena cava (directly above the right atrium)
- right atrium
- cranial inferior vena cava (directly below the right atrium, with the catheter tip pointing away from the hepatic veins)
- caudal inferior vena cava (withdrawal from the last position by approx. 5-10 cm).
- prior to blood sampling, after repositioning of the MPC, first aspirate approx. 5 ml of blood (this will be discarded). The oximetry should be performed rapidly without interruption and oximetric analyses must be performed immediately after collection.
2) Determination of the right cardiac/pulmonary arterial hemodynamics (right heart catheterization):

The following applies to all registrations: After zero adjustment of the pressure transducer, the pressure curves are registered in resting respiratory position over 10 cardiac cycles (no ventricular extrasystoles). The quality of the curves must be checked immediately and, if necessary, the maneuver repeated if necessary, e.g. in case of strong artifacts or implausible values.

Following collection of the saturation levels, the MPC is initially positioned in the trunk of the pulmonary artery. After rinsing the MPC with approx. 5 ml NaCl 0.9% and connecting the catheter to the manifold, the pressure curves are registered via the pressure transducer (see above). Then the catheter is repositioned under fluoroscopy in the left pulmonary artery and the pressure curves are registered in the same manner as described above. Then, during deep inspiration, proceed carefully into the peripheral pulmonary circulation until an artifact-free pulmonary capillary wedge pressure curve is obtained. The catheter is subsequently withdrawn under continuous registration into the left pulmonary artery where 10 more cardiac cycles are recorded. After repositioning in the right pulmonary artery, the above-described procedure is repeated. Finally, under continuous registration, the catheter is withdrawn from the trunk of the pulmonary artery via the right ventricle into the right atrium (registration over 10 cardiac cycles/localization (see evaluation under 3.3.4.).

3.3.3 Arterial puncture and sheath insertion

Using the single-wall puncture technique, the CFA is punctured approx. 1-2 cm below the inguinal ligament at an angle of approx. 30-45° to the skin surface, following the presumed proximal course of the vessel. The guide wire is advanced through the indwelling cannula into the cranial artery; the puncture needle is withdrawn under compression and the sheath with integrated dilator is inserted through the guide wire. The dilator is subsequently removed. Following aspiration of approx. 5 ml of blood, blood is collected via the sheath using a 2 ml plastic syringe to determine the arterial saturation. This is followed by intra-arterial administration of 2500 IU of fractionated heparin/10 ml NaCl using a 10 ml syringe through the sheath under repeating aspiration.

3.3.4 Catheterization of the left ventricle and ventriculography

Ventriculography is performed according to the relevant standards and the respective study protocol. The pigtail catheter is placed via the indwelling guide wire in the ascending aorta in 30° LAO projection at the level of the sinus valsalvae and then positioned freely in the middle of the left ventricle by retrograde catheterization of the aortic valve. After removal of the guide wire, the pigtail catheter is connected to the rotator of the manifold. With the patient in resting expiratory position, the ventricular pressure curves are registered over 10 cardiac cycles (caveat: no ventricular extrasystoles) via the pressure transducer. After this, the 4 F pigtail catheter is connected to the high-pressure injection pump.

Ventriculography is performed in 2 projection planes with the participant at respiratory rest in deep inspiration over 5 cardiac cycles:

1. 30° RAO, contrast agent volume according to local standard, flow rate 15 ml/sec.
2. 60° LAO, contrast agent volume according to local standard, flow rate 15 ml/sec.

After ventriculography, ventricular pressure curves are registered again over 10 cardiac cycles with the participant at respiratory rest, and aortic pressure curves are registered over 10 cardiac cycles after retraction into the ascending aorta (to determine any retraction gradient across the aortic valve) (see evaluation in section 3.3.5).

### 3.3.5 Coronary angiography

Coronary angiography is performed in accordance with the relevant standards and the respective study protocol (see coronary angiography findings in section 3.3.5). Literature reference: Clinical Research in Cardiology, Vol. 97, No. 8, Clin Res Cardiol 97:475–512 (2008).

### 3.3.6 Left ventricular endomyocardial biopsy

Myocardial biopsy sampling is performed in accordance with the relevant standards and the respective study protocol. After the coronary angiography has been performed the arterial 4F sheath is exchanged for the 8F sheath via the guide wire. This is followed by retrograde catheterization of the aortic valve in 30° RAO projection and placement of a 7F guiding catheter into the left ventricle. Under fluoroscopy, the tip of the catheter is positioned in the target region. Biopsy forceps are inserted through the 7F guiding catheter and biopsies are collected from different areas of the left ventricle. Immediately after collecting the myocardial biopsy, transthoracic echocardiography is performed to exclude the presence of pericardial effusion.

### 3.3.7 Right ventricular myocardial biopsy

A standard bioptome (e.g. B-18110; Medizintechnik Meiners, Mannheim, Germany) is advanced through the sheath under X-ray control. The right ventricle is accessed through the right atrium and a small biopsy is taken from different sites of the septum. The correct position of the bioptome in the right ventricle should always be ensured by radiographic control before sampling. Another common access route is via the jugular vein.

### 3.3.8 Number of biopsies

The recommended number of biopsies depends on the clinical question under and whether material is to be obtained for scientific questions. The latter is only possible if an application for ethical approval exists.

For the clinical clarification of, e.g. storage diseases, experience has shown that 1-2 samples are needed for histological analyses, 1 sample for immune-histological analysis and, where applicable, 1-3 samples for molecular biology questions. For questions related to inflammatory responses and/or virus identification, experience has shown that 6 additional samples are required to exclude a sampler error. It is important to note that the quality/size of each biopsy obtained also determines the number of samples taken.
3.4 FOLLOW-UP AND DATA COLLECTION

3.4.1 Follow-up

Follow-up is performed in accordance with the relevant standards and the respective study protocol. After excluding the presence of postprocedural pericardial effusion, the venous and arterial sheaths are withdrawn. First, manual compression is applied to the puncture site(s) until bleeding stops. Then, a compression bandage is applied circularly around the hip using elastic bandages. This remains in place for 6 hours with the participant at bed rest. After transfer to the ward, the compression bandage is closely monitored. On the following day, elective patients can be discharged once pericardial effusion has once again been excluded by echocardiography.

3.4.2 Conservation/transport/processing of samples

Samples intended for histological studies should be fixed in 4-5% formalin immediately after collection. Samples intended for immune-histological and molecular biology investigations should be placed in so-called RNAlater tubes for fixation. For subsequent shipment of specimens in RNAlater, biopsies must be placed in the prepared tubes immediately after collection, then seal the tube tightly and invert immediately so that the biopsy is submerged in the liquid and the material is preserved for all further studies.

Afterwards the samples must be shipped without delay or stored in the refrigerator at +4°C until shipment. Samples may be dispatched to the laboratory at room temperature in a padded envelope.

The RNAlater tubes should be stored at room temperature prior to use. Slight formation of crystals does not impair fixation of the samples.

For parallel detection of systemic viral infection in blood, please send an additional EDTA tube. Shipment also takes place at room temperature.

Biopsy analysis should be performed in a laboratory that specializes in myocardial biopsy analyses. Simultaneous biopsy processing of histologic, immunohistologic, and molecular biology analyses should be sought. Use of additional FDA-approved laboratories is desirable.

3.4.3 Diagnosis

Examples of possible documentation of findings (see appendix).

1. **Ventriculography (see appendix 1):**

   Qualitative evaluation of left ventricular (pump) function:

   1. Assessment of wall motion abnormalities according to the nomenclature defined by Herman et al. (*Herman et al.*).
   2. Documentation of the classification and assessment of individual wall areas is performed according to the Coronary Artery Disease Reporting System of the American Heart Association (AHA) (*Austen et al.*).
Hemodynamics of the left ventricle (in mmHg):

1. end-systolic and end-diastolic ventricular pressure prior to angiography
2. end-systolic and end-diastolic ventricular pressure after angiography
3. following catheter withdrawal into the aortic bulb, systolic, diastolic and mean aortic pressure (if necessary, “peak-to-peak” withdrawal gradient)
4. classification of mitral regurgitation according to Sellers (Sellers et al. 1964):

<table>
<thead>
<tr>
<th>Grade I</th>
<th>contrast medium reflux with only minimal staining in the left atrium</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade II</td>
<td>contrast medium regurgitation jet with moderate contrast staining of the left atrium</td>
</tr>
<tr>
<td>Grade III</td>
<td>complete contrast staining of the left atrium corresponding to the contrast density of the left ventricle</td>
</tr>
<tr>
<td>Grade IV</td>
<td>Enlarged left atrium with greater contrast density compared to the left ventricle and reflux into the pulmonary veins</td>
</tr>
</tbody>
</table>

2. **Coronary angiography (see appendix 2):**

Coronary angiography reporting is semiquantitative according to AHA guidelines (Austen et al.):

- supply type
- stenosis localization according to the AHA classification segments (see appendix 2),
- collateralization
- suitable for PTCA and/or bypass intervention
- the diagnosis (as well as the type of vascular disease) is noted
3. **Right heart catheterization (see appendix 3):**

**General hemodynamics:**

**Cardiac output (CO)** (l/min):
- Calculation according to Fick’s equation: \( \text{vO}_2 \times \text{avDO}_2 \)
  
  \[
  \text{vO}_2 \text{ Men} = \text{BSA} \times (161 - \text{age} \times 0.54) \text{ (ml min}^{-1} \text{)} \text{ (empiric)}
  \]
  
  \[
  \text{vO}_2 \text{ Women} = \text{BSA} \times (147.5 - \text{age} \times 0.47) \text{ (ml min}^{-1} \text{)} \text{ (empiric)}
  \]
  
  \[
  \text{vO}_2 \text{art} = \text{O}_2 \text{ saturation (femoral artery)} \times \text{Hb} \times 1.34
  \]
  
  \[
  \text{CO}_2\text{ven} = \text{O}_2 \text{ saturation (pulmonary artery)} \times \text{Hb} \times 1.34
  \]

- **Abbreviations:**
  - \( \text{vO}_2 \): oxygen consumption; \( \text{avDO}_2 \): arteriovenous \( \text{O}_2 \) difference;
  - \( \text{CO}_2\text{art} \): arterial \( \text{O}_2 \) content;
  - \( \text{CO}_2\text{ven} \): central venous \( \text{O}_2 \) content;
  - \( \text{Hb} \): hemoglobin.

**Cardiac index (CI)** (l/min/m\(^2\)):
- Calculation: \( \text{CO} / \text{BSA} \)
- **Abbreviations:**
  - \( \text{BSA} \): body surface area

**Pulmonary vascular resistance (PVR)** (dyn*sec*cm\(^{-5}\)):
- Calculation: \( 80 \times (\text{mPAP} - \text{mPCPW}) \times \text{CO}^{-1} \) (normal range: 45-120)
- **Abbreviations:**
  - \( \text{mPAP} \): mean pulmonary arterial pressure;
  - \( \text{mPCPW} \): mean pulmonary capillary wedge pressure.

**Systemic (peripheral) vascular resistance (SVR)** (dyn*sec*cm\(^{-5}\)):
- Calculation: \( 80 \times (\text{mAP} - \text{CVP}) \times \text{CO}^{-1} \) (normal range: 900-1400)
- **Abbreviations:**
  - \( \text{mAP} \): mean arterial pressure;
  - \( \text{CVP} \): central venous pressure = mean pressure right atrium.
Mixed venous oxygen saturation (MVO$_2$) (%):

- Calculation: $(3\times$venO$_2$VCS + venO$_2$VCI) / 4
- Abbreviations:
  - venO$_2$VCS: venous oxygen saturation Vena cava superior; venO$_2$VCI: venous oxygen saturation Vena cava inferior.

Shunt calculation (Fick’s principle): A shunt calculation should be performed when there is a significant (more than 5%) difference in oxygen saturation between two sampling sites:

**Left-to-Right Shunt** (l/min)
Calculation: $(Q_{pulm} - Q_{syst})$

**Right-to-Left Shunt** (l/min)
- Calculation: $(Q_{syst} - Q_{pulm})$
  - $Q_{syst} = vO_2* (((SAO_2-MVO_2)*10)^{-1})$
  - $Q_{pulm} = vO_2* (((SAO_2-PAO_2)*10)^{-1})$
  - SAO$_2$= arterial saturation*Hb*1.34 (ml*(100 ml$^{-1}$))
  - PAO$_2$= pulmonary arterial saturation*Hb*1.34 (ml*(100 ml$^{-1}$))
- Abbreviations: $Q_{pulm}$: cardiac output in pulmonary circulation; $Q_{syst}$: cardiac output in systemic circulation; SAO$_2$: systemic arterial oxygen content; (* corresponds to pulmonary venous O$_2$ content); PAO$_2$: pulmonary arterial O$_2$ content

### 3.5 DEALING WITH DEVIATIONS

This SOP describes a standard procedure under optimal examination conditions from which it is necessary to deviate when problems occur. For instance, ventriculography must be omitted in patients with mechanical aortic valve replacement because retrograde catheterization of the prosthetic aortic valve should be avoided. If the right common femoral artery approach is problematic (e.g. in case of severe pAOD, status post stent implantation or bypass surgery, severe kinking of the artery etc.) alternative approaches must be selected. Similarly, a reduction in the amount of contrast medium must be considered in case of severe renal insufficiency.

The value of right ventricular angiography for diagnosis of ARVC is unclear, because standardized reporting has not been established. Nevertheless, performance can be considered in individual cases.
4 LITERATURE AND REFERENCES


5 MODIFICATIONS

Modifications to the previous version.

<table>
<thead>
<tr>
<th>Section</th>
<th>Description of the modification to the previous version</th>
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<tbody>
<tr>
<td>eCRF</td>
<td>LVEDP now at 2. left heart catheterization</td>
</tr>
<tr>
<td>eCRF</td>
<td>5.1.2 Fibrosis detection not applicable</td>
</tr>
<tr>
<td>eCRF</td>
<td>8. procedural complications (more detailed)</td>
</tr>
<tr>
<td>....</td>
<td></td>
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</tbody>
</table>

6 PERSONS INVOLVED

<table>
<thead>
<tr>
<th>Name</th>
<th>Function</th>
<th>Contribution</th>
</tr>
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<tbody>
<tr>
<td>Dr. Ralf Bauer</td>
<td>Author</td>
<td>Drafted the SOP</td>
</tr>
<tr>
<td>Prof. Dr. Carsten Tschöpe</td>
<td>Author</td>
<td>Drafted the SOP</td>
</tr>
<tr>
<td>Dr. Natalie Arnold</td>
<td>WG Data standardization</td>
<td>Scientific review</td>
</tr>
<tr>
<td>Prof. Marcus Dörr</td>
<td>WG Data standardization</td>
<td>Scientific review</td>
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<tr>
<td>Prof. Frank Edelmann</td>
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<tr>
<td>Dr. Christoph Gertler</td>
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<tr>
<td>Prof. Stefan Kääb</td>
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<tr>
<td>Prof. Till Keller</td>
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</tr>
<tr>
<td>Dr. Monika Kraus</td>
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<tr>
<td>Dr. Kristin Lehnert</td>
<td>WG Data standardization</td>
<td>Scientific review</td>
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The text elements highlighted in gray in this SOP are mandatory (= basic data set). The text elements that are not highlighted must be adhered to if possible.
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<tr>
<td>Prof. Benjamin Meder</td>
<td>WG Data standardization</td>
<td>Scientific review</td>
</tr>
<tr>
<td>Prof. Eike Nagel</td>
<td>WG Data standardization</td>
<td>Scientific review</td>
</tr>
<tr>
<td>Prof. Matthias Nauck</td>
<td>WG Data standardization</td>
<td>Scientific review</td>
</tr>
<tr>
<td>Dr. Jürgen Prochaska</td>
<td>WG Data standardization</td>
<td>Scientific review</td>
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<tr>
<td>PD Dr. Anja Sandek</td>
<td>WG Data standardization</td>
<td>Scientific review</td>
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<tr>
<td>Christian Schäfer</td>
<td>WG Data standardization</td>
<td>Scientific review</td>
</tr>
<tr>
<td>Dipl.-Ing. Jens Schaller</td>
<td>WG Data standardization</td>
<td>Scientific review</td>
</tr>
<tr>
<td>Tabea Scharfe</td>
<td>WG Data standardization</td>
<td>Scientific review</td>
</tr>
<tr>
<td>Prof. Renate Schnabel</td>
<td>WG Data standardization</td>
<td>Scientific review</td>
</tr>
<tr>
<td>Dr. Farbod Sedaghat-Hamedani</td>
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<tr>
<td>Dana Stahl</td>
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<td>Dr. Johannis Trebing</td>
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<td>Prof. Philipp Wild</td>
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<td>Prof. Tanja Zeller</td>
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</tr>
<tr>
<td>Mahsa Lee</td>
<td>WG Data standardization</td>
<td>IT implementation</td>
</tr>
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<td>Dipl.-Inf. Sabine Hanß</td>
<td>WG Data standardization</td>
<td>IT implementation</td>
</tr>
<tr>
<td>Dr. Julia Hoffmann, Dr. Ilka Wilhelmi</td>
<td>WG Data standardization</td>
<td>Coordination</td>
</tr>
</tbody>
</table>

The text elements highlighted in gray in this SOP are mandatory (= basic data set). The text elements that are not highlighted must be adhered to if possible.
7 Appendix

7.1 Appendix 1: Ventriculography Findings

Anlage 1

Klinikum der Universität Heidelberg
Medizinische Klinik
Abteilung Innere Medizin III (Kardiologie)
Direktor: Prof. Dr. H. A. Katus

Ventriculographie - Befund

Name:
Vorname:
Anschrift: 
geb. am: 
Untersuchungsdatum: 

EF: 
Cardiac Index: 
Mitralklappensteno.: 

Ao.-Druck (syst./diast.): prä Angio / mmHg
post Angio / mmHg
LV-Druck (syst./LVEDP): prä Angio / mmHg
post Angio / mmHg

Letzte Änderung:

<table>
<thead>
<tr>
<th>Segment</th>
<th>Normal</th>
<th>Hypokinesie</th>
<th>Akinesie</th>
<th>Dyskinesie</th>
<th>Auswurfrate</th>
<th>nicht dargestellt</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Anterobasal</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Anterolateral</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Apikal</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Diaphragm</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Posterobasal</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Septal</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Posteriorlateral</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Diagnosen:

Maßnahmen:

Rücksprachen:
7.2 APPENDIX 2: CORONARY ANGIOGRAPHY FINDINGS

Klinikum der Universität Heidelberg
Medizinische Klinik
Abteilung Innere Medizin III (Kardiologie)
Direktor: Prof. Dr. H. A. Katus

Koronarangiographie - Befund

Name: 
Gewicht (kg): 
Station: 
Öffnungswinkel (º):

Untersuchungsdatum: 
Untersucher: 
Registrierer: 
Befundor: 

Rechtversorgungstyp: 
Linkversorgungstyp: 
Art der Intervention: x: vor Intervention o: nach Intervention

Auswahl; Versorgungstyp: 
Katheter:

Komplications:

RCA 1
RCA 2
RCA 3
RCA 4
LCA 5
LAD 6
LAD 7
LAD 8
LAD 9
LAD 10
CIRC 11
CIRC 12
CIRC 13
CIRC 14
CIRC 15

Art der Intervention: x: vor Intervention o: nach Intervention

The text elements highlighted in gray in this SOP are mandatory (= basic data set). The text elements that are not highlighted must be adhered to if possible.
7.3 APPENDIX 3: RIGHT HEART CATHETERIZATION FINDINGS
### 7.4 eCRF MODUL

#### Cardiac catheterization

**Examination details**

<table>
<thead>
<tr>
<th>Level</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 1</td>
<td>The examination is performed in accordance with the guidelines of the medical associations.</td>
</tr>
<tr>
<td>Level 2</td>
<td>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.</td>
</tr>
<tr>
<td>Level 3</td>
<td>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).</td>
</tr>
</tbody>
</table>

#### 1. Right heart catheterisation

1. Was the right heart catheterisation performed?*
   - [ ] yes
   - [ ] no
   - [ ] unknown
   - [ ] not assessed

2. Date of examination*
   - [ ] mm/dd
   - [ ] unknown
   - [ ] not assessed

3. Cardiac output*
   - [ ] ml/min
   - [ ] unknown
   - [ ] not assessed

4. Systolic pulmonary artery pressure*
   - [ ] mmHg
   - [ ] unknown
   - [ ] not assessed

5. Diastolic pulmonary artery pressure*
   - [ ] mmHg
   - [ ] unknown
   - [ ] not assessed

6. Mean pulmonary artery pressure*
   - [ ] mmHg
   - [ ] unknown
   - [ ] not assessed

7. Pulmonary capillary pressure (PCWP)*
   - [ ] mmHg
   - [ ] unknown
   - [ ] not assessed

8. Mean RA*
   - [ ] mmHg
   - [ ] unknown
   - [ ] not assessed

9. Central venous oxygen saturation*
   - [ ] %
   - [ ] unknown
   - [ ] not assessed

10. Arterial oxygen saturation*
    - [ ] %
    - [ ] unknown
    - [ ] not assessed

11. Transpulmonary gradient*
    - [ ] mmHg
    - [ ] unknown
    - [ ] not assessed

12. Pulmonary vascular resistance*
    - [ ] dyns·cm⁻⁵
    - [ ] unknown
    - [ ] not assessed

13. Systemic vascular resistance (SVR)*
    - [ ] dyns·cm⁻⁵
    - [ ] unknown
    - [ ] not assessed
The text elements highlighted in gray in this SOP are mandatory (= basic data set). The text elements that are not highlighted must be adhered to if possible.

<table>
<thead>
<tr>
<th>Section</th>
<th>Question</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1.4. Body height*</td>
<td>unknown, not assessed</td>
</tr>
<tr>
<td></td>
<td>1.5. Weight*</td>
<td>kg, unknown, not assessed</td>
</tr>
<tr>
<td></td>
<td>1.6. Haemoglobin*</td>
<td>unknown, not assessed</td>
</tr>
<tr>
<td></td>
<td>Unit</td>
<td></td>
</tr>
<tr>
<td>2. Left heart catheterisation</td>
<td>2.1. Was the left heart catheterisation performed?*</td>
<td>yes, no, unknown, not assessed</td>
</tr>
<tr>
<td></td>
<td>2.2. Date of recording*</td>
<td>mm, dd</td>
</tr>
<tr>
<td></td>
<td>2.3. Left ventricular end-diastolic pressure (LVEDP)*</td>
<td>unknown, not assessed</td>
</tr>
<tr>
<td></td>
<td>2.4. Coronary heart disease (CHD)*</td>
<td>none, coronary, 1-vessel, 2-vessel, 3-vessel, unknown, not assessed</td>
</tr>
<tr>
<td></td>
<td>2.5. Pump function*</td>
<td>good, slightly limited, moderately limited, highly limited, restricted, unknown, not assessed</td>
</tr>
<tr>
<td>3. Myocardial biopsy</td>
<td>3.1. Was the myocardial biopsy performed?*</td>
<td>yes, no, unknown, not assessed</td>
</tr>
<tr>
<td></td>
<td>3.1.1. Date of recording*</td>
<td>mm, dd</td>
</tr>
<tr>
<td></td>
<td>3.1.2. Ventricle*</td>
<td>LV, RV, LV and RV, unknown, not assessed</td>
</tr>
<tr>
<td></td>
<td>3.1.3. Institute made the findings*</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3.2. Previous biopsies available*</td>
<td>yes, no, unknown, not assessed</td>
</tr>
<tr>
<td></td>
<td>3.2.1. Date of previous biopsy*</td>
<td>mm, dd</td>
</tr>
<tr>
<td></td>
<td>3.2.2. Previous diagnosis*</td>
<td>unknown, not assessed</td>
</tr>
<tr>
<td>3.2.3. Number of biopsies*</td>
<td>![Blank Box]</td>
<td></td>
</tr>
<tr>
<td>---------------------------</td>
<td>-------------</td>
<td></td>
</tr>
<tr>
<td>3.2.4. Ventricle*</td>
<td>![Blank Box]</td>
<td></td>
</tr>
<tr>
<td>3.2.5. Institute made the findings*</td>
<td>![Blank Box]</td>
<td></td>
</tr>
</tbody>
</table>

4. Storage diseases

4.1. Storage diseases* ![Blank Box]
4.2. Amyloidosis* ![Blank Box]
4.3. Other storage disease* Please specify* ![Blank Box]

5. Histological findings

5.1. Histological findings available* ![Blank Box]
5.2. Dallas criteria positive (including cell analysis)* ![Blank Box]
5.3. Fibrosis positive* ![Blank Box]
5.4. Necrosis* ![Blank Box]
5.5. Granulomas* ![Blank Box]
5.6. Giant cells* ![Blank Box]
5.7. Myocyte hypertrophy* ![Blank Box]

6. Immunohistological findings

6.1. Immunohistological findings present* ![Blank Box]
6.2. Inflammation positive* ![Blank Box]

7. Viral findings

The text elements highlighted in gray in this SOP are mandatory (= basic data set). The text elements that are not highlighted must be adhered to if possible.
| 7.1. | Virus and other pathogen detection in myocardium positive* | ☐ yes ☐ no ☐ unknown ☐ not assessed |
| 7.2. | Adenovirus* | ☐ yes ☐ no ☐ unknown ☐ not assessed |
| 7.3. | Coxsackievirus* | ☐ yes ☐ no ☐ unknown ☐ not assessed |
| 7.4. | Epstein-Barr virus* | ☐ yes ☐ no ☐ unknown ☐ not assessed |
| 7.5. | Parvovirus B19* | ☐ yes ☐ no ☐ unknown ☐ not assessed |
| 7.6. | Herpes simplex virus 1/2* | ☐ yes ☐ no ☐ unknown ☐ not assessed |
| 7.7. | Human herpes virus 6* | ☐ yes ☐ no ☐ unknown ☐ not assessed |
| 7.8. | Humanes cytomegalovirus* | ☐ yes ☐ no ☐ unknown ☐ not assessed |
| 7.9. | Influenza A und B* | ☐ yes ☐ no ☐ unknown ☐ not assessed |
| 7.10. | Hepatitis C* | ☐ yes ☐ no ☐ unknown ☐ not assessed |
| 7.11. | Other pathogens in the myocardium* | ☐ yes ☐ no ☐ unknown ☐ not assessed |
| 7.11.1 | Chagas* | ☐ yes ☐ no ☐ unknown ☐ not assessed |
| 7.11.2 | Borrelia* | ☐ yes ☐ no ☐ unknown ☐ not assessed |
| 7.11.3 | Fungi* | ☐ yes ☐ no ☐ unknown ☐ not assessed |
| 7.11.4 | Other* | ☐ yes ☐ no ☐ unknown ☐ not assessed |

7.12. Virus detection in blood positive* ☐ yes ☐ no ☐ unknown ☐ not assessed

7.12.1 Determined from* | ☐ plasma ☐ serum ☐ unknown ☐ not assessed

Please specify virus*

8. **Procedural complications**

8.1. Procedural complications* ☐ yes ☐ no ☐ unknown ☐ not assessed

8.1.1. Apoplexy* | ☐ yes ☐ no ☐ unknown ☐ not assessed

8.1.2. Pericardial effusion* | ☐ yes ☐ no ☐ unknown ☐ not assessed

8.1.3. Pericardial tamponade* | ☐ yes ☐ no ☐ unknown ☐ not assessed
8.1.4. Access site*  ☐ yes  ☐ no  ☐ unknown  ☐ not assessed
8.1.5. Minor bleeding*  ☐ yes  ☐ no  ☐ unknown  ☐ not assessed
8.1.6. Major bleeding*  ☐ yes  ☐ no  ☐ unknown  ☐ not assessed
8.1.7. Death*  ☐ yes  ☐ no  ☐ unknown  ☐ not assessed
8.1.8. Other*  ☐ yes  ☐ no  ☐ unknown  ☐ not assessed

**Other, please specify**

## Mögliche Angaben
Bitte wählen Sie bei den oben mit Anmerkungen versehenen Feldern eine der hier aufgeführten Angaben.

1)  
1.  
2.  
3.  

2)  
<table>
<thead>
<tr>
<th>g/dl</th>
<th>mmol/l</th>
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