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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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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1 INTRODUCTION

1.1 LIST OF ABBREVIATIONS

Abbreviation	Plain text
A.	artery
ARVC	arrhythmogenic right ventricular cardiomyopathy
avDO2	arteriovenous difference of O2 content
BSA	body surface area
CC	cardiac catheterization
CFA	common femoral artery
CI	cardiac index
CO	cardiac output
CO2art	arterial O2 content
CO2ven	central venous O2 content
CVP	central venous pressure = mean pressure right atrium
ECG	electrocardiogram
FDA	Food and Drug Administration
Hb	haemoglobin
i.S.	in serum
INR	international normalized ratio
IU	international units
JL	Judkins left catheter
JR	Judkins right catheter
LAO	left anterior oblique
LVEDP	left ventricular end diastolic pressure
mAP	mean arterial pressure
mPAP	mean pulmonary arterial pressure
MPC	multipurpose catheter
mPCWP	mean pulmonary capillary wedge pressure
MRi	magnet resonance imaging

MVO2	mixed venous oxygen saturation
NaCl	natrium chloride
PAO2	pulmonary arterial oxygen content
pAOD	peripheral arterial occlusive disease
PCWP	pulmonary capillary wedge pressure
PTCA	percutaneous transluminal coronary angioplasty
PT	parameter of functional performance of the extrinsic blood coagulation pathway
PTT	partial thromboplastin time
Q-pulm	cardiac output in the pulmonary circulation
Q-syst	cardiac output in the systemic circulation
RA mean	mean right atrial pressure
RAO	right anterior oblique
SAO2	systemic arterial oxygen content
SVR	systemic peripheral vascular resistance
TSH	thyroid stimulating hormone
V.	Vena
venO2VCI	venous oxygen saturation Vena cava inferior
venO2VCS	venous O2 saturation Vena cava superior
vO2	oxygen consumption
WG	working group

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_HerzkatheterraeumeH.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.

DZHK Quality Level	
Implementation	
Level 1	The examination is performed in accordance with the guidelines of the scientific societies.
Level 2	The examination is performed in accordance with the specifications of the DZHK SOP. Minimum requirements 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 and certification of the investigators: Definition of intra-observer and inter-observer variability (standard of epidemiological studies).

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: (http://leitlinien.dgk.org/files/2001_Leitlinie_Einrichtung_und_Betreiben_von_Herzkatheterraeumen.pdf):

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 nitroglycerine/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
    - chagas
    - borrelia
    - fungi
    - other (Please specify as free text)
- virus detection in blood positive
- determined from
    - plasma
    - serum
    - unknown
    - not assessed
    - virus please specify as free text

Procedural complications

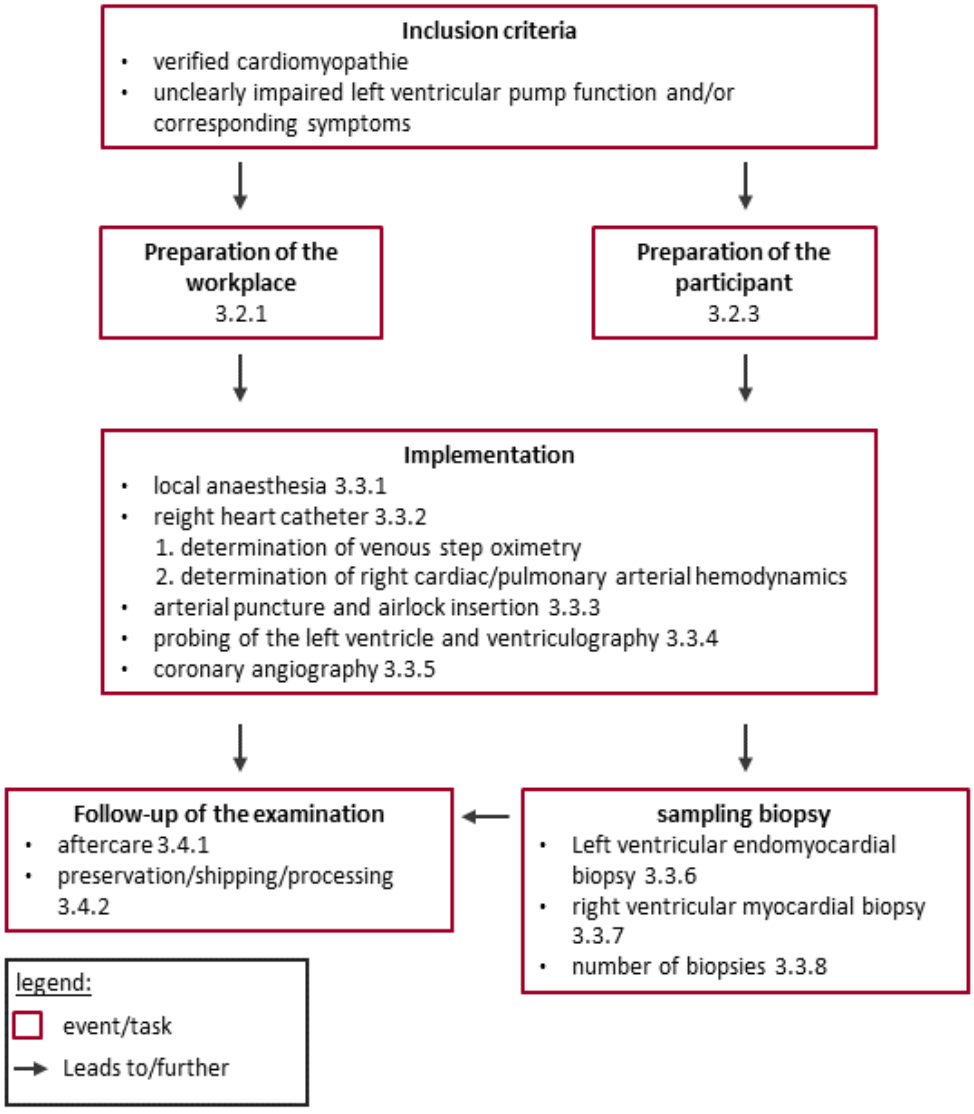
- apoplexy
- pericardial effusion
- pericardial tamponade
- access site
- minor bleeding
- major bleeding
- death
- other (please specify as free text)

2.5 STAFF

The corresponding legal regulations apply.

3 PROCESS OF IMPLEMENTATION/WORK PROCESS/WORK STEPS

3.1 PROCESS FLOW CHART



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%

- 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®).

3.2.2 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.

3.3 PERFORMING THE EXAMINATION

Because of the performance of coronary angiography with LV angiography in conjunction with right eart 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 dilatator is inserted through the guide wire. The dilatator 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*):

Grade I	contrast medium reflux with only minimal staining in the left atrium
Grade II	contrast medium regurgitation jet with moderate contrast staining of the left atrium
Grade III	complete contrast staining of the left atrium corresponding to the contrast density of the left ventricle
Grade IV	Enlarged left atrium with greater contrast density compared to the left ventricle and reflux into the pulmonary veins

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:(vO_2 *$avDO_2^{-1}$)

  vO_2 $_{Men}$= BSA*(161-age*0.54) (ml*min^{-1}) (empiric)

  vO_2 $_{Women}$= BSA*(147.5-age*0.47) (ml*min^{-1}) (empiric)

  $avDO_2$= CO_{2art}-CO_{2ven}

  CO_{2art}=O2 saturation (femoral artery)*Hb*1.34

  CO_{2ven}=O2 saturation (pulmonary artery)*Hb*1.34

- *Abbreviations: vO_2 :*
  - *oxygen consumption; $avDO_2$:*
  - *arteriovenous O_2 difference;*
  - *CO_{2art}: arterial O_2 content;*
  - *CO_{2ven}: central venous O_2 content;*
  - *Hb: hemoglobin.*

Cardiac index (CI) (l/min/m^2):

- Calculation: CO/BSA
- *Abbreviations:*
  - *BSA: body surface area*

Pulmonary vascular resistance (PVR) (dyn*sec*cm^{-5}):

- Calculation: 80*(mPAP-mPCPW)*CO^{-1}(*normal range: 45-120*)
- *Abbreviations:*
  - *mPAP: mean pulmonary arterial pressure;*
  - *mPCPW: mean pulmonary capillary wedge pressure.*

Systemic (peripheral) vascular resistance (SVR) (dyn*sec*cm^{-5}):

- Calculation: 80*(mAP-CVP)*CO^{-1}(*normal range: 900-1400*)
- *Abbreviations:*
  - *mAP: mean arterial pressure;*
  - *CVP: central venous pressure = mean pressure right atrium.*

Mixed venous oxygen saturation (MVO_2) (%):

- Calculation: (3*$venO_2VCS$) + $venO_2VCI$)) / 4
- *Abbreviations:*
    - *$venO_2VCS$: venous oxygen saturation Vena cava superior; $venO_2VCI$: 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

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5 MODIFICATIONS

Modifications to the previous version.

Section	Description of the modification to the previous version
eCRF	LVEDP now at 2. left heart catheterization
eCRF	5.1.2 Fibrosis detection not applicable
eCRF	8. procedural complications (more detailed)
….	

6 PERSONS INVOLVED

Name	**Function**	**Contribution**
Dr. Ralf Bauer	Author	Drafted the SOP
Prof. Dr. Carsten Tschöpe	Author	Drafted the SOP
Dr. Natalie Arnold	WG Data standardization	Scientific review
Prof. Marcus Dörr	WG Data standardization	Scientific review
Prof. Frank Edelmann	WG Data standardization	Scientific review
Dr. Christoph Gertler	WG Data standardization	Scientific review
Prof. Stefan Kääb	WG Data standardization	Scientific review
Prof. Till Keller	WG Data standardization	Scientific review
Dr. Monika Kraus	WG Data standardization	Scientific review
Dr. Kristin Lehnert	WG Data standardization	Scientific review

Prof. Benjamin Meder	WG Data standardization	Scientific review
Prof. Eike Nagel	WG Data standardization	Scientific review
Prof. Matthias Nauck	WG Data standardization	Scientific review
Dr. Jürgen Prochaska	WG Data standardization	Scientific review
PD Dr. Anja Sandek	WG Data standardization	Scientific review
Christian Schäfer	WG Data standardization	Scientific review
Dipl.-Ing. Jens Schaller	WG Data standardization	Scientific review
Tabea Scharfe	WG Data standardization	Scientific review
Prof. Renate Schnabel	WG Data standardization	Scientific review
Dr. Farbod Sedaghat-Hamedani	WG Data standardization	Scientific review
Dana Stahl	WG Data standardization	Scientific review
Dr. Johannis Trebing	WG Data standardization	Scientific review
Prof. Philipp Wild	WG Data standardization	Scientific review
Prof. Tanja Zeller	WG Data standardization	Scientific review
Mahsa Lee	WG Data standardization	IT implementation
Dipl.-Inf. Sabine Hanß	WG Data standardization	IT implementation
Dr. Julia Hoffmann, Dr. Ilka Wilhelmi	WG Data standardization	Coordination

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

Ventrikulographie - Befund

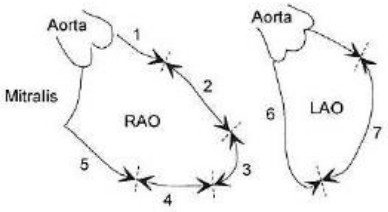
Name:

Vorname:

Anschrift:

geb. am:

Untersuchungsdatum:



EF:

Cardiac Index: l/min/m²

Mitralregurgitation:

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

Letzte Änderung:

Segment	Normal	Hypokinesie	Akinesie	Dyskinesie	Aneurysma	nicht dargestellt
1. Anterobasal						
2. Anterolateral						
3. Apikal						
4. Diaphragmal						
5. Posterobasal						
6. Septal						
7. Posterolateral						

x : vor Intervention o : nach Intervention

Diagnosen:

Maßnahmen:

Rücksprachen:

7.2 APPENDIX 2: CORONARY ANGIOGRAPHY FINDINGS

Anlage 2

Klinikum der Universität Heidelberg
Medizinische Klinik

Abteilung Innere Medizin III (Kardiologie)
Direktor: Prof. Dr. H. A. Katus

Untersuchungsnum

Koronarangiographie - Befund

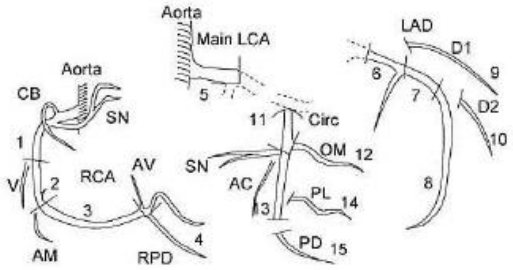
Name:
Vorname:
geb. am:
Anschrift:

Größe (cm):
Gewicht (kg):
Station:

Hb (g %):
Oberfläche (m²):

Überweisender Arzt:
Untersucher:
Registrierer:
Befunder:

Untersuchungsdatum:
Letzte Änderung:
Endbefund: ☐



Rechtsversorgungstyp: ☐
Linksversorgungstyp: ☐
Ausgegl. Versorgungstyp: ☐
Katheter:

	unauf-fallig	WUR	Stenosegrad 25 %	50 %	75 %	90 %	99 %	100%	geeignet für PTCA	Bypass	Kollateralen angefärbt durch	Abgabe von	klein	nicht vorh.
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														

x : vor Intervention o : nach Intervention

Art der Intervention:

Bemerkungen:

Komplikationen:

7.3 APPENDIX 3: RIGHT HEART CATHETERIZATION FINDINGS

Anlage 3

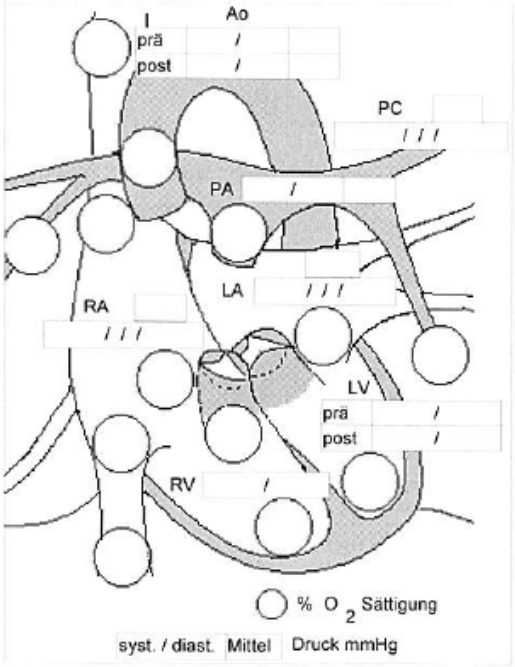
Klinikum der Universität Heidelberg
Medizinische Klinik

Abteilung Innere Medizin III (Kardiologie)
Direktor: Prof. Dr. H. A. Katus

Vitiumbogen

Name: | Größe (cm): | Hb (g %):
Vorname: | Gewicht (kg): | Oberfläche (m²):
geb. am: | Station:
Anschrift:

Überweisender Arzt:
Untersucher:
Untersuchungsdatum: | Registrierer:
Letzte Änderung: | Befunder:
Endbefund: ☐



O_2 Verbrauch: ml/min

HZV
Gr.: l/min
Kl.: l/min
Eff.: l/min

Li-Re Shunt: ml/min %
Re-Li Shunt: ml/min %

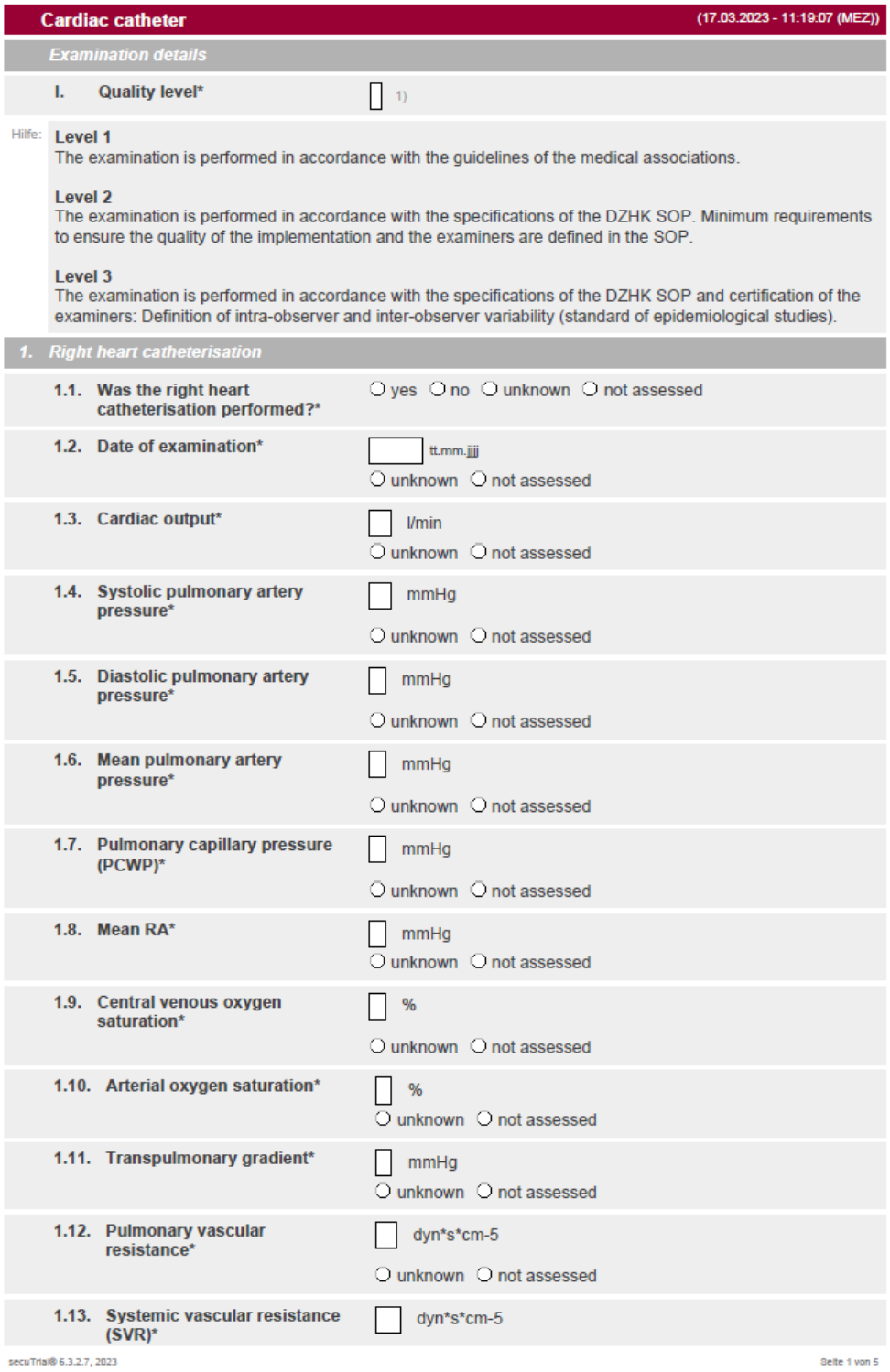
Pulm.Art.-R.: dyn.sec.cm^-5
syst.Art.-R.: dyn.sec.cm^-5

Bemerkungen:

Diagnosen:

Maßnahmen:

7.4 eCRF Modul



Cardiac catheter (17.03.2023 - 11:19:07 (MEZ))

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. Cardiac output*	☐ l/min ○ unknown ○ not assessed
1.4. Systolic pulmonary artery pressure*	☐ mmHg ○ unknown ○ not assessed
1.5. Diastolic pulmonary artery pressure*	☐ mmHg ○ unknown ○ not assessed
1.6. Mean pulmonary artery pressure*	☐ mmHg ○ unknown ○ not assessed
1.7. Pulmonary capillary pressure (PCWP)*	☐ mmHg ○ unknown ○ not assessed
1.8. Mean RA*	☐ mmHg ○ unknown ○ not assessed
1.9. Central venous oxygen saturation*	☐ % ○ unknown ○ not assessed
1.10. Arterial oxygen saturation*	☐ % ○ unknown ○ not assessed
1.11. Transpulmonary gradient*	☐ mmHg ○ unknown ○ not assessed
1.12. Pulmonary vascular resistance*	☐ dyn*s*cm-5 ○ unknown ○ not assessed
1.13. Systemic vascular resistance (SVR)*	☐ dyn*s*cm-5

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	○ unknown ○ not assessed
1.14. Body height*	☐ cm ○ unknown ○ not assessed
1.15. Weight*	☐ kg ○ unknown ○ not assessed
1.16. 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. Left ventricular end-diastolic pressure (LVEDP)*	☐ mmHg ○ unknown ○ not assessed
2.4. Coronary heart disease (CHD)*	○ none ○ coronary sclerosis ○ 1-vessel CHD ○ 2-vessel CHD ○ 3-vessel CHD ○ unknown ○ not assessed
2.5. Pump function*	○ good ○ slightly limited ○ moderately limited ○ highly restricted ○ 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. Institute made the findings*	☐
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. Institute made the findings*	

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 findings

5.1. Histological findings available*	○ yes ○ no ○ unknown ○ not assessed
5.2. Dallas criteria positive (including cell analysis)*	○ yes ○ no ○ unknown ○ not assessed
5.3. Fibrosis positive*	○ yes ○ no ○ unknown ○ not assessed
5.4. Necrosis*	○ yes ○ no ○ unknown ○ not assessed
5.5. Granulomas*	○ yes ○ no ○ unknown ○ not assessed
5.6. Giant cells*	○ yes ○ no ○ unknown ○ not assessed
5.7. Myocyte hypertrophy*	○ yes ○ no ○ unknown ○ not assessed

6. Immunohistological findings

6.1. Immunohistological findings present*	○ yes ○ no ○ unknown ○ not assessed
6.2. Inflammation positive*	○ yes ○ no ○ unknown ○ not assessed

7. Viral findings

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.	Humanes 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
	Please specify*	
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

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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 aufgelisteten Angaben.

1)

1
2
3

2)

g/dl
mmol/l