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

DZHK-SOP-C-08

Transthoracic echocardiography

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

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1 INTRODUCTION

1.1 LIST OF ABBREVIATIONS

Abbreviation	Plain text
2CH/2KB	Two-chamber view
4CH/4KB	Four-chamber view
A	Image
A-duration	A-wave duration
A'lat	Velocity of the lateral A'-wave
A'med	Velocity of the medial A'-wave
Acc-time PV	Acceleration time pulmonary valve
AR Decel slope	Deceleration profile ("slowing down") in the context of aortic regurgitation (m/s^2)
AR PHT	Pressure half-time in the context of aortic regurgitation
ASE	American Society of Echocardiography
AV Pgmax	Maximum aortic valve gradient
AV Pgmean	Mean gradient aortic valve
AV Vmax	Maximum velocity across the aortic valve
C	Celsius
cm	centimetre
CW	Continuous-wave
Diam IVC	inferior vena cava diameter
Diam IVC insp	Inspiratory collapse of ICV (>50% decrease in diameter during inspiration)
DT	Deceleration time of the early diastolic mitral inflow (E-wave)
DZHK	Deutsches Zentrum für Herz-Kreislauf-Forschung e.V. (German Centre for Cardiovascular Research)
E-duration	E-wave duration
E'lat	Velocity of the lateral E'-wave
E'med	Velocity of the medial E'-wave
E/A	E/A ratio
E/E‘	Ratio of E/E’lat
eCRF	Electronic case report form
ED	End-diastolic
EF	Ejection fraction
ECG/EKG	Electrocardiography/electrocardiogram
ES	End-systolic
HOCM	Hypertrophic obstructive cardiomyopathy
hPa	Hectopascal
Hz	Hertz
IVRT	Isovolumetric relaxation time

IVSd	Interventricular septum thickness at end of diastole
IVSs	Interventricular septum thickness at end of systole
LA	Left atrium
LA Vol	Volume of the left atrium
LA Vol Ind	Volume of the left atrium indexed to body surface area (biplane)
Laes long	End-systolic longitudinal diameter of LA
Laes transverse	End-systolic transverse diameter of LA
LAX	Parasternal long axis of the left ventricle
LKS	Left coronary aortic cusp
LV	Left ventricle
LVED	Left ventricular end-diastolic diameter
LVEDs	Left ventricular end-systolic diameter
LVEF	Left ventricular ejection fraction
LVOT	Left ventricular outflow tract
LVOT Pgmax	LVOT peak gradient
LVOT Vmax (m/s)	Maximum velocity in the LVOT
LVPWd	Left ventricular posterior wall in diastole
LVPWs	Left ventricular posterior wall in systole
m	metre
MAPSE	Mitral annular plane systolic excursion
Min	minutes
MV	Mitral valve
mm	millimetre
MOD	Magneto Optical Disc
MR VC Diam	Vena contracta mitral regurgitation
MR VTI	Velocity time integral of mitral regurgitation/mitral insufficiency
ms	milliseconds
MSS distance	Distance from septum to mitral leaflet coaptation point
MV A Vmax	Maximum velocity of A-wave
MV E Vmax	Maximum velocity of E-wave
MV PG mean	Mean gradient mitral valve
NKS	Non-coronary aortic cusp
PAPsys	Pulmonary artery systolic pressure
PISA	Proximal flow convergence zone
PV PGmax	Maximum gradient of pulmonary valve
PV V max	Maximum velocity of pulmonary valve
PVa dur	AR-wave duration ("atrial reversal") of pulmonary vein flow
PVd Vel	Maximum D-wave flow velocity of pulmonary vein flow
PVs Vel	Maximum S-wave flow velocity of pulmonary vein flow
PW	Pulse wave
Q	Quality criteria

R	Reading
RA	Right atrium
RKS	Right coronary aortic cusp
RVED1	Basal diameter of right ventricle
RVED2	Mean diameter of right ventricle
RVED3	Longitudinal diameter of right ventricle
S	Structures to be visualised and assessed
S	second
S'lat	Velocity of the lateral S'-wave
S'med	Velocity of the medial S'-wave
SAX	Parasternal short axis of the left ventricle
SOP	Standard Operating Procedure
SR	Sinus rhythm
TAPSE	Tricuspid annular plane systolic excursion
TV	Tricuspid valve
TR PGmax	Maximum systolic pressure gradient across the tricuspid valve
TR VTI	Velocity time integral of tricuspid regurgitation
TV PGmean	Mean gradient of tricuspid valve
TV Vmax	Maximum velocity of tricuspid valve
VAC	Alternating voltage
IVC	Inferior vena cava
AFib	Atrial fibrillation
Vp	Propagation velocity of the mitral valve
WG	working group

1.2 OBJECTIVE

The aim of the SOP transthoracic echocardiography is to define a catalogue of common parameters and settings with a focus on quality criteria to be observed, which is binding for the performance and evaluation of echocardiography within the DZHK. This should enable the performance of echocardiography and their evaluation in other DZHK partner centers in the context of joint studies, cohorts and registries.

1.3 TARGET GROUP

This SOP applies to all persons performing or evaluating echocardiographic examinations (studyphysicians, study assistants) in all studies and registries conducted by the DZHK.

1.3.1 Inclusion criteria

There are no general inclusion criteria for this examination.

1.3.2 Exclusion criteria

There are no general exclusion criteria for this examination.

1.4 APPLICATION AND TASKS

As part of cardiovascular diagnostics and during the conduct of studies, echocardiographic parameters are collected from participating subjects according to the specifications of the study protocol or registry.

1.5 TERMS AND DEFINITIONS

Acceleration time

- time from onset of increase until the maximum is reached

Backup

- storage of a data copy for safety reasons

Frame rate

- number of images generated/unit of time (s); the frame rate of the color Doppler is lower than that of the 2D image

Cineloop sequence

- storage of the last images by "freezing" and possibility of displaying frame by frame or as a film sequence

CW Doppler

- continuous, linear ultrasound beam (1.8-2 MHz), suitable for detecting high flow velocities

Deceleration time

- time interval of the decrease of a velocity from maximum to zero

2D mode

- generating a sectional image within a cone-shaped sector by fast generation and sweeping of ultrasonic beams

DICOM format

- standard format (Digital Imaging and Communications in Medicine) for exchanging digital images between devices from different manufacturers

EF according to modified Simpson's formula [1, 2]

- measurement of ejection fraction by bypassing the end-diastolic and end-systolic ventricular contours of the endocardium (="slice summation method")

Color Doppler

- pulsed Doppler method with color coding of measured, spatially distributed individual velocities

Gradient

- cardiological term for a pressure gradient at constrictions of a cross-section (e.g. stenoses)

Calibration (technical)

- measuring process to determine and document the deviation of a measuring device in a reliable and reproducible way

Convergence zone

- process for evaluating flow rates through constrictions of the flow cross-section. For simplicity, it is assumed that blood moves in concentric hemispheres of equal velocity towards a flow cross-section constriction (e. g. a paravalvular leak of a prosthesis)

Log file

- event log file; contains the automatically generated log of all or of certain processes that run on a computer

Medical device

- an object or substance that is used for medical therapeutic or diagnostic purposes

M-mode

- method with a one-dimensional ultrasound beam with a high pulse repetition rate/temporal resolution; used for linear measurements, e. g. of the diameter

MOD

- magneto optical disc, a rotating storage medium that can be written to magnetically and read optically

Nyquist limit

- limit speed for PW and color Doppler above which reliable speed measurement is no longer possible (Nyquist rate = highest identifiable speed)

Planimetry

- circumferential measurement of the largest area

Propagation velocity

- speed of propagation

Pulse repetition frequency

- time interval between transmission and reception, determines the upper limit for the temporal resolving power of pulsed ultrasound

PW Doppler

- pulsed Doppler mode of operation, in which the spatial allocation of a measurement takes place in a specific range (sample volume)

Reading

- acquisition and measurement/calculation of all relevant parameters

Sample volume

- size of the Doppler acquisition area

Sound output parameters (technical)

- thermal index (estimation of temperature rise), mechanical index (probability of tissue damage due to cavitation and spatial peak intensity)

Sound output power (technical)

- total measure of ultrasound exposure in tissue, defined by the sound output parameters, also dependent on the selected operating mode

Sound quality (medical)

- definition of the achieved quality of imaging of cardiac structures (depending on examining and participating person), classification into 1. good, 2. limited and 3. not possible

Depth

- maximum distance (far field) for image acquisition (lower depths allows higher frame rates)

Vena contracta

- narrowest proximal jet diameter of the color Doppler below the opening of an insufficient valve

Gain

- parameter of 2D measurement; by regulating the signal amplitude structures can be displayed with optimal contrast(usually depth and lateral controls)

Wall filter

- wall motion filter; high-intensity motions are filtered out, while weaker but interesting motions are emphasized

Worklist

- predefined list containing data of the participating person; enables an error-free transfer of the data to the echo menu

1.6 CORRELATIONS TO OTHER EXAMINATIONS

Mandatory preliminary examination:	-
Recommended preliminary examination:	-
Preliminary examination to be excluded:	If possible, *no stress tests* (e.g. spiroergometry, ergometry, 6-minute walking test, etc.): If this cannot be avoided, a sufficient rest period should be ensured before the start of the (= until the resting heart rate is reached).
Interference with other parts of the examination	-

Mandatory follow-up examination:	-
Recommended follow-up examination:	-
Follow-up examination to be excluded:	-

1.7 LEVEL OF QUALITY

The DZHK defines the following quality levels for investigations and data collection:

DZHK quality level	
Performance	
Level 1	The examination is performed in accordance with the guidelines of the scientific societies.
Level 2	The examination is performed in accordance with the specifications of the DZHK SOP. Minimum requirements for ensuring the quality of the implementation and the examiners are defined in the SOP.
Level 3	The examination is performed in accordance with the specifications of the DZHK SOP and certification of the examiners: Definition of intra-observer and inter-observer variability (standard of epidemiological studies).
Reading/evaluation	
Reading Level 1	Reading/evaluation by the study center as specified in the SOP.
Reading Level 2	Reading/evaluation by (independent) CoreLab.

This SOP describes the data collection of quality levels 2 and 3 as well as the evaluation of Reading Level 1 of the DZHK. Each DZHK study and each DZHK registry must define in the study protocol which quality levels are required.

Recording the sound quality

The examiner is responsible for recording the sound quality. Each standard setting (e.g. parasternal short axis) is placed in one of the following three categories:

1. performed with good sound quality
2. performed with very limited sound quality
3. no echo window – examination not possible

Sound quality is documented in the eCRF/CRF as part of the examination.

2 PREREQUISITES OF THE EXAMINATION

2.1 REQUIREMENTS REGARDING ROOMS/EQUIPMENT

- possibility of dimming (use prior to start the examination)
    - refer to the specific equipment description for further details on operating the echocardiography unit: minimum size of the examination room: 1.50 m x 5.00 m; a minimum distance of 4.50 m to other devices that emit strong electromagnetic radiation must be ensured
    - ventilation or circulation of air must be possible.
    - There must be no carpeting, as this can become electrostatically charged if walked on continuously
- for ultrasonic devices, a separate mains socket must be used which is designed for 100-230 VAC, 50/60 Hz a room temperature of 22 – 26 °C is recommended when examining a person

Room equipment

- examination/echocardiography couch with a height-adjustable headrest
- examiner chair, height adjustable
- computer/laptop for reading /data entry (eCRF), if applicable
- storage space for clothing of the participating person

2.2 DEVICES/ HARDWARE

2.2.1 Device designation and description

The ultrasound device should be a class 1, type CF device according to IEC60601-1. Furthermore, it should comply with the requirements of EU Directive 93/42/EEC for medical devices and should also comply with the emission limits for a group 1, class A medical device according to EN60601-1-2 (IEC60601-1-2). For transthoracic echocardiography, a transducer with a fundamental frequency of 2.5 MHz (so-called broadband transducer including harmonic imaging) is standard. The technical specifications of echocardiography devices that are used for DZHK studies must basically be suitable to meet the quality requirements. Furthermore, it must be ensured that only original peripheral devices are connected, as otherwise there is a risk of electromagnetic emissions from inadequately shielded peripheral devices. The definition of the sound output parameters is manufacturer-specific and is regulated by corresponding standards [e.g. FDA 510(k) 09/09/2008].

As a general technical requirement, a digital storage facility is still necessary. The images should be archived on a local server with backup. Storage is at least in the DICOM format and, if necessary, also as echo raw data of the respective device. The possibility for exporting the data to CD-ROM, DVD, MOD or via network should be given.

2.2.2 Procedure in case of defective devices

The device must not be used in case of defects or malfunctions. In any case, the responsible person on site is obliged to inform the manufacturer's customer service. If an error or system malfunction occurs, refer to the manufacturer's manual to find instructions on how to generate a log file to localize the problem.

2.2.3 Maintenance/device care

At least once a year, a safety inspection has to be carried out by trained personnel in accordance with the requirements of standard IEC 60601-1 standard on patient safety. Once a month or whenever a problem is suspected, the following items should be checked:

- plugs on cables for damage
- all cables for cuts and abrasion
- equipment for loose or missing parts
- the control panel for defects
- the brakes on the equipment cart

Tests for electrical leakage currents have to be carried out in regular intervals by the manufacturer's customer service or by qualified hospital personnel (procedure in accordance with standard EN60601-1/IEC 60601-1 §19). External peripheral devices have to be CE marked and must comply with the applicable standards (EN60601-1 und EN60950). Compliance with the provisions of standard EN60601-1-1 must be verified.

The air filters of the device have to be cleaned weekly; for this purpose, the device must be switched off and disconnected from the power outlet. The air filters are cleaned by trained personnel according to the specifications of the respective device manufacturer.

The system housing of the ultrasonic unit must be cleaned monthly with a soft cloth and mild all-purpose detergent. The LCD screen must also be cleaned monthly with a mild and suitable cleaning solution. For the monthly cleaning of the consoles, the power supply to the system must be switched off.

After every use, the probe has to be cleaned (using a soft cloth and lukewarm soap solution), dried and disinfected (see list of suitable disinfectants provided by the manufacturer or probe cleaning sheet).

2.3 SPECIAL CLINICAL CONSUMABLES

- thermal paper for thermal printer
- paper towels and soap dispenser for participating person for cleaning after the examination
- cleaning wipes (for regular cleaning of equipment) and soap solution

- disinfectant
- disposable razors (if applicable)

2.4 REQUIRED DOCUMENTS

In the context of DZHK studies or registries, informed consent for the study and the use of the generated data should be available prior to implementation according to the specific requirements. It is recommended to keep a paper copy version of the eCRF at hand. Information about any other essential documents can be found in the protocol of the respective study or registry.

2.5 REQUIRED INFORMATION

The verification of the participation criteria is dependent on the provisions of the respective study / registry.

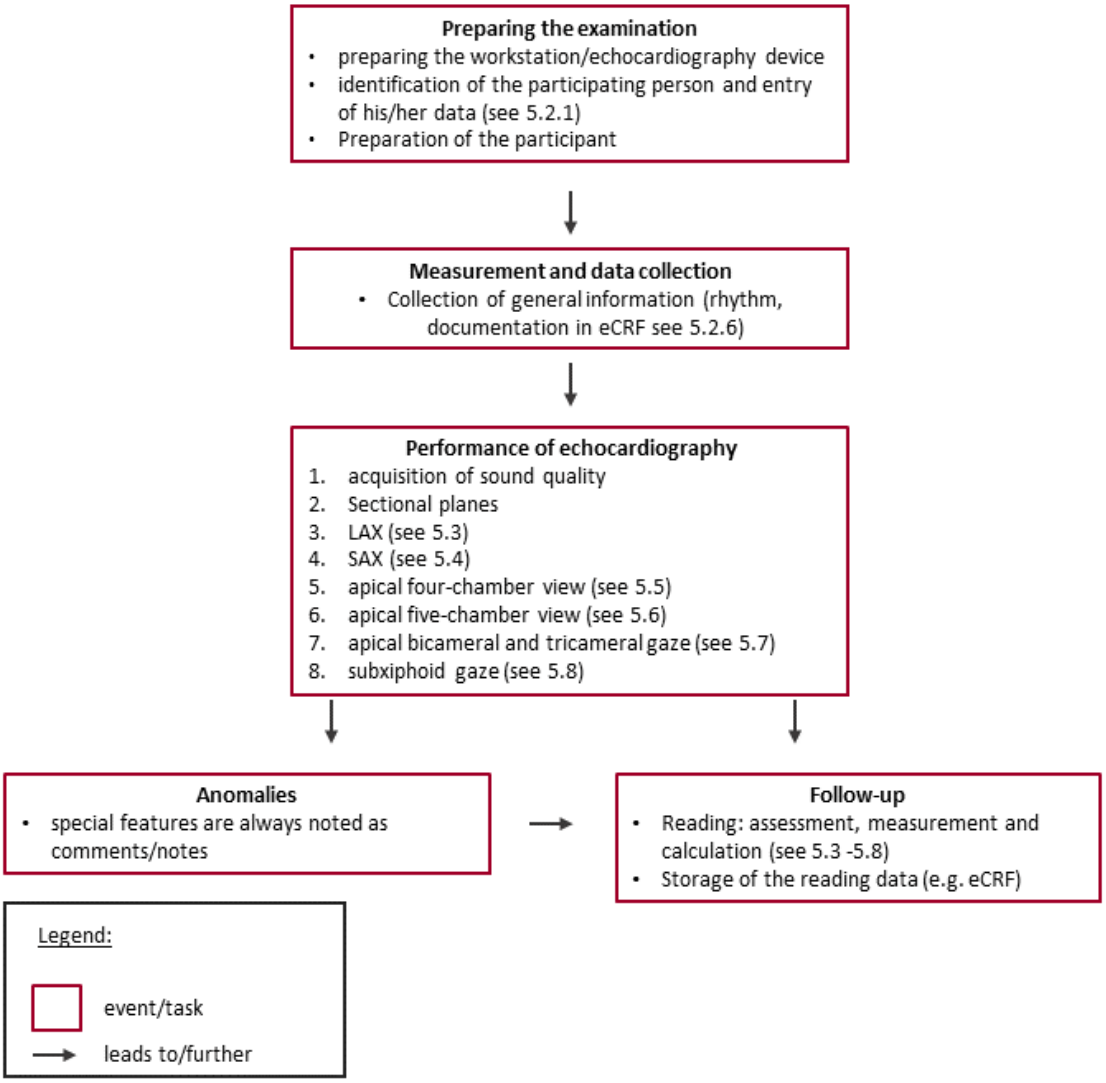
- For each examination, the following information must be documented in the eCRF/CRF: date of examination [dd.mm.yyyy]; assignment to study time point, if applicable (e.g. baseline visit, visit 1, etc.)
- heart rate [1 bpm]
- rhythm [sinus rhythm, atrial fibrillation, pacemaker + sinus rhythm, pacemaker + atrial fibrillation, pacing mode, other rhythm]

2.6 STAFF

The examiner should have a level of qualification that corresponds at least to level 2 of the AHA recommendations [3] (≥ 6 months of training, ≥ 150 examinations performed, ≥ 300 clinical reports).

3 IMPLEMENTATION/WORKFLOW/WORK STEPS

3.1 FLOWCHART OF THE PROCEDURE



3.2 PREPARING FOR THE EXAMINATION

At the beginning of the examination, identification of the participating person is necessary; if necessary, a check of the informed consent must also be carried out. For data storage and analysis within the study/registry, entry of relevant information is required. Depending on the device, this can either be done manually or via a worklist import. The respective study/registry (see study protocol) determines which information is necessary.

Basic data include the number, age and gender of the patient and the details of the examiner, as well as the date of the examination and if applicable the course of the study protocol (e.g. screening visit). Enter the subject ID and the examiner ID as shown below:

- patient ID: PID (PID from the study database/RDE system)
- surname: Project description, study center, visit and sequential number
- example: HP_4.1_BO_V2_112
    - date/time of examination
    - date of birth
    - sex
    - examiner's number

3.2.1 Principles of preparing the participant for the examination

No specific explanations about the examination are required. Explanation of the examination procedure depends on the respective study/registry.

Examination position:

The optimal measuring position is in 30° elevation and left side position of the upper body. The application of the ECG electrodes and the exact position of the electrodes can be found in the operating instructions of the device. It may be necessary to separately prepare the skin at the electrode contact points to ensure an optimal quality of the recording.

The parasternal axes are derived in the left lateral position and the apical axes in the oblique left lateral position. The left arm is crossed behind the head in order to widen the intercostal spaces, while the right arm rests on the thigh.

3.2.2 Preparing the workplace

The room should be darkened to ensure optimal recognition of the screen data.

3.3 GENERAL REQUIREMENTS

3.3.1 Recording modalities for all settings

1. 3 cardiac cycles are recorded (applies to still images and Cineloop/sequence) and digitally stored for sinus rhythm; 5 cardiac cycles are recorded and stored for atrial fibrillation
2. ES measurement means end of the T-wave or greatest thickness of myocardium
3. ED measurement means close to the peak of the Q-wave or start of the QRS complex
4. throughput speed 50-100/min.
5. during the whole examination, ensure a simultaneous ECG curve with correct reproduction of the P-wave (if available) and QRS complex
6. ideally 3 measurements of the given parameters are performed in sinus rhythm, or 3 values are calculated; in atrial fibrillation, ideally 5 measurements/calculations are performed; in case of extrasystoles, ideally 3 measurements of normal heartbeats are not performed before or after an extrasystole. Deviations (e.g. single measurements/calculations) are defined in the respective study protocols.

3.3.2 Parameters of 2D *image rendering/M-mode*

Depending on the manufacturer's specifications, always use the lowest sound output power at which ultrasound images with sufficient quality can be obtained. Adjust the overall gain and depth regulation until the structures in the 2D image sector are optimally delineated. The same applies to the gain in the longitudinal and lateral direction; adjust the settings depending on the section plane and the desired image quality. To achieve an optimal image contrast, adjust the compression individually depending on the examination conditions. A frame rate of 50 frames/second is recommended.

3.3.3 Parameters of Doppler investigation

The gain of the color Doppler should only be slightly ahead of the background; adjust the gain of the spectral Doppler curves until the respective envelope curves are optimally visualized. Adjust the zero line and velocity range until the flow profiles to be measured are complete; the velocity range should be slightly above the maximum velocity. The sample volume of the PW Doppler should be 3 mm, the sample volume of the tissue Doppler 5 mm. Recommendations for adjusting the wall filter and the pulse repetition frequency of the color Doppler may be found in the individual settings.

3.3.4 Recording speed

For the 2D image/M-mode and color Doppler, a recording speed of 50 mm/s should be selected; for spectral and tissue Doppler, a speed of 100 mm/s should be selected. For M-mode color recordings (propagation speed) 100-200 mm/s should be selected.

3.3.5 Frame rate

For 2D echo images (B-mode), a frame rate of 50 frames per second should be achieved.

For tissue Doppler examinations, a frame rate of at least 100 frames per second, ideally > 140 frames per second, is recommended [13]

3.3.6 Principles of preparing the participant for the examination

Verification of participation criteria

- Depending on specifications of the respective study/registry (see study protocol).

Explanations, instructions for the participant

- No specific explanations required. An explanation of the examination procedure depends on the respective study/registry.

3.4 PERFORMING THE EXAMINATION

3.4.1 Measurement, data collection and reading

For sinus rhythm, ideally 3 cardiac cycles are recorded (this applies to still images and Cineloop/sequence) and digitally stored; for atrial fibrillation, 5 cardiac cycles are recorded and stored. Deviations (e.g. single measurements/determinations) are defined in the respective study protocols.

- ES measurement: in the image immediately before the opening of the mitral valve or the image with the smallest diameter/volume (depending on the parameter to be measured) [2]
- ED measurement: at the level of the onset of the QRS complex (preferably the image immediately after closure of the mitral valve or the image at the time of maximum dilatation) [2]
- throughout the examination, allow simultaneous ECG tracing with correct reproduction of P-wave (if available) and QRS complex
- in case of sinus rhythm, 3 measurements of the predefined parameters are performed, respectively 3 values are calculated; in case of atrial fibrillation, 5 measurements/calculations are performed
- documentation (Cineloops, spectral Doppler) should be done during passive end expiration to minimize breath-dependend changes
- for spectral Doppler curves and tissue Doppler curves, the "modal" velocity should be measured (tracing of the brightest signal line within the signal envelope with the rationale that the brightness or signal strength is proportional to the sum of the reflectors and thus represents a weighted mean value of the flow velocities in the ‘sample volume’) [4, 5]

Recording general information about the examination in the eCRF

The following information has to be documented in the eCRF/CRF for each examination:

- date of the examination [dd/mm/yyyy]; if applicable, assignment to study end point (e.g. baseline visit, visit 1, etc.)
- heart rate [1bpm]

- rhythm [sinus rhythm, atrial fibrillation, pacemaker, other rhythm, (if pacemaker, then: pacemaker + sinus rhythm, pacemaker + atrial fibrillation, pacing mode)]

Systematics of examination requirements

For all standard echocardiographic sections, recommendations for data collection regarding modality (e.g. M-mode, 2D), structures to be imaged, quality criteria and reading are summarized in the following section. The following abbreviations are used:

- **A: recording**
- **S: structures to be visualized and assessed**
- **Q: quality criteria**
- **R: reading**

3.5 TRANSTHORACIC ECHOCARDIOGRAPHY METHODS

3.5.1 LAX

The explanations for A, S, Q and R as well as tables listed, if applicable, refer to the respective figure under which they appear.

3.5.1.1 2D mode overview

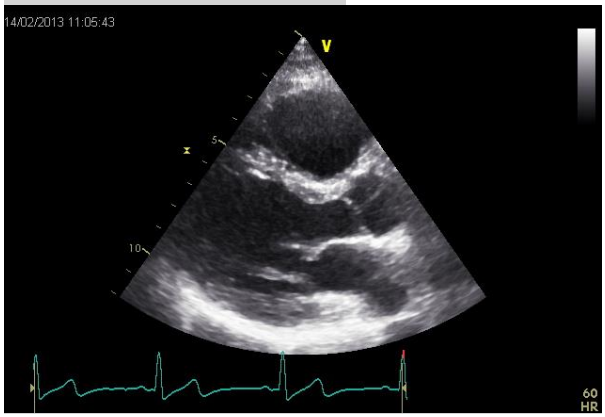


Figure 1: 2D mode overview

A: 2D sequence

S: 1. left ventricle, right ventricle

2. mitral and aortic valve

3. left atrium

Q: 1. pericardium should be fully visible at the bottom of the image

2. septum should be horizontal

3. left ventricle should be shown optimally stretched out

4. mitral and aortic valve should be clearly visable

R: visual assessment

3.5.1.2 M-mode aortic root in the long axis (LAX)

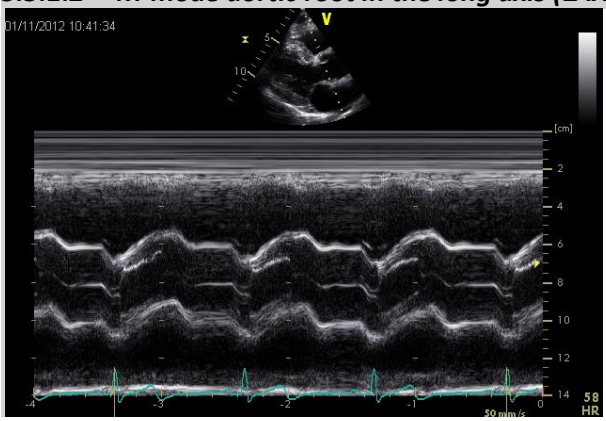


Figure 2: M-mode aortic root in the long axis (LAX)

A: M-mode in the long axis or alternatively in the short axis, see 3.5.2.8 (a measurement convention should be agreed upon as part of the study protocol for the trial)

S: 1. aortic valve with right and non-coronary leaflet

2. aortic root (start of systole)

3. left atrium end systolic

Q: 1. M-mode should be perpendicular to outflow tract and left atrium

2. aortic valve separation should be fully visualized

R: measurements (see **Table 1 – LA and aortic root**)

Within the study/registry it is necessary to agree on a measurement convention to measure the parameters in the "M-mode aortic valve". The ASE/Leading Edge method (alternatively the Penn method) is the standard method for DZHK studies/registries [2, 6].

If it is not possible to perform an orthogonal measurement in M-mode, measurements should alternatively be performed using one of the following methods:

- anatomical M-mode
- measurement in 2D image

It has to be recorded in the eCRF which of the alternative methods was used.

Table 1 – LA and aortic root parameters

Measured parameters (unit)	Time of measurement (ED/ES)	Position of measuring points (measuring point 1 and 2)
AoW (mm)	ED	1. outer border of the anterior wall of the aorta 2. inner border of the posterior wall of the aorta
LA diam (mm)	ES	1. anterior wall of the LA 2. posterior wall of the LA
Aortic valve separation (mm)	systolic	at maximum valve opening

3.5.1.3 M-mode at mitral valve leaflet tips (LAX)

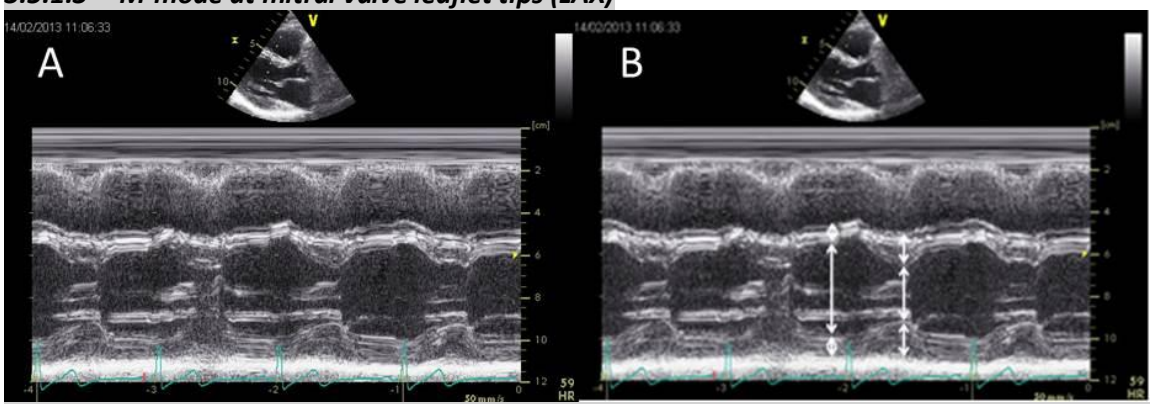


Figure 3: M-mode at mitral valve leaflet tips without (A) and with measurement (B)

A: M-mode at mitral valve leaflet tips measuring convention

S: 1. interventricular septum

2. mitral valve (M-mode)

3. left ventricular posterior wall

4. LV size

Q: 1. M-mode should be perpendicular to the structure to be measured

2. caveat: parts of the right ventricle (e.g. trabeculae) should not be imaged if possible

3. LV parameters should be measured in M-mode at the level of mitral valve tips

R: measurements (see Table 2 - Measuring convention to measure the M-mode at the mitral valve leaflet **tips**)

Within the study/registry it is necessary to agree on a measurement convention to measure the parameters in the "M-mode mitral valve leaflet tips". The ASE/Leading Edge method (alternatively the Penn method) is the standard method for DZHK studies/registries.

If it is not possible to perform orthogonal measurement in M-mode, the measurement should alternatively be performed using one of the following methods:

- anatomical M-mode
- measurement in 2D image

It has to be recorded in the eCRF which of the alternative methods was used.

Table 2 - Measuring convention to measure the M-mode at the mitral valve leaflet tips

Measured parameters (unit)	**Time of Measurement (ED/ES)**	**Position of the measuring points (measuring point 1 and 2)**
IVSs/IVSd (mm)	ES/ED	1. right ventricular septal border (caveat: do not measure parts of the right ventricle) 2. left ventricular septal border
(LVEDs/LVEDd) (mm)	ES/ED	1. left ventricular septal border 2. onset left ventricular posterior wall
LVPWd/LVPWs (mm)	ES/ED	1. onset left ventricular posterior wall 2. border between left ventricular posterior wall and pericardium
Pericardial separation / effusion (mm)	ED	1. border LV wall to intrapericardial space 2. border intrapericardial space to pericardium

3.5.1.3.1 Pericardial effusion

Pericardial effusion is present if an anechoic pericardial separation can be demonstrated end-diastolically (>1 mm [7]).

A pericardial effusion should always be evaluated in different sectional planes, usually in parasternal long axis, apical 4-chamber view and subcostal sectional plane (see also 0 and 3.5.6.1.1). Effusion width can be determined at the end-diastolically using M-mode recording in the parasternal long axis, if possible orthogonally to the effusion separation or alternatively by means of apical cross-sectional images [6]. End-diastolic visible effusions can be classified as small (<10 mm), moderate (10-20 mm), and large (>20 mm) [8].

3.5.1.4 M-mode at mitral valve

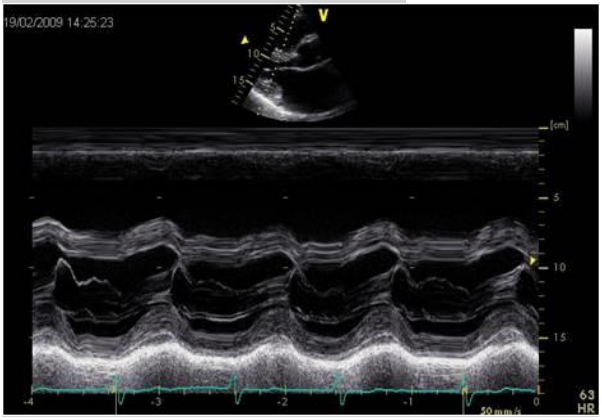


Figure 4: M-mode at mitral valve

A: M-mode at the level of the mitral valve

S: 1. anterior leaflet of the mitral valve

2. posterior leaflet of the mitral valve

Q: first M-mode should be perpendicular to the structure to be measured

R: visual assessment of mitral valve function (opening, flutter), MSS distance

Table 3:- Measuring convention to measure MSS in M-mode at the level of the mitral valve

Measured parameters (unit)	**Time of measurement (ED/ES)**	**Position of the measuring points (measuring point 1 and 2)**
MSS distance	systolic, point of least distance	1. left ventricular septal border 2. mitral valve leaflet

3.5.1.5 Color Doppler over the mitral valve/aortic valve

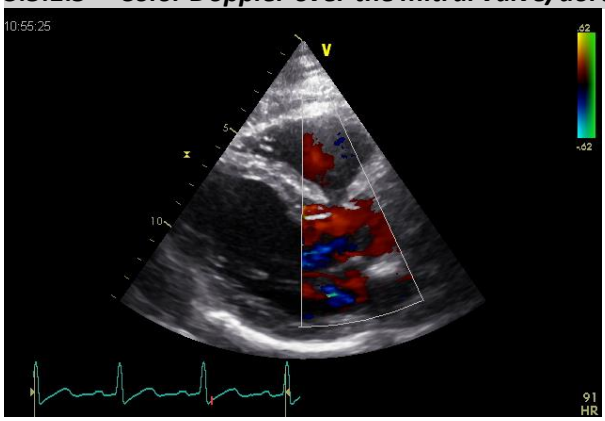


Figure 5: Color Doppler over the mitral valve/aortic valve

A: Color Doppler of mitral and aortic valve (sequence)

S: flow profile over mitral and aortic valve

Q: the color Doppler window should include complete atrium and as much of the LV outflow tract as possible

R: visual assessment of flow profile over mitral valve/aortic valve

3.5.1.6 2D mode aortic root

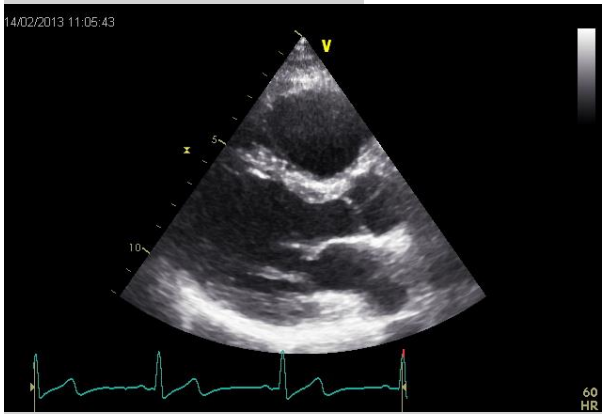


Figure 6: 2D mode aortic root

A: 2D sequence

S: 1. aortic root

2. aortic valve with right and non-coronary leaflet

Q: 1. scending aorta should reach the right sector margin

2. non-coronary and right coronary leaflet of the aortic valve should be clearly visible and should close centrally

R: Visual assessment and Table 4 - Measuring convention to measure the LVOT Diameter in the 2D mode aortic root

Table 4 - Measuring convention to measure the LVOT Diameter in the 2D mode aortic root

Measured parameters (unit)	**Time of measurement (ED/ES)**	**Position of the measuring points (measuring point 1 and 2)**
LVOT diameter (in case of aortic stenosis)	mid-systolic	0.5-1.0 cm from the valve orifice, parallel to aortic valve plane 1. septal endocardium 2. anterior mitral valve leaflet [9]

3.5.2 SAX

The explanations for A, S, Q and R as well as any tables listed refer in each case to the figure under which they appear.

3.5.2.1 2D mode apical

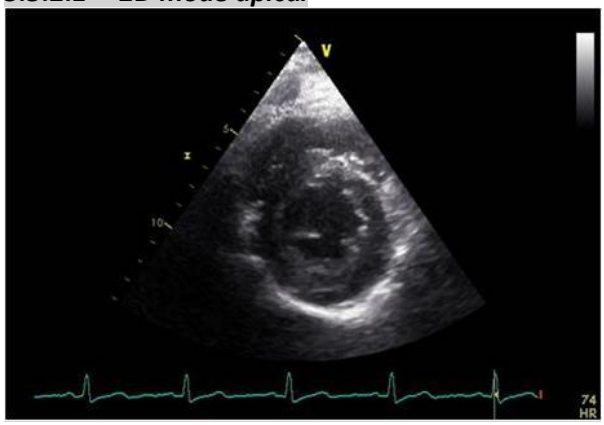


Figure 7: 2D mode apical

A: 2D sequence

S: wall motion/structure LV apex

Q: first left ventricle should be round on image

R: visual assessment

3.5.2.2 2D mode at mitral valve

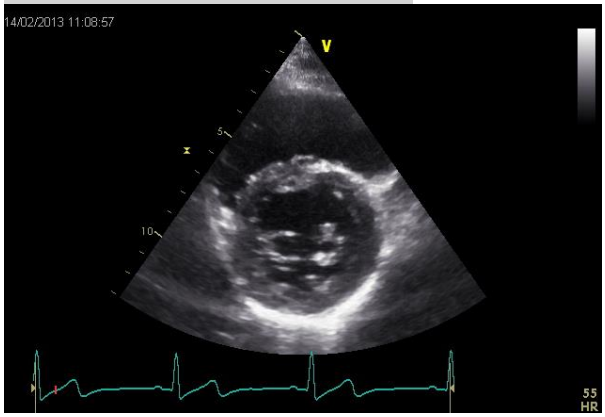


Figure 8: **2D mode at mitral valve**

A: 2D sequence

S: 1. mitral valve with “fish mouth”

2. wall motion/structure of left ventricle

Q: 1. left ventricle should be round on image

2. both mitral valve leaflets should be clearly visible

R: visual assessment

3.5.2.3 color Doppler at mitral valve

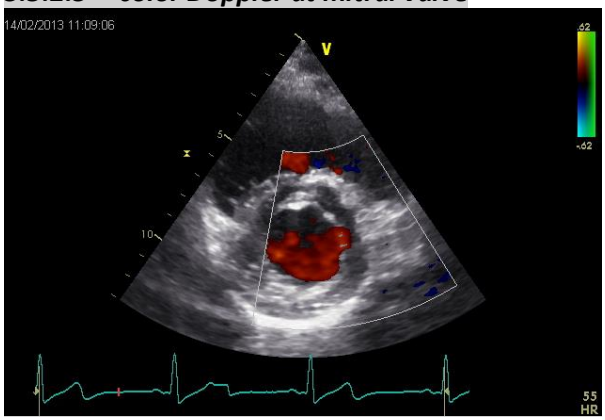


Figure 9: color Doppler at mitral valve

A: color Doppler over mitral valve (sequence)

S: flow profile over mitral valve

Q: 1. mitral valve should be shown with the anterior and posterior leaflet

2. color Doppler should encompass the complete orifice area

R: visual assessment of the flow profile over the mitral valve

3.5.2.4 M-mode at mitral valve leaflet tips (SAX)

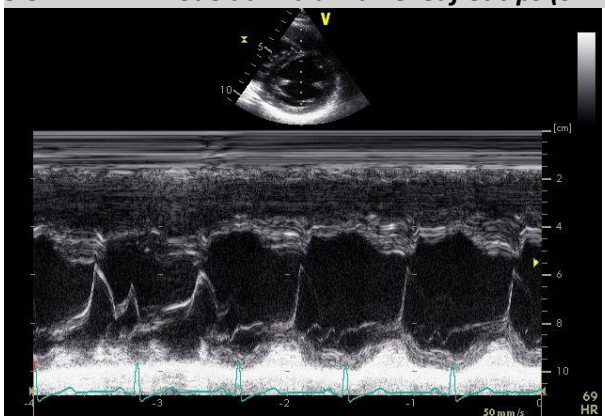


Figure 10: M-mode at mitral valve leaflet tips in the short axis (alternative method)

A: M-mode at mitral valve leaflet tips (SAX)

S: 1. interventricular septum

2. mitral valve (M-mode)

3. left ventricular posterior wall

4. LV size

Q: 1. left ventricle should be round on image

2. both mitral valve leaflets should be clearly visible and cut in the area of the tips

3. M-mode should be perpendicular to the structure to be measured

4. caveat: parts of the right ventricle (e.g. trabeculae) should not be imaged, if possible

R: measurements (see Table 2 - Measuring convention to measure the M-mode **at the mitral valve leaflet tips**)

Within the study/registry it is necessary to agree on one a measurement convention for measuring the parameters in the "M-mode mitral valve leaflet tips". The ASE/Leading Edge method (alternatively the Penn method) is the standard method for DZHK studies/registries.

If it is not possible to perform an orthogonal measurement in the M-mode, measurement should alternatively be performed using one of the following methods:

- anatomical M-mode
- measurement on the 2D image

It has to be recorded in the eCRF which of the alternative methods was used.

Table 5 - Measuring convention to measure the M-mode at the mitral valve leaflet tips

Measured parameters (unit)	**Time of measurement (ED/ES)**	**Position of the measuring points (measuring point 1 and 2)**
IVSs/IVSd (mm)	ES/ED	1. right ventricular septum border (caveat: do not measure parts of the right ventricle) 2. left ventricular septal border
(LVEDs/LVEDd) (mm)	ES/ED	1. left ventricular septal border 2. onset eft ventricular posterior wall
LVPWd/LVPWs (mm)	ES/ED	1. onset left ventricular posterior wall 2. border between left ventricular posterior wall and pericardium
Pericardial separation/outflow effusion (mm)	ED	1. border LV wall to intrapericardial space 2. border intrapericardial space to pericardium

3.5.2.5 2D mode at papillary muscles

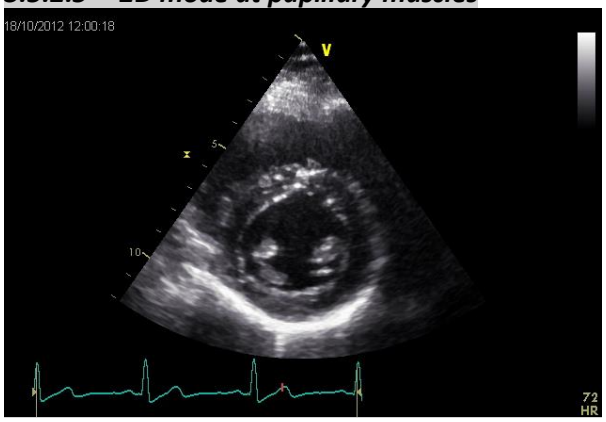


Figure 11: 2D mode at papillary muscles

A: 2D sequence

S: 1. papillary muscles

2. wall motion/structure of left ventricle

Q: 1. left ventricle should be round on image

2. papillary muscles should be clearly visible at 5 and 7 o'clock

R: visual assessment

3.5.2.6 2D mode at aortic valve

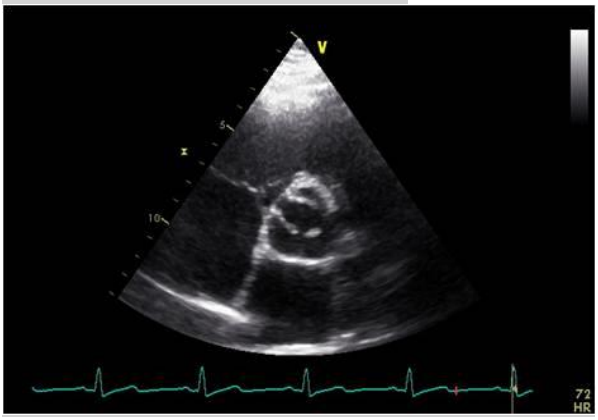


Figure 12: 2D mode at aortic valve

A: 2D sequence

S: 1. aortic valve

2. pulmonary valve

Q: 1. aortic valve should be round in the center of the image

2. aortic valve pockets (RKS, NKS and LKS) should be well delineated

R: visual assessment (see **Table 6 - Visual assessment of the aortic and pulmonary valve**

Table 6 - Visual assessment of the aortic and pulmonary valve

Parameter to be assessed	**Visual assessment of the valve**
Aortic valve	Native, post-surgical (status post biological aortic valve replacement surgery, status post mechanical aortic valve replacement, status post interventional aortic valve replacement), unknown, not assessed
Aortic valve morphology	Selection between inconspicuous or conspicuous. If conspicuous: then sclerosis, calcification, disturbed separation, bicuspid, not assessable (=unknown), not assessed (multiple selection possible)

Pulmonary valve	Native, post-surgical, unknown, not assessed (additional information [depending on study/registry], if applicable: status post valve-preserving surgical therapy (yes/no), status post biological valve replacement (yes/no), status post mechanical valve replacement, (yes/no))
Pulmonary valve morphology	Selection between inconspicuous or conspicuous. If conspicuous: sclerosis, calcification, disturbed separation, not assessable (=unknown), not assessed

3.5.2.7 Color Doppler of aortic valve

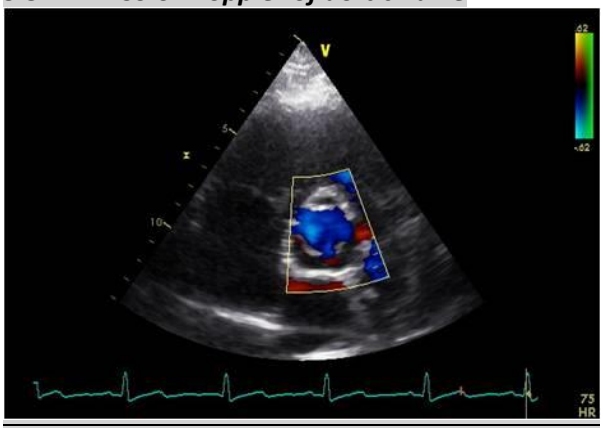


Figure 13: Color Doppler of aortic valve

A: color Doppler (sequence)

S: aortic valve

Q: limitation of color Doppler to the area to be measured

R: visual assessment of the flow profile over the aortic valve

3.5.2.8 M-mode aortic root in the short axis (SAX)

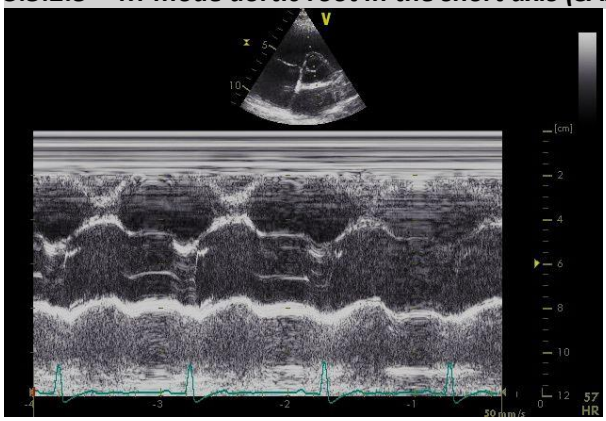


Figure 14 M-mode aortic root in the short axis (SAX) (alternative method)

A: M-mode in the long axis or alternatively in the short axis, see 3.5.1.2 (a measurement convention should be agreed upon as part of the study protocol of the trial)

S: 1. aortic valve

2. pulmonary valve

3. left atrium

Q: 1. aortic valve should appear round in the center of the image

2. aortic valve pockets (right, non-coronary and left cusp) should be well delineated

3. M-mode should be perpendicular to the outflow tract and left atrium

4. aortic valve separation should be completely shown

R: measurements (see Table 1 – **Table 1 – LA and aortic root** parameters)

Within the study/registry it is necessary to agree on one measurement convention to measure the parameters in the "M-mode aortic valve". The ASE/Leading Edge method (alternatively the Penn method) is the standard method for DZHK studies/registries [2, 6].

If orthogonal measurement in M-mode is not possible, the measurement should be performed alternatively using one of the following methods:

- anatomical M-mode
- measurement in 2D image

It has to be recorded in the eCRF which of the alternative methods was used.

Table 7 – LA and aortic root parameters

Measured parameters (unit)	Time of measurement (ED/ES)	Position of measuring points (measuring point 1 and 2)
AoW (mm)	ED	1. outer border of the anterior wall of the aorta 2. inner border of the posterior wall of the aorta
LA diam (mm)	ES	1. anterior wall of the LA 2. posterior wall of the LA
Aortic valve separation (mm)	systolic	at maximum valve opening

3.5.2.9 Color Doppler of pulmonary valve:

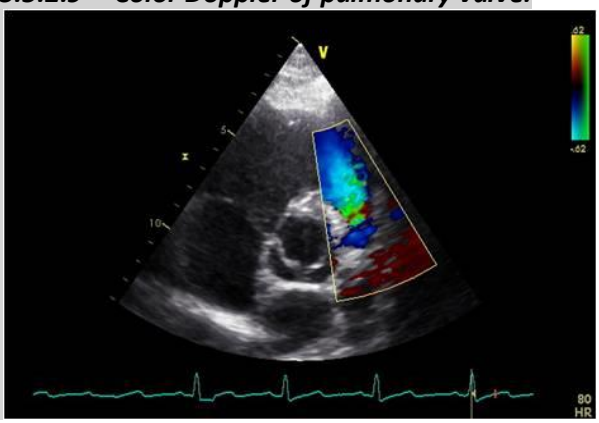


Figure 15: Color Doppler of pulmonary valve

A: color Doppler (sequence)

S: pulmonary valve

Q: limitation of the color Doppler to the area to be measured

R: visual assessment of the flow profile across the pulmonary valve

3.5.2.10 CW and PW Doppler of pulmonary valve

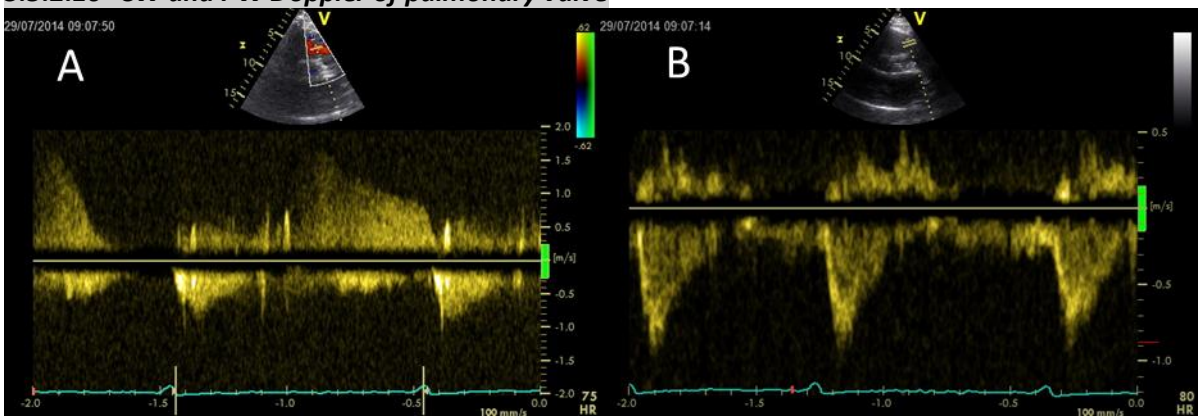


Figure 16: CW Doppler of pulmonary valve regurgitation (A) and PW Doppler of pulmonary valve (B)

A: CW Doppler (sequence) and PW Doppler (sequence)

S: flow profile across the pulmonary valve

Q: 1. CW Doppler and PW Doppler should be parallel to blood flow

2. Doppler signal should fill 2/3 of the screen; in case of concomitant pulmonary valve regurgitation 2 separate images are required, quantification of regurgitation using CW Doppler, flow profile of the outflow using PW Doppler

3. if possible, adjust wall filter to ± 0.05 – 0.1 m/s

R: measurement (see Table 8 - Measuring points for pulmonary valve echocardiography) and calculation (see Table 9 - Calculated values of the pulmonary valve echocardiography)

Table 8 - Measuring points for pulmonary valve echocardiography

Measured parameters (unit)	**Time of measurement (ED/ES)**	**Position of the measuring points**
PV V max (m/s)		point of maximum velocity on the PW Doppler envelope curve
Acc-time PV (s)	ES	start of PW Doppler envelope curve - straight line up to velocity max

Table 9 - Calculated values of the pulmonary valve echocardiography

Calculated parameters (unit)	Calculation based on measured value:	Result
PV PGmax (mmHg)	PV V max (ES)	3-5 calculated single values and calculation of the mean value

3.5.2.11 Color Doppler tricuspid valve

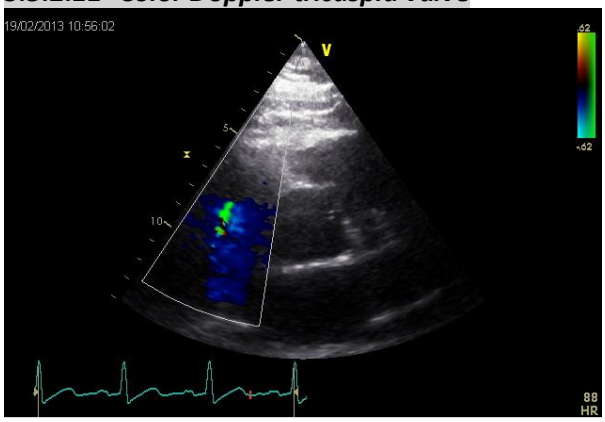


Figure 17: Color Doppler tricuspid valve

A: color Doppler (sequence)

S: tricuspid valve/color Doppler signal

Q: limitation of color Doppler to the area to be measured

R: visual assessment of the flow profile of the tricuspid valve

3.5.2.12 CW Doppler tricuspid valve

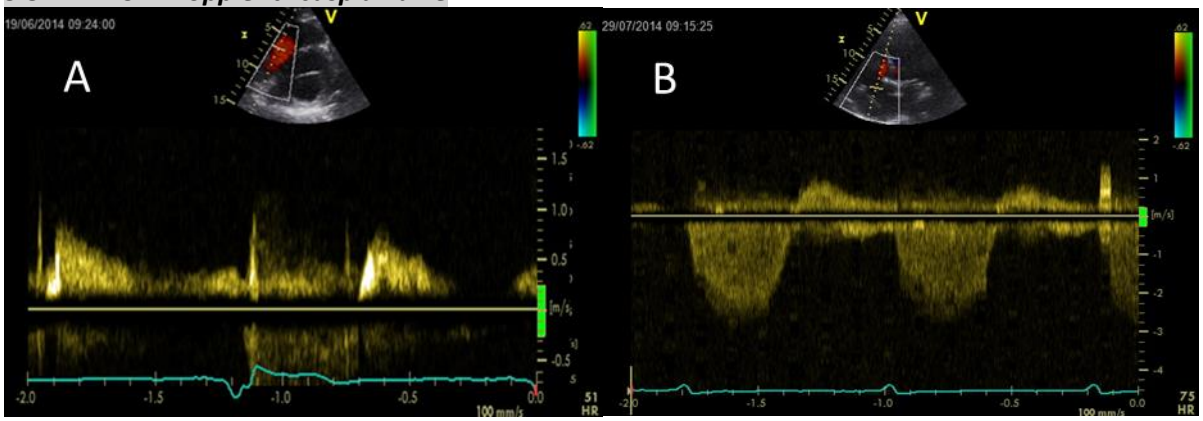


Figure 18: CW Doppler of tricuspid valve (A) and CW Doppler of tricuspid valve regurgitation (B)

A: CW Doppler (sequence)

S: CW flow profile across the tricuspid valve

Q: 1. CW Doppler should be parallel to the blood flow

2. Doppler signal should fill 2/3 of the screen; in case of concomitant tricuspid valve regurgitation, 2 separate images are required

3. if possible, the wall filter should be set to ± 0.05 – 0.1 m/s

R: measurement (see Table 10 - Measured values of the tricuspid valve and Table 11 - Calculated values for the tricuspid valve echocardiography)

Table 10 - Measured values of the tricuspid valve

Measured parameters (unit)	Time of measurement (ED/ES)	Position of the measuring points
TV Vmax (m/s)		Highest point (maximum velocity) of the CW Doppler signal of the tricuspid valve
TR VTI	Systolic	Envelope curve of the reflux signal

Table 11 - Calculated values for the tricuspid valve echocardiography

Calculated parameters (unit)	Calculation based on measured value:	Result
TV PGmean (mmHg)	TV V max (ED)	3-5 calculated single values and calculation of the mean value
TR PGmax (mmHg)	TR VTI (systolic)	3-5 calculated single values and calculation of the mean value

3.5.3 Apical 4-chamber view

The explanations for A, S, Q and R as well as tables listed, if applicable, refer to the respective figure under which they appear.

3.5.3.1 2D mode 4-CH (with LA/RA)

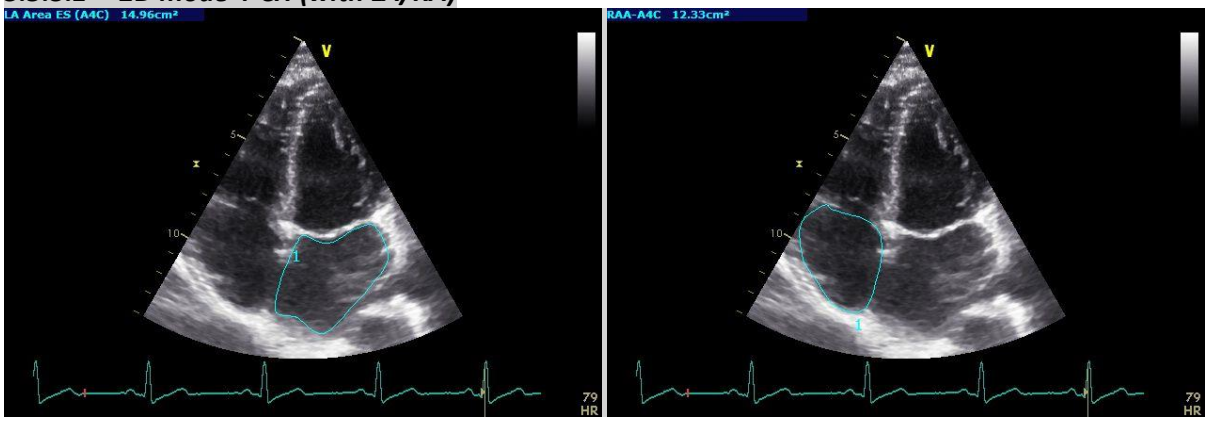


Figure 19: **Apical four-chamber view with planimetry LA (left) and planimetry RA (right)**

A: 2D mode (sequence)

S: 1. atrial and ventricular septum

2. lateral wall of the LV

3. LA+RA area

4. tricuspid valve (anterior and septal leaflet) and mitral valve (anterior and posterior leaflet)

5. LVEF (visual estimation)

Q: 1. septum should be perpendicular

2. the septal mitral valve should be at the same height as the tricuspid valve

3. the left ventricle should be visualized in such a way that an axis as long as possible (from the center of the line connecting the mitral leaflet insertion points to the apex) is displayed

4. the depth should be minimized in order to visualize the LA as large as possible and as complete as possible

R: measurements (see Table 12 - Measurements in apical four-chamber view)

Table 12 - Measurements in apical four-chamber view

Measured parameter (unit)	Time of measurement (ED/ES)	Position of the measuring point
LAes_long (mm)	ES	largest possible longitudinal diameter left atrium
LAes_transverse (mm)	ES	Largest possible transverse diameter left atrium
LA area (4CH) (cm^2)	ES	planimetry
RA area (4CH) (cm^2)	ES	planimetry

3.5.3.2 2D mode – 4CH (without LA/RA)

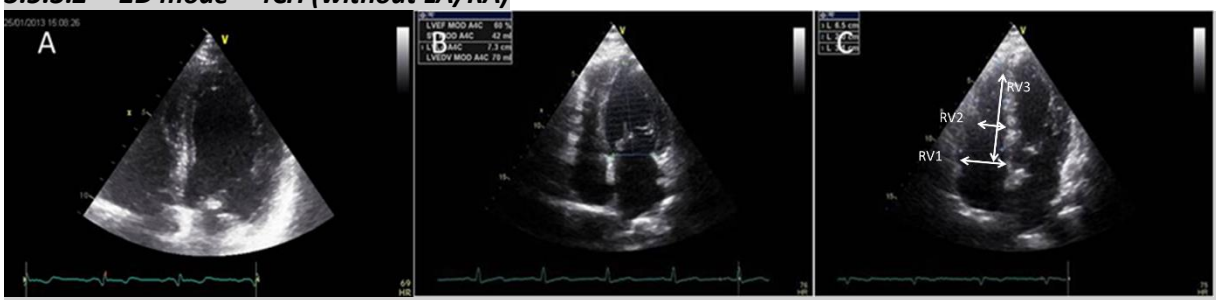


Figure 20: **Apical four-chamber view without LA/RA (A), with Simpson's planimetry (B) and RVED 1 to 3 (C)**

A: 2D mode (sequence)

S: 1. ventricular septum

2. lateral wall of the LV

3. tricuspid valve (anterior and septal leaflet)

4. mitral valve (anterior and posterior leaflet)

5. LVEF (biplane according to Simpson, see also 2-CH) [1, 2]

6. RV area and function

7. assessment: pericardium/ -suture

Q: 1. The LV should be scanned along its long axis to avoid shortening. Separate recordings may be necessary for LV and RV assessment, as optimal simultaneous imaging is not always possible. (right-optimized image for right-ventricular measurements)

2. The penetration depth should be minimized to visualize the LV as large as possible and with complete apex (the LA should be truncated)

R: 1. Visual assessment of LV function/kinetics of septal and lateral wall (wall motion disturbance: yes, no, unknown, not assessed)

2. measurements (see Table 13 - Measured values for left and right ventricular diameter [2, 10], Table 14 – Heart valve parameters in 2D image and Table 15 - Calculated parameters from planimetry)

Table 13 - Measured values for left and right ventricular diameter [2, 10]

Measured parameters (unit)	Time of measurement (ED/ES)	Position of the measuring points
LV outline diastolic/end-diastolic	ED/ES	circumvent the LV endocardial line starting at the anterior mitral valve annulus to the posterior annulus end-diastolic and end-systolic; if papillary muscle is visible it must be intersected, i.e. omitted
left ventricular end-diastolic volume LVEDV (ml)	ED	planimetry
left ventricular end-systolic volume LVESV (ml)	ES	planimetry
left ventricular ejection fraction (%), visual		visual assessment of the LV-EF (1. normal, 2. slightly impaired, 3. moderately impaired, 4. severely impaired)
RVED1 (mm)	ED	1st measuring point: endocardium above the septal leaflet of the tricuspid valve 2nd measuring point: endocardium above the desanterior leaflet of the tricuspid valve
(RVED2) (mm)	ED	1st measuring point: endocardium septal near the middle third of the RV 2nd measuring point: endocardium lateral RV near the middle third of the RV
RVED3 (mm)	ED	1st measuring point: apical maximum of the RV 2nd measuring point: end of a perpendicular from measuring point 1 in the tricuspid valve plane
pericardial separation/effusion	ED	Visual

3.5.3.2.1 RV dilation

RV dilation is defined using the mid-ventricular end-diastolic diameter (RVED2). ***RV dilation is defined as RVED2 > 34 mm*** [2]

3.5.3.2.2 Pericardial effusion

A Pericardial effusion is present if an anechoic pericardial separation is demonstrated at the end of the diastole (>1 mm [7]). For more details: see 0 and 3.5.6.1.1.

Table 14 – Heart valve parameters in 2D image

Valve parameters (unit)	Visual assessment of the valve
mitral valve	native, post-surgical (mitral valve reconstruction, biological mitral valve replacement, mechanical mitral valve replacement, interventional reconstruction/clipping, unknown, not assessed)
mitral valve morphology	selection between inconspicuous or conspicuous; is conspicuous: sclerosis, calcification of mitral leaflet, calcification of mitral ring, disturbed separation, flail leaflet, myxomatous prolapse, prolapse in fibroelastic deficiency, pseudoprolapse, not assessable (= unknown), not assessed (multiple selection possible)
tricuspid valve	Native, post-surgical, unknown, not assessed (additional information [depending on study/register], if applicable: status post valve-sparing surgical therapy (yes/no), status post biological valve replacement (yes/no), status post mechanical valve replacement (yes/no))
tricuspid valve morphology	selection between inconspicuous or conspicuous. If conspicuous: sclerosis, calcification, Ebstein anomaly, disturbed separation, not assessable (=unknown), not assessed (multiple selection possible)

Table 15 - Calculated parameters from planimetry

Calculated parameters (unit)	Calculation based on measured value:	Result
LV-EF (mod. Simpson rule) (biplane 4CH/2CH, monoplane 4CH)	LV-EF measurement	3-5 calculated single values and calculation of the mean value (according to the modified Simpson formula)

3.5.3.3 Color Doppler MV – MV jet

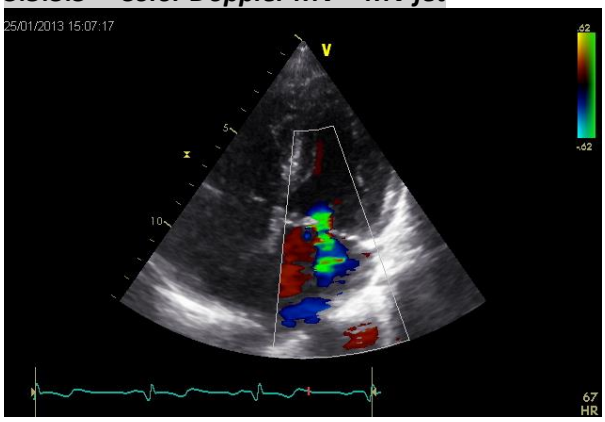


Figure 21: **Color Doppler of mitral valve**

A: 2D with color Doppler (sequence)

S: mitral valve reflux/insufficiency jet

Q: 1. penetration depth should be minimized to visualize the LA as large as possible

2. LA should be completely imaged

3. for the determination of the proximal convergence zone, the color Doppler for the Nyquist limit of the color Doppler should be around 50-60 cm/s (then shift the zero line until a change in color occurs); to avoid underestimation of the regurgitation volume, the ratio of the aliasing velocity (Va) to peak orifice velocity (vel) in the Doppler (see 3.5.3.7) should be less than 1/10 [10].

R: 1. visual assessment: mild, moderate, severe insufficiency

2. measurements (see Table 16 - Parameters measured in color M-mode over mitral valve)

Table 16 - Parameters measured in color M-mode over mitral valve

Measured parameters (unit)	Time of measurement	Position of the measuring points
PISA (cm)	systolic	distance from the leak to the limit color change
MR VC Diam (cm)	systolic	narrowest diameter of the regurgitation orifice during the passage of the MV

3.5.3.4 MV propagation velocity (velocity of flow progression)

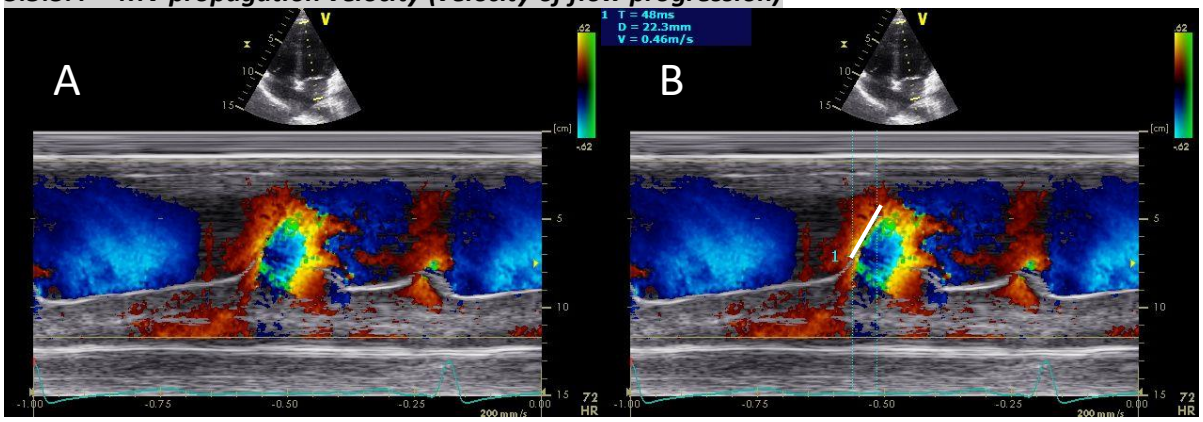


Figure 22: **Color M-mode across mitral valve: mitral valve propagation velocity (A) and slope measurement (B)**

A: color M-mode across the MV

imaging should be performed at 100-200 mm/s

S: speed of blood flow progression into the left ventricle during diastole

Q: 1. the narrow sector of the color Doppler should be placed between the MV and LV apex

2. if necessary, adjust the depth to focus on the LV and only a small section of the LA

3. the M-mode beam should be positioned in the center of blood flow at the entrance of the LV

4. if no spontaneous aliasing is observed, the Nyquist limit should be reduced

R: measurements (see Table 17 - Propagation velocity of the mitral valve)

Table 17 - Propagation velocity of the mitral valve

Measured parameters (unit)	**Time of measurement**	**Position of the measuring points**

Vp (cm/s)	early diastolic	slope of the first color change of the E-wave

3.5.3.5 PW Doppler/ CW Doppler MV (at rest) – mitral influx

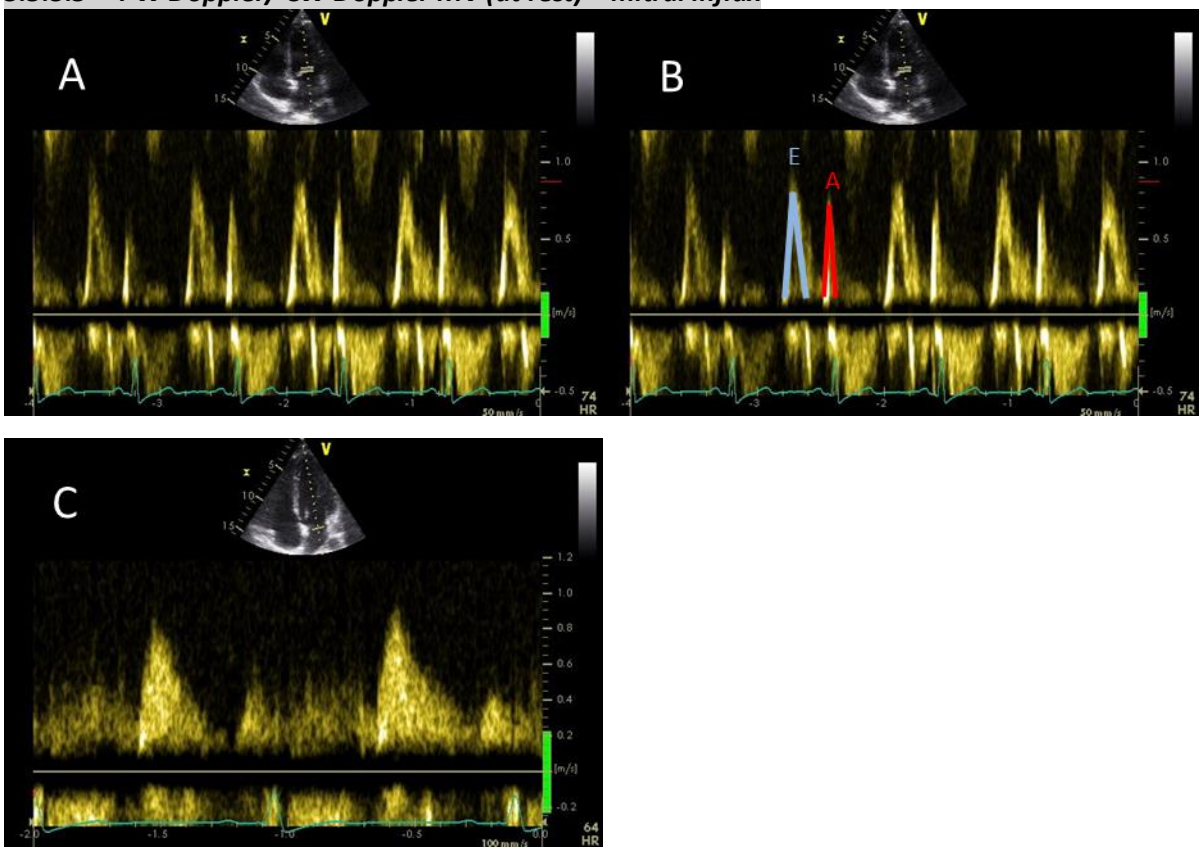


Figure 23: **PW Doppler of mitral valve without measurement (A), with measurement (B), CW Doppler of mitral valve (C) (in order to detect high velocities to exclude mitral stenosis)**

A: PW Doppler MV/ CW Doppler MV

S: 1. E-wave with duration and maximum velocity

2. A-wave (only for SR) with duration and maximum velocity

Q: 1. the sample volume should be placed in the middle of the mitral valve leaflet tips in the LV

2. if possible, the wall filter should be adjusted to ± 0.05 – 0.1 m/s

R: measured values of mitral valve influx profile (see Table 18 - Measured values for PW Doppler (at rest) – mitral influx)

Table 18 - Measured values for PW Doppler (at rest) – mitral influx

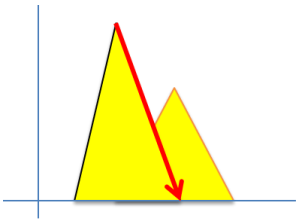
Measured parameters (unit)	**Time of measurement**	**Position of the measuring points**
E-duration (ms)	early diastole	start of E-wave to end of E-wave
A-duration (ms)	late diastole	start of A-wave until end of A-wave
MV A Vmax (ms)	early diastole	highest point of the Doppler signal of the A-wave
MV E Vmax (ms)	late diastole	highest point of the Doppler signal of the E-wave
DT (ms)	early diastole	highest point of the Doppler signal of the E-wave and descent of the E-wave when E- and A-waves merge, measurement to the extrapolated end of the E-wave 

Table 19 - Calculated values for PW Doppler (at rest) – mitral influx

Calculated parameters (unit)	Calculation based on measured value:	Result
MV PG mean	envelope curve E- and A-wave	3-5 calculated single values and calculation of the mean value
E/A	MV A V_{max}	3-5 calculated single values and calculation of the mean value

Table 20 - Calculated values for CW Doppler MV (at rest) – mitral influx

Calculated parameters (unit)	Calculation based on measured value:	Result
MV PG mean	envelope curve E- and A-wave	3-5 calculated single values and calculation of the mean value

3.5.3.6 PW Doppler MV (Valsalva maneuver)

Study of mitral influx during a Valsalva maneuver. The measurements are performed as in "PW Doppler MV (at rest) – mitral inflow" (see previous chapter).

3.5.3.7 CW Doppler – MV

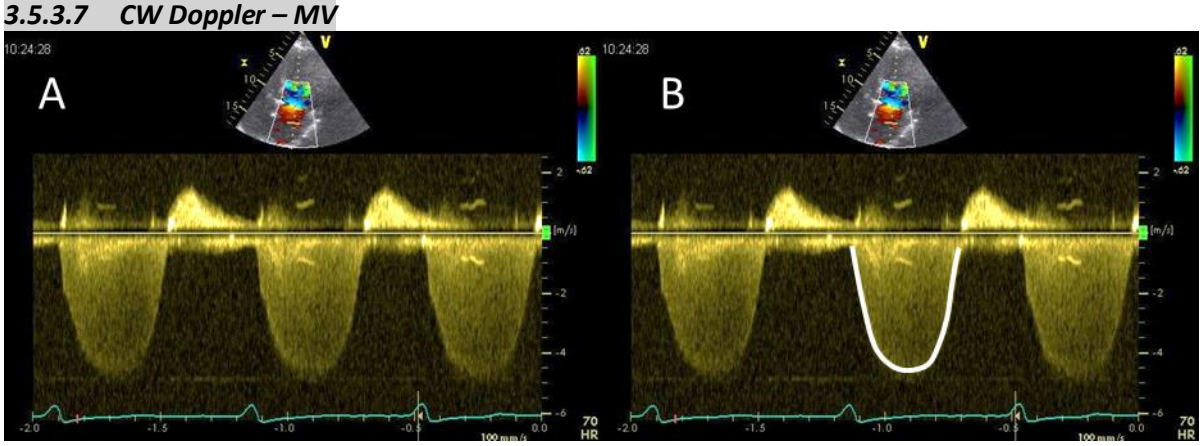


Figure 24: **CW Doppler MV (A) and measurement of MV insufficiency jet (B)**

A: CW Doppler (still image)

S: if available, envelope curve of mitral insufficiency jet

Q: 1. the sample volume should be placed as centrally as possible in the vena contracta

2. the velocity range should be adjusted to visualize the Doppler signal large enough (without truncating the maximum velocities)

3. if possible, the wall filter should be adjusted to ± 0.05 – 0.1 m/s

R: measurements see Table 21 - Time integral of mitral reflux

Table 21 - Time integral of mitral valve reflux

Calculated parameter (unit)	Time of measurement	Calculation based on measurement:	Result
MR VTI	systolic	envelope curve of the reflux signal	3-5 calculated single values and calculation of the mean value

3.5.3.8 MAPSE (mitral annular plane systolic excursion)

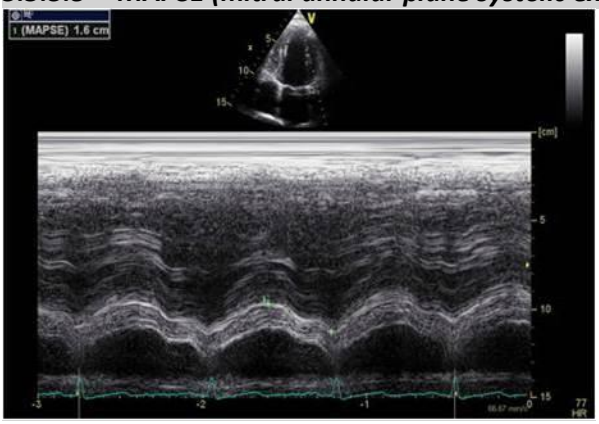


Figure 25: **MAPSE**

A: M-mode

S: distance between end-diastolic and end-systolic motion of the lateral and septal mitral annulus

Q: 1. the M-mode beam should be placed in the lateral and septal mitral valve annulus

2. the lateral and septal mitral valve annulus should be visualized throughout the entire systolic movement in the plane of the M-mode, the direction of movement of the lateral and septal mitral annulus must be parallel to the M-mode examination line; the positioning of the probe may have to be adjusted for this.

R: measurements (see

Table 22 **-** MAPSE **measurements**)

Table 22 - MAPSE measurements

Measured parameter (unit)	**Time of measurement**	**Position of the measuring points**
MAPSE at (mm)	ES to ED	endocardial borderline (ES), endocardial borderline (ED)
MAPSE sep (mm)	ES to ED	endocardial borderline (ES), endocardial borderline (ED)

3.5.3.9 Color Doppler TV – TV jet

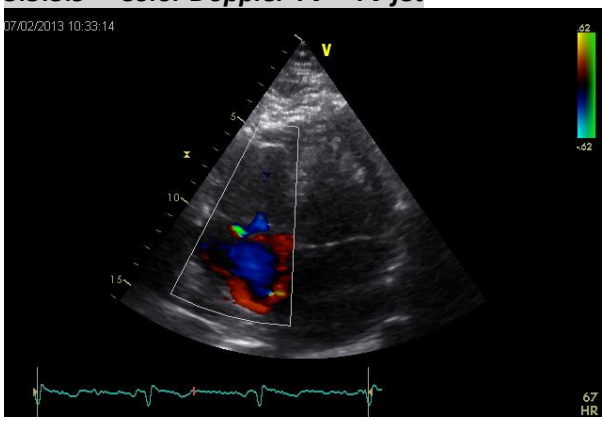


Figure 26: **Color Doppler TV**

A: 2D with color Doppler (sequence)

S: tricuspid valve reflux/insufficiency jet

Q: 1. penetration depth should be minimized to image the RA as large as possible

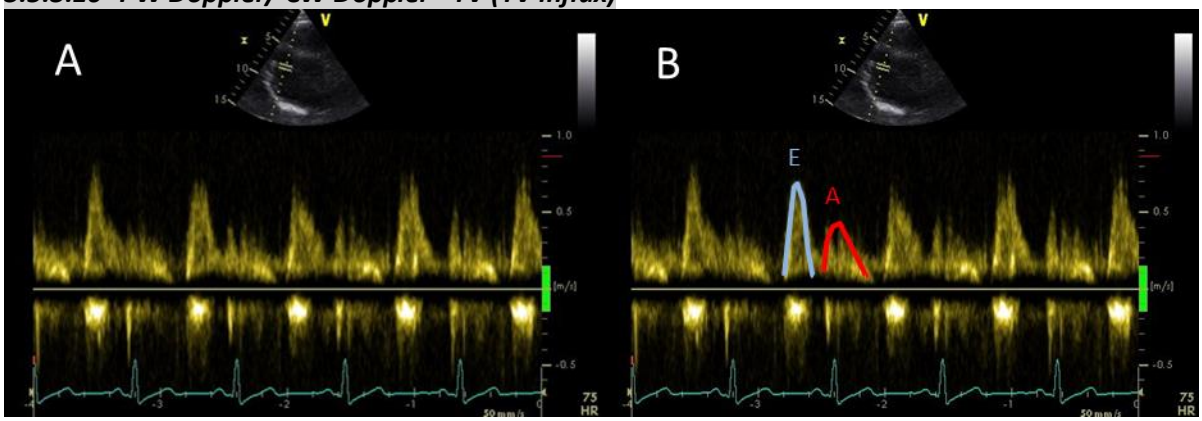
2. RA should be completely visualized

3. color Doppler velocity range should start at 40-60 cm/s

4. gain should be just above background

R: visual assessment: mild, moderate, severe insufficiency

3.5.3.10 PW Doppler/ CW Doppler - TV (TV influx)



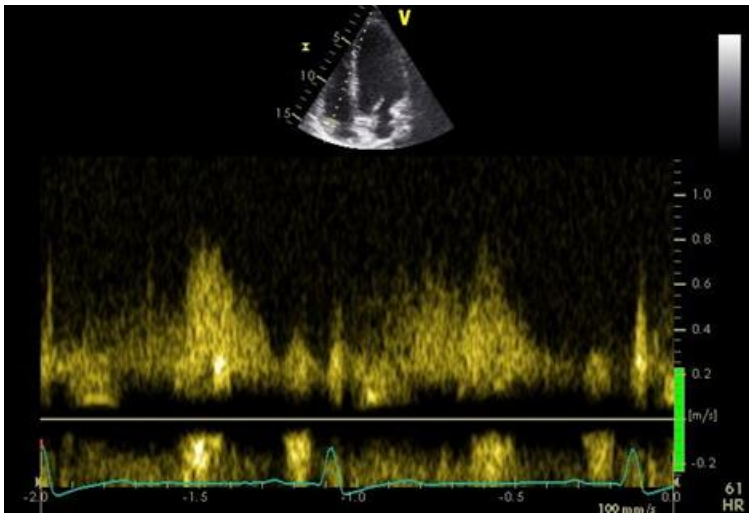


Figure 27: **PW Doppler TV (A) and measurement PW Doppler TV (B), CW Doppler TV (C) to detect high velocities (exclusion of tricuspid stenosis)**

A: PW Doppler TV/ CW Doppler TV

S: E, A (E-wave and A-wave with max. velocity)

Q: 1. sample volume should be placed at the tip of the tricuspid valve in the RV

2. measurement area and zero line should be adjusted to show the Doppler signal large enough

R: see

Table 23 - Measured values PW Doppler - TV (TV influx**)** and Table 24 - Calculated values PW Doppler - TV (TV inflow)

Table 23 - Measured values PW Doppler - TV (TV influx)

Measured parameter (unit)	**Time of measurement**	**Position of the measuring points**
TV Vmax (m/s)	diastole	trace the entire envelope curve of the Doppler signal of the tricuspid valve

Table 24 - Calculated values PW Doppler - TV (TV inflow)

Calculated parameters (unit)	Calculation based on measured value	Result
TV PGmean (mmHg)	TV V_{max}	3-5 calculated single values and calculation of mean value

Table 25 - Calculated values CW Doppler - TV (TV inflow)

Calculated parameters (unit)	Calculation based on measured value	Result
TV PGmean (mmHg)	TV V_{max}	3-5 calculated single values and calculation of mean value

3.5.3.11 CW Doppler - TV (TV jet, TV PAPsys)

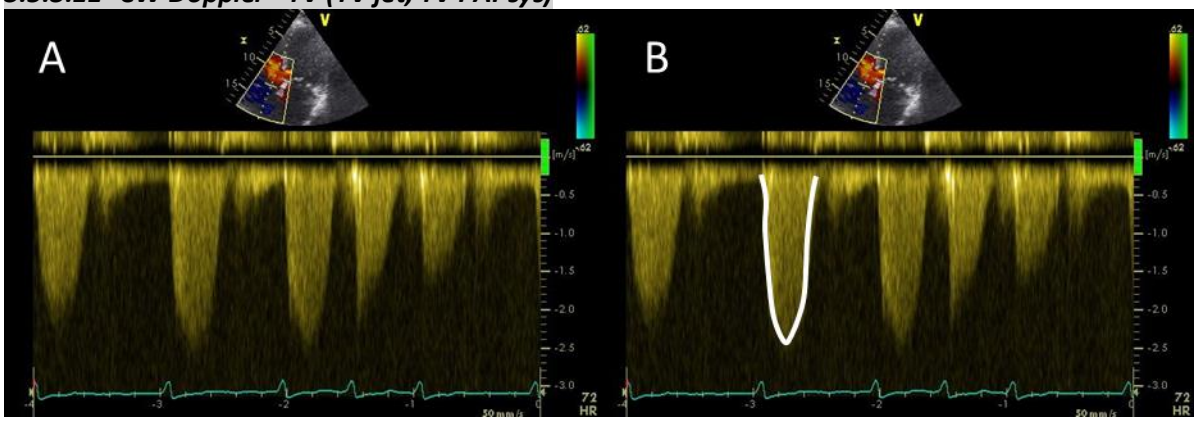


Figure 28: CW Doppler TV (A) and measurement CW Doppler TV (B)

A: CW Doppler

S: envelope curve of the systolic insufficiency jet

Q: 1. sample volume should be placed on the vena contracta, as parallel as possible to the tricuspid reflux

2. velocity range should be adjusted to show the Doppler signal large enough

3. wall filter should be adjusted to +/- 0.05 – 0.1 m/s

R: see Table 26 - Measured values CW Doppler - TV (TV jet, TV PAPsys) and

Table 27 - Calculated values CW Doppler - TV (TV jet, TV PAPsys)

Table 26 - Measured values CW Doppler - TV (TV jet, TV PAPsys)

Measured parameter (unit)	**Time of measurement**	**Position of the measuring points**
TR VTI	systolic	envelope curve of the reflux signal/insufficiency signal

Table 27 - Calculated values CW Doppler - TV (TV jet, TV PAPsys)

Calculated parameters (unit)	Calculation based on measured value:	Number of calculated values (SR/A Fib)	Result
TR Pgmax	TR VTI	3/5	3 -5 calculated single values and calculated mean value

3.5.3.12 TAPSE (tricuspid annular plane systolic excursion)

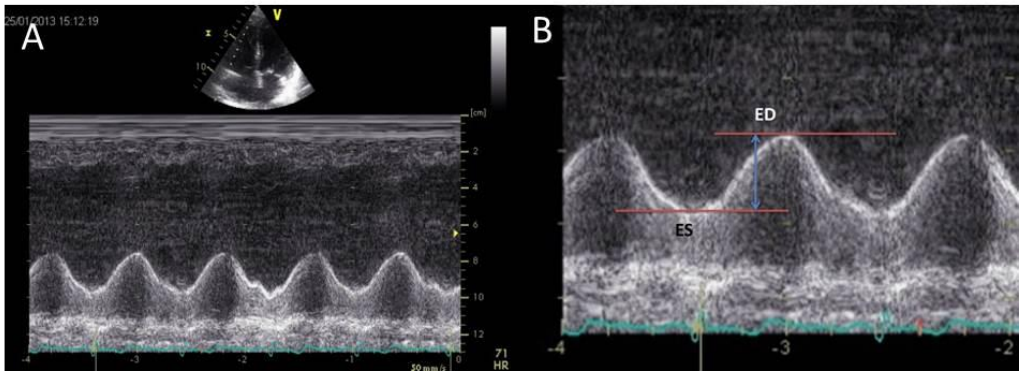


Figure 29: **TAPSE (A) and measurement of TAPSE (B)**

A: M-mode

S: distance between end-diastolic and end-systolic motion of the lateral tricuspid valve insertion

Q: the M-mode beam should be placed in the lateral tricuspid valve annulus; the direction of motion of the lateral valve annulus must be parallel to the M-mode scan line; the angle of insonation may need to be adjusted for this. purpose

R: measurements (see **Table 28 - M-mode lateral tricuspid valve insertion**)

Table 28 - M-mode lateral tricuspid valve insertion

Measured parameter (unit)	time of measurement	Position of the measuring points
TAPSE (mm)	ES to ED	endocardial border line (ES) endocardial border line (ED)

3.5.3.13 Tissue Doppler lateral MV

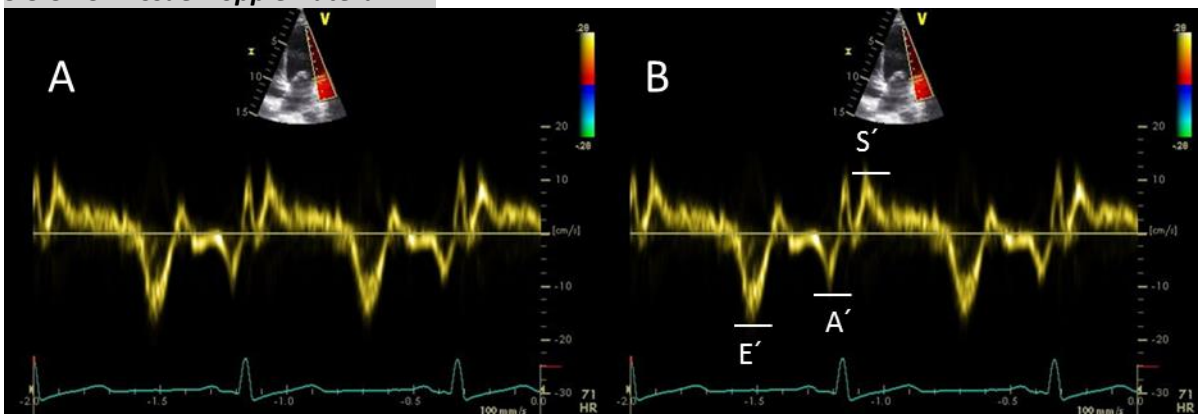


Figure 30: **Tissue Doppler lateral MV (A) and measurement of tissue Doppler lateral MV (B)**

A: tissue Doppler

S: tissue Doppler signal at the lateral mitral valve annulus (E'lat-wave, A'lat-wave)

Q: 1. optimization of the grey scale image to avoid reverberation artifacts that can produce artifacts, narrowing of the B-image sector and reduction of the penetration depth if necessary to maximize the frame rate

2. sample volume of the PW-TDI should be placed at the lateral mitral ring and should be 5 mm

3. the TDI focus should be narrowed to the area of interest; a frame rate (in color mode) of >100/s (better >130/s) should be aimed for [11, 12]

4. filter should be set to 100 Hz

5. at least 3-5 cycles with adequate Doppler signal should be recorded (during quiet breathing or breath holding)

6. adjustment of zero line and velocity range should be done until the spectral range fills approximately ¾ of the screen; the direction of movement of the valve annulus must be parallel to the line of insonation

R: see Table 29 - Tissue Doppler lateral MV and Table 30 - Calculated values from tissue Doppler lateral MV

Table 29 - Tissue Doppler lateral MV

Measured parameters	Time of measurement	Position of the measuring points
E'lat (cm/s)	early diastole	V_{max} of the E'-wave
A'lat (cm/s)	late diastole	V_{max} of the A'-wave
S'lat (cm/s)	systolic	V_{max} of the S'-wave

Table 30 - Calculated values from tissue Doppler lateral MV

Calculated parameters	Calculation based on measured value	Result
E/E‘	MV E $V_{max, E'at}$	3-5 calculated single valuesand calculated mean value

3.5.3.14 Tissue Doppler medial MV

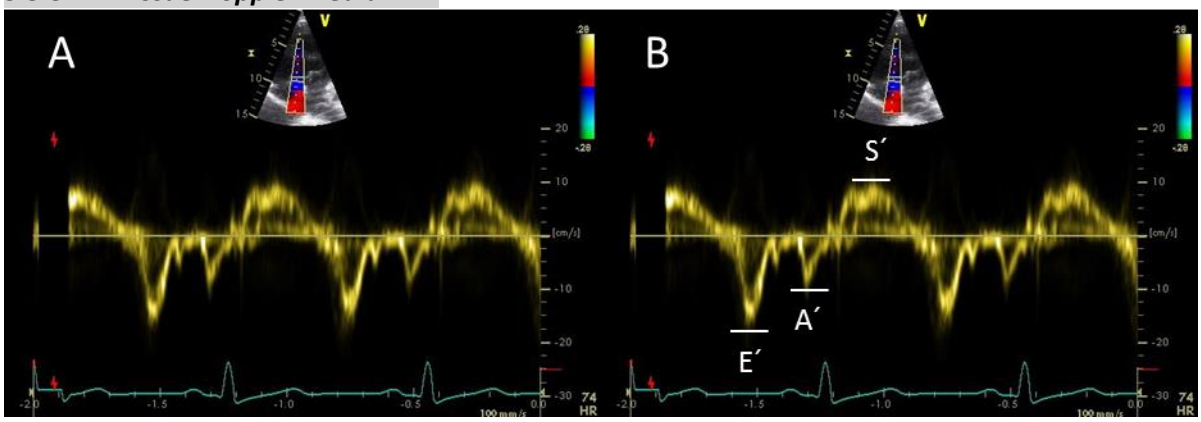


Figure 31: **Tissue Doppler medial MV (A) and measurement of tissue Doppler medial MV (B)**

A: tissue Doppler

S: tissue Doppler signal at the medial mitral valve annulus (E'med-wave, A'med-wave)

Q: 1. optimization of the grey scale image to avoid reverberation artifacts that produce artifacts, narrowing the B-image sector and reduction of the penetration depth if necessary to maximize the frame rate

2. sample volume of the PW-TDI should be placed at the medial mitral ring and should be 5 mm

3. TDI focus should be narrowed to the area of interest; a frame rate (in color mode) of >100/s should be aimed for

4. filter should be set to 100 Hz

5. at least 10-20 cycles with an adequate Doppler signal should be recorded (during quiet breathing or breath holding)

6. adjustment of zero line and velocity range should be done until the spectral range fills approximately ¾ of the screen

R: **see** Table 31 - Measured values tissue Doppler medial MV

Table 31 - Measured values tissue Doppler medial MV

Measured parameters	Time of measurement	Position of the measuring points
E'med (cm/s)	early diastole	V_{max} of the E'-wave
A'med (cm/s)	late diastole	V_{max} of the A'-wave
S'med (cm/s)	systolic	V_{max} of the S'-wave

3.5.3.15 PW Doppler pulmonary veins

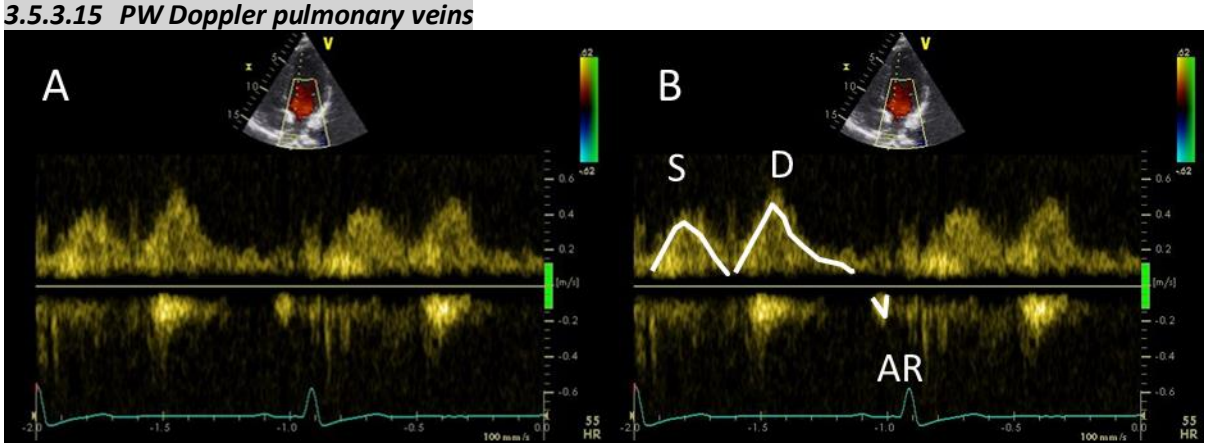


Figure 32: PW Doppler pulmonary veins (A) and measurement PW Doppler pulmonary veins (B)

A: PW Doppler

S: 1. left atrium

2. influx from the pulmonary vein closest to the interatrial septum

Q: 1. placement of the measurement probe in the 4-chamber view at the pulmonary vein confluence, usually the upper right pulmonary vein (located septally in the apical four-chamber view)

2. wall filter should be adjusted to ± 0.05 – 0.1 m/s

R: measurements (see Table 32 – Measured values PW Doppler pulmonary veins)

Table 32 – Measured values PW Doppler pulmonary veins

Measured parameters (unit)	Time of measurement	Position of the measuring points
PVs Vel (m/s)	systolic	max. flow rate of antegrade systolic flow
PVd Vel (m/s)	diastolic	max. flow rate of antegrade diastolic flow
PVa dur (ms)	ED	start of retrograde diastolic flow to end
PVa Vel (m/s)	diastolic	max. flow rate of retrograde diastolic flow

3.5.4 Apical five-chamber view

The explanations for A, S, Q and R as well as tables, if applicable, refer to the respective figure under which they appear.

3.5.4.1 2D mode

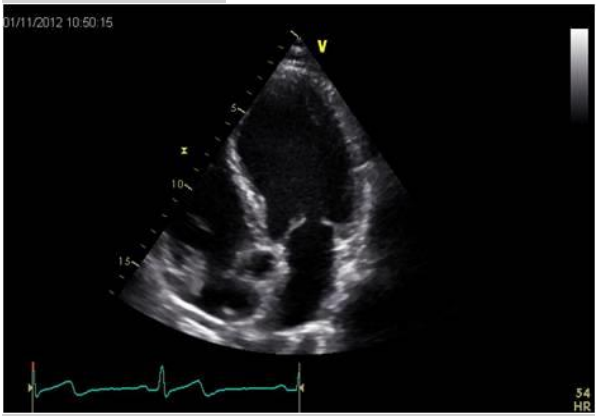


Figure 33: **Apical five-chamber view**

A: 2D mode (sequence)

S: 1. left and right ventricle

2. bulbus aortae/aortic valve

3. left and right atrium

Q: 1. bulbus aortae and both AV valves should be at the same level

2. left ventricle should be displayed in the optimal length and stretched out

3. septum should be displayed perpendicular to the lower edge of the image

R: visual assessment of kinetics and of the valve structure of the aortic valve

3.5.4.2 PW Doppler of the LVOT in the five-chamber view

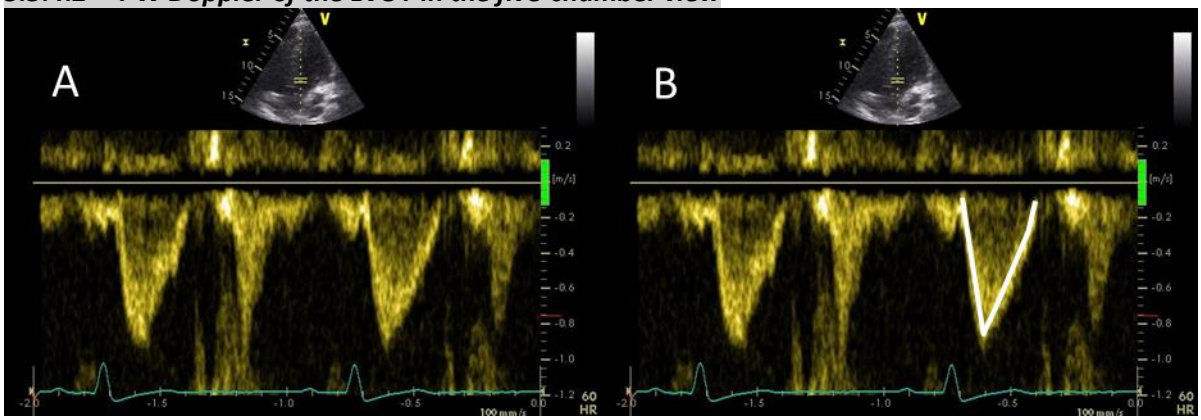


Figure 34: **PW Doppler LVOT (A) and measurement PW Doppler LVOT (B)**

A: PW Doppler

S: patterning of the left ventricular cavity by slowly advancing the measurement volume from apical towards the aortic valve up to a maximum of 5 mm above the valve plane

Q: 1. optimized insonation angle (angle < 25 degrees)

2. the length of the sample volume should be 3 mm at the beginning, if necessary adjust the Nyquist limit of the PW Doppler by shifting the zero line until the mantle curve is fully displayed

3. if the measured velocity exceeds > 1.5 m/s or aliasing occurs (illustration of an inverted PW curve signal), repeat the survey with CW Doppler

R: measurements (see Table 33 - PW Doppler measured values of LVOT and Table 34 - Calculated values from PW Doppler LVOT)

Table 33 - PW Doppler measured values of LVOT

Measured parameter (unit)	Time of measurement	Position of the measuring points
LVOT Vmax (m/s)	end-systolic	point of maximum velocity on PW envelope curve in LVOT
LVOT VTI (cm)	end-systolic	tracing of the PW envelope curve

Table 34 - Calculated values from PW Doppler LVOT

Calculated parameter	Calculation based on measured value
LVOT Pgmax (mmHg)	VTI
LVOT dPmean (mmHg)	VTI

3.5.4.3 Color Doppler in LVOT

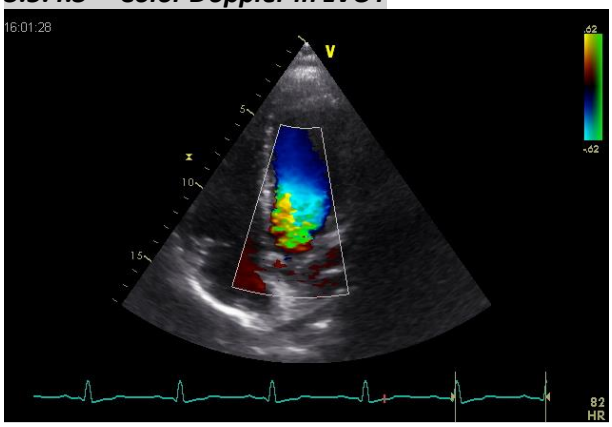


Figure 35: **Color Doppler LVOT**

A: color Doppler (sequence)

S: color Doppler in the area of the left ventricular outflow tract

Q: 1. color Doppler window as narrow as possible, elongated

2. optimized insonation angle (angle < 25 degrees)

3. color Doppler velocity range should be 40-60cm/s

R: visual assessment of diastolic (e.g. mitral stenosis) or systolic (e.g. HOCM) turbulent flow acceleration

3.5.4.4 Color Doppler examination of the aortic valve

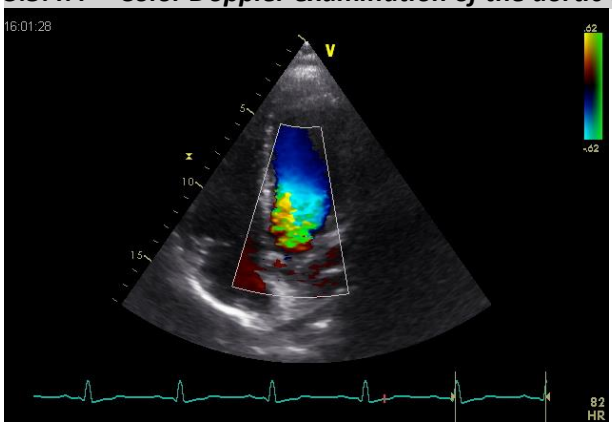


Figure 36: **Color Doppler aortic valve**

A: 1. color Doppler

S: 1. left and right ventricle

2. bulbus aortea/aortic valve

3. left and right atrium

Q: 1. visualization of the aortic root, the separation of the leaflets should be visually recognizable

2. color Doppler window should be as narrow as possible; the jet of the aortic valve regurgitation should be fully detected

3. optimized insonation angle (angle < 25 degrees),

4. the Nyquist limit for color Doppler imaging of aortic valve regurgitation should be 60 cm/s

5. if possible, the wall filter should be adjusted to ± 0.05 – 0.1 m/s

6. if aortic stenosis is detected: measurement in second plane (e.g. three-chamber view)

R: visual assessment of the kinetics and of the valve structure of the aortic valve, assessment of transaortic outflow, indications for flow acceleration, in case of evidence of aortic regurgitation: assessment of the infundibular flow width and of the extent of the diastolic regurgitation jet

3.5.4.5 CW Doppler examination of the aortic valve

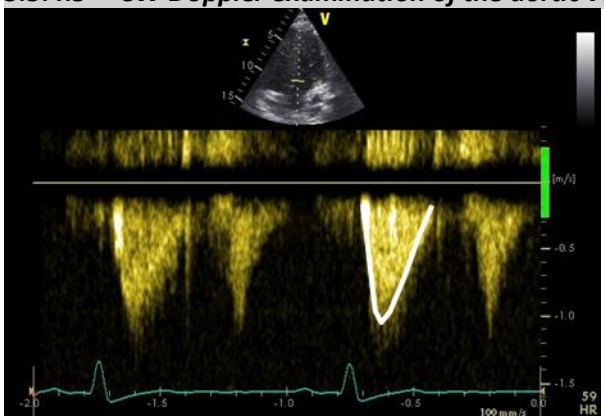


Figure 37: **CW Doppler aortic valve**

A: CW Doppler

S: 1. left and right ventricle

2. bulbus aortae/aortic valve

3. left and right atrium

Q: 1. representation of the aortic root, the separation of the leaflets should be visually recognizable

2. optimized insonation angle (angle < 25 degrees)

3. if possible, the wall filter should be adjusted to ± 0.05 – 0.1 m/s

4. if aortic stenosis is detected: measurement in second plane (e.g. three-chamber view)

R: measurements (see Table 35 – Assessment of aortic valve ,

Table 36 - **Measured values aortic valve** and Table 37 - Calculated measured values aortic valve)

Table 35 – Assessment of aortic valve

Assessed parameter (unit)	**Visual assessment of the valve**
Aortic valve	native, post-surgical (status post biological valve replacement (yes/no), status post mechanical valve replacement (yes/no), status post interventional valve replacement (yes/no)), unknown, not assessed

Table 36 - Measured values aortic valve

Measured parameters (unit)	Position of the measuring points
AV Vmax (m/s)	point of maximum velocity on CW envelope curve over aortic valve
AV VTI (cm)	tracing of CW envelope curve
AR DT (m/s²)	connection between maximum and minimum velocity of the insufficiency jet
AR PHT (ms)	connection between maximum and minimum velocity of the insufficiency jet

Table 37 - Calculated measured values aortic valve

Calculated parameters	Calculation based on measured value	Result
AV Pgmean (mmHg)	AV VTI	3-5 calculated single values and mean value
AV Pgmax (mmHg)	AV VTI	3-5 calculated single values and mean value

3.5.4.6 IVRT measurement

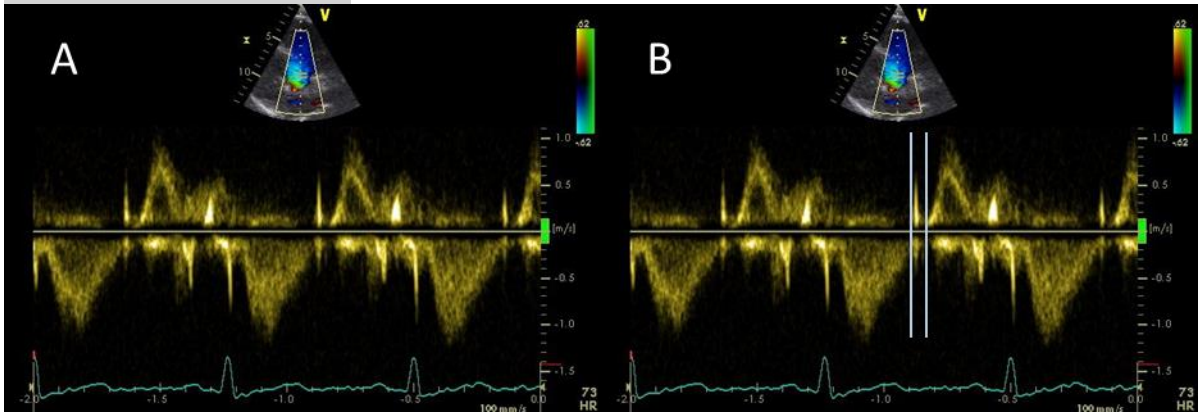


Figure 38: PW Doppler LVOT/MV (IVRT determination) (A) and IVRT measurement (B)

A: PW Doppler

S: position the PW Doppler between the left ventricular outflow tract and the base of the anterior mitral valve leaflet

Q: 1. the aortic valve closure and the mitral valve opening artifact (mitral valve opening click) (10-20 ms before the onset of mitral valve influx) should be delineable

2. if possible, the wall filter should be adjusted to ± 0.05 – 0.1 m/s

3. envelope curve of aortic valve and mitral valve should be clearly contoured

R: measurements (see **Table 38 - IVRT Doppler measurement**)

Table 38 - IVRT Doppler measurement

Measured parameter (unit)	Time of measurement	Position of the measuring points
IVRT (ms)	systolic/early diastole	1st measuring point: middle of the aortic closure click 2nd measuring point: start of mitral valve influx

3.5.5 Apical two-chamber view and three-chamber view

The explanations for A, S, Q and R as well as tables, if applicable, refer to the respective figure under which they appear.

3.5.5.1 Apical two-chamber view

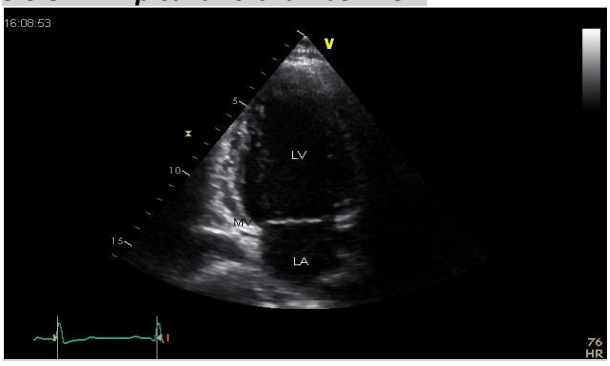


Figure 39: **Two-chamber view**

A: 2D (sequence)

S: Complete imaging of the anterior and inferior part of the LV and of the left atrium and mitral valve, segment P1, A2 and P3 (optionally coronary sinus/left atrial appendage), measurements of mitral valve as described under four-chamber view

Q: 1. the left ventricle should be visualized in the optimal length and completely stretched

2. the septum should be perpendicular to the lower edge of the image

R: Visual assessment of the kinetics of the anterior and inferior wall sections, the measurements in the mitral valve area are analogous to the measurement in the four-chamber view

the LA volumetry (end-systolic) should be documented biplanarly (from the insonation in the four- and two-chamber view)

3.5.5.2 Three-chamber view

The explanations for A, S, Q and R as well as tables, if applicable, refer to the respective figure under which they appear.

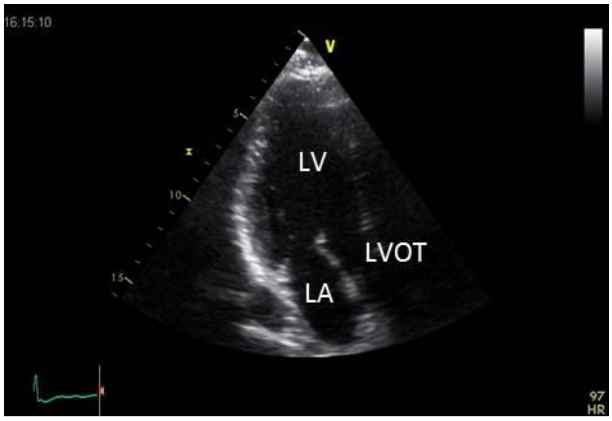


Figure 40: **Three-chamber view**

A: 2D (sequence)

S: left atrium and left ventricle (septal and inferolateral segments), aortic valve (right coronary and non-coronary leaflet) as well as A2- and P2-segments of the mitral valve, measurements of the aortic valve/mitral valve in the three-chamber view only complementary, performed as previously described

Q: 1. left ventricle should be visualized in optimal length and completely stretched out

2. the septum should be perpendicular to the lower edge of the image

R: visual assessment of the anteroseptal and inferolateral wall sections, measurements of the aortic valve are analogous to the measurements in apical five-chamber view

3.5.6 Subxiphoid view with IVC

The explanations for A, S, Q and R as well as tables, if applicable, refer to the respective figure under which they appear.

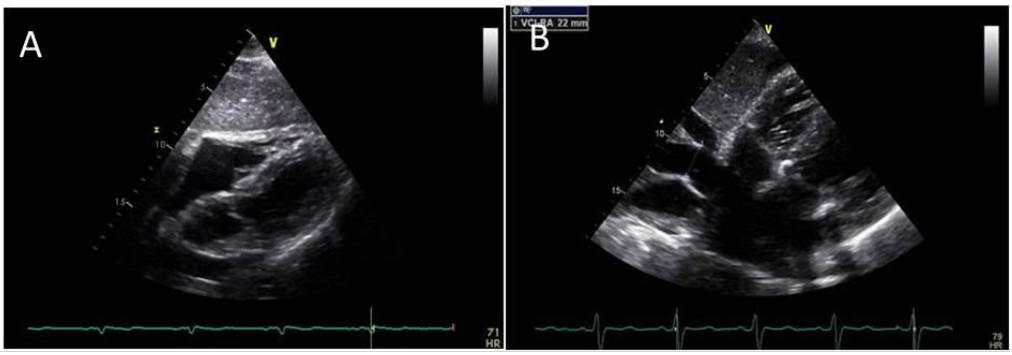


Figure 41: **Four-chamber view subxiphoid (A) and IVC measurement (B)**

S: left/right atrium with visualization of the inflowing IVC, left/right ventricle

Q: visualization and measurement of IVC during inspiration/expiration approximately 1.5 cm before the right atrium [9]

R: 1. visualization/quantification if pericardial effusion present

2. measurement of diameter of IVC (see **Table 39 - IVC measurements**)

Table 39 - IVC measurements

Measured parameters (unit)	Time of measurements	Position of the measuring points
Diam VCI (mm)	end-diastolic	distance: approximately 1.5 cm in front of the right atrium outer limit of the superior wall of the IVC, second inner limit of the inferior wall of the VCI
Diam IVC insp	end-diastolic	distance: approximately 1.5 cm in front of the right atrium outer limit of the superior wall of the IVC, second inner limit of the inferior wall of the VCI
pericardial separation/effusion	end-diastolic	visually

3.5.6.1.1 Pericardial effusion

Pericardial effusion is present when echo free pericardial separation is demonstrated at the end of the diastole (>1 mm [7]).For more details: see 0 and 3.5.3.2.2.

3.5.6.2 Subxiphoid view with color Doppler and/or spectral Doppler vena hepatica (especially to classify the degree of tricuspid regurgitation)

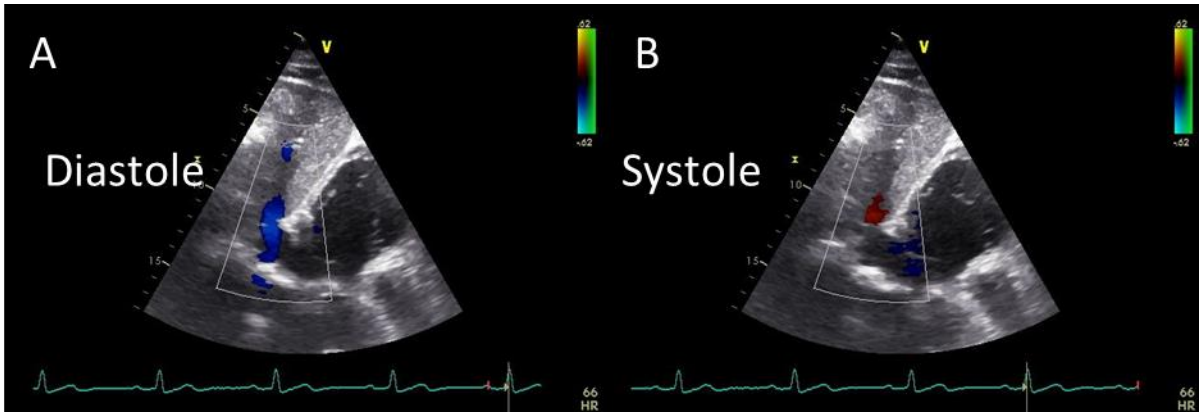


Figure 42: Subcostal echo in a person with tricuspid regurgitation, color Doppler of the hepatic vein in diastole and systole shows systolic flow reversal (red), alternatively with positioning of the PW Doppler in the hepatic vein there is also evidence of retrograde systolic flow

3.5.7 Quantification of valve defects

The listed criteria for quantifying defects are always based on different parameters. The assessment of whether and to which degree of severity a defect is present is the responsibility of the examiner, who has to consider the various parameters. They should be applied to "native heart valves", not after replacement (biological or mechanical).

3.5.7.1 Mitral regurgitation

	Severity		
Criteria	**1 (mild)**	**2 (moderate)**	**3 (severe)**
Qualitative			
mitral valve morphology	normal/changed	normal/changed	flail leaflet/ruptured papillary muscles
color Doppler of the insufficiency jet	small, central	intermediate	very large central jet or eccentric jet reaching the posterior wall of the LA
flow convergence zone (Nyquist 50-60 cm/s)	none or small	intermediate	large
CW signal of the insufficiency jet	weak signal/ parabolic	intense signal/ parabolic	intense signal/ triangular
Semi-quantitative			
vena contracta width (mm)	<3	intermediate	≥7 (>8 for means of a biplane measurement)
pulmonary vein flow[1]	predominantly systolic	systolic flattening	systolic flow reversal
mitral inflow	A-wave dominant[2]	variable	E-wave dominant (≥1.5 cm/s)[3]
TVI mit/ TVI Ao	<1	intermediate	>1.4
Quantitative			
EROA (mm^2)	<20	20-29; 30-39[4]	≥40

R Vol (mL)	<30	30-44; 45-59[4]	≥60
+ LV and LA size and the systolic pulmonary arterial pressure[5]			
Abbreviations: CW, continuous wave; LA, left atrium; EROA, effective regurgitant orifice area; LV, left ventricle; MR, mitral regurgitation; R Vol, regurgitant volume; VC, vena contracta			
[1]Limited assessment in other reasons for systolic flow flattening (atrial fibrillation, elevated atrial pressure) [2] Usually at 50 years of age or older [3] In the absence of other reasons for increased LA pressure and mitral stenosis [4] Classification of severity for organic MR into mild, moderate, and severe, and subclassification is into 'mild-to-moderate' (EROA 20-29 mm² or a R Vol 30-44 mL) and 'moderate-to-severe' (EROA 30–39 mm² or a R Vol 45–59 mL) [5] Unless for other reasons, the LA and LV size and systolic pulmonary pressure are normal in individuals with mild MR. In acute severe MR, pulmonary pressures are usually elevated while the LV size is still often normal. In chronic severe MR, the LV is typically dilated. Accepted cut-off values for non-significant left-sided chamber enlargement: LA volume <36 mL/m², LV end-diastolic diameter <56 mm, LV end-diastolic volume <82 mL/m², LV end-systolic diameter <40 mm, LV end-systolic volume <30 mL/m², LA diameter <39 mm, LA volume <29 mL/m².			

Figure 43: Recommendations of the European Association of Echocardiography [13]

3.5.7.2 Mitral valve stenosis

	Severity		
Criteria	**1 (mild)**	**2 (moderate)**	**3 (severe)**
specific findings			
valve opening area (cm²)	>1.5	1.0-1.5	<1.0
supportive findings			
mean gradient (mmHg)[1]	<5	5-10	>10
pulmonary artery pressure (mmHg)	<30	30-50	>50
1 At heart rates between 60 and 80 bpm and in sinus rhythm			

Figure 44: Recommendations of the European Association of Echocardiography and of the American Society of Echocardiography [9]

3.5.7.3 Aortic regurgitation

	Severity		
Criteria	**1 (mild)**	**2 (moderate)**	**3 (severe)**
Qualitative			
aortic valve morphology	normal/changed	normal/changed	changed/flail/ lack of coaptation
color flow AR jet (width Nyquist 50-60 cm/s)	small/central	intermediate	large central jet, variable for eccentric jets
CW signal of AR jet	weak/incomplete	intense signal	intense signal
diastolic flow reversal in descending aorta	short, protodiastolic flow reversal	intermediate	holodiastolic flow reversal (end-diastolic velocity >20 cm/s)
Semi-quantitative			
vena contracta width (mm)	<3	intermediate	>6
pressure half-time (ms)[1]	>500	intermediate	<200

Quantitative			
EROA (mm^2)	<10	10-19; 20-29[2]	≥30
R Vol (mL)	<30	30-44; 45-59[2]	≥60
+ LV size[3]			
Abbreviations: AR, aortic regurgitation; CW, continuous wave; LA, left atrium; EROA, effective regurgitant orifice area; IVC, inferior vena cava; LV, left ventricle; R Vol, regurgitant volume; VC, vena contracta			
[1] Pressure half-time is shortened with elevated LV diastolic pressure, vasodilator therapy, and in individuals with a dilated elastic aorta or prolonged in chronic AR [2] Classification of the severity for AR is into mild, moderate, or severe, and subclassification is into 'mild-to-moderate' (EROA of 10–19 mm^2 or an R Vol of 30–44 mL) and 'moderate-to-severe' (EROA of 20–29 mm^2 or an R Vol of 45–59 mL) [3] Unless for other reasons, the LV size is usually normal in individuals with mild AR. In acute severe AR, the LV size is often normal. In chronic severe AR, the LV is classically dilated. Accepted cut-off values for non-significant LV enlargement: LV end-diastolic diameter <56 mm, LV end-diastolic volume <82 mL/m^2, LV end-systolic diameter <40 mm, LV end-systolic volume <30 mL/m^2			

Figure 45: Recommendations of the European Association of Echocardiography [10]

3.5.7.4 Aortic stenosis

	Severity			
Criteria	**Aortic sclerosis**	**1 (mild)**	**2 (moderate)**	**3 (severe)**
aortic valve jet velocity (Vmax)(m/s)	≤2.5 m/s	2.6-2.9	3.0-4.0	>4.0
mean gradient (mmHg)	-	<20 (<30[1])	20-40[2] (30-50[1])	>40[2] (>50[1])
valve opening area (cm^2)		>1.5	1.0-1.5	<1.0
valve opening area per body surface area (cm^2/m^2)		>0.85	0.60-0.85	<0.6
velocity ratio[3]		>0.5	0.25-0.50	<0.25
[1] ESC guidelines. [2] AHA/ACC guidelines. [3] Subvalvular (LVOT) velocity (m/s)/ maximum velocity across the valve (m/s)				

Figure 46: Recommendations of the European Association of Echocardiography and of the American Society of Echocardiography [9]

3.5.7.5 Pulmonary valve regurgitation

	Severity		
Criteria	**1 (mild)**	**2 (moderate)**	**3 (severe)**
Qualitative			
pulmonary valve morphology	normal	normal/changed	changed
color Doppler PR jet width (for Nyquist 50-60 cm/s)	small, usually <10 mm with a narrow origin	intermediate	large with a broad origin; may be of short duration
CW signal of PR jet[1]	weak/slow deceleration	intense/variable intense signal	intense signal/steep deceleration, early end of diastolic flow
pulmonary vs. aortic flow by PW Doppler	normal or slightly increased	intermediate	markedly increased
Semi-quantitative			
Vena contracta width (mm)	not defined	not defined	not defined
Quantitative			
EROA (mm^2)	not defined	not defined	not defined
R Vol (mL)	not defined	not defined	not defined
+ RV size[2]			
Abbreviations: PR, pulmonic regurgitation; CW, continuous wave; EROA, effective regurgitant orifice area; PW, pulse wave; RV, right ventricle; R Vol, regurgitant volume; VC, vena contracta			
[1] Steep deceleration is not specific for severe PR. [2] Unless for other reasons, the RV size is usually normal in individuals with mild PR. In acute severe PR, the RV size is often normal. Accepted cut-off values for non-significant RV enlargement (measured in apical 4-chamber view) are: mmidline length ≤33 mm, RV end-diastolic area ≤28 cm^2, RV end-systolic area ≤16 cm2, RV fractional area change >32%, maximum.			

Figure 47: Recommendations of the European Association of Echocardiography [10]

3.5.7.6 Tricuspid regurgitation

	Severity		
Criteria	1 (mild)	2 (moderate)	3 (severe)
Qualitative			
tricuspid valve morphology	normal/changed	normal/changed	changed/flail/lack of coaptation
color Doppler TR jet (at Nyquist 50-60 cm/s)	small, central	intermediate	very large central jet or eccentric wall-impinging jet
CW signal of TR jet	weak/parabolic	intense signal/parabolic	intense signal/triangular with early peak (peak <2 m/s with massive TR)
Semi-quantitative			
vena contracta width [1] (mm)	not defined	<7	≥7
PISA radius (mm)[2]	≤5	6-9	>9
flow profile of hepatic vein[3]	predominantly systolic	systolic flattening	systolic flow reversal
tricuspid inflow	normal	normal	predominantly E-wave (≥ 1cm/s)[4]
Quantitative			

EROA (mm^2)	not defined	not defined	≥40
R Vol (mL)	not defined	not defined	≥45
+ RA/RV/IVC size[5]			

Abbreviations: CW, continuous wave; EROA, effective regurgitant orifice area; IVC, inferior vena cava; RA, right atrium; RV, right ventricle; R Vol, regurgitation volume; TR, tricuspid regurgitation; VC, vena contracta

[1] At Nyquist limit 50-60 cm/s
[2] Baseline Nyquist limit shift 28 cm/s
[3] Unless other reasons of systolic flattening (atrial fibrillation, increased RA pressure)
[4] In the absence of other reasons for increased RA pressure
[5] Unless for other reasons, the RA, RV and IVC size are usually normal in individuals with mild TR. An end-systolic RV eccentricity index >2 is indicative of severe TR. In acute TR, the RV size is usually normal. In chronic severe TR, the RV is classically dilated. Accepted cut-off values for non-significant right-sided enlargement (measured in an apical 4-chamber view): RV midline length ≤33 mm, RV end-diastolic area ≤28 cm^2, RV end-systolic area ≤16 cm^2, RV fractional area change >32%, maximal RA volume ≤33 mL/m^2. An IVC diameter <1.5 cm is considered normal.

Figure 48: Recommendations of the European Association of Echocardiography [13]

3.6 FOLLOW-UP AND DATA COLLECTION

Ultrasound images are stored on the server for offline analysis. Follow-up depends on the requirements of the respective study/registry (see study protocol). For example: 3.6.1 follow-up interview, feedback on findings.

3.6.1 Follow-up interview, feedback on findings

Depending on the requirements of the respective study/registry (see study protocol). For example: in a blinded analysis, feedback to the participating person is not possible. In case of unexpected pathological results of the echocardiography, it is up to the investigating physician to decide whether the blinding has to be removed, so that an immediate evaluation and therapeutic consequence is possible.

3.7 DEALING WITH DEVIATIONS

Specifics are always recorded in comments/notes. Please note any questions that are not covered in the SOP and forward them to the SOP responsible (forschungsplattform@dzhk.de).

4 LITERATURE AND REFERENCES

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5 MODIFICATIONS

Modifications compared to the previous version

Section	Description of the modification to the previous version
	General editorial changes of the whole document
	New document “Checklist”

6 PERSONS INVOLVED

Name	Role	Involvement
Prof. Dr. Marcus Dörr	first author	Drafted the SOP
Dr. S. Goder	author	scientific review
Dr. M. Bahls	author	scientific review
Dr. K. Lehnert	author	scientific review
Dr. Derliz Mereles	reviewer	expert review
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 LIST OF TABLES

7.2 LIST OF FIGURES

7.3 SPECIFIC EXAMINATION PROGRAMS OF THE DZHK STUDIES AND REGISTERS:

A summary of the parameters and calculated values contained in this SOP can be found in the corresponding Excel file "DZHK_SOP_ECHO_Parameterliste_V0.9_19NOV2013.xlsx". From column "E" onwards, the parameters that are used/required by a specific study/cohort/register can be marked

A	B	C	D	E	F
Schnittebene, Modalität	Strukturen, Parameterbezeichnung	Abkürzung	Einheit	Studie 1	Studie 2
PARASTERNALE LANGE ACHSE					
Cineloops					
2D	linker Ventrikel		visuelle Beurteilung		
	Aortenwurzel		visuelle Beurteilung		
Farbdoppler	Farbdoppler über Mitral- und Aortenklappe		visuelle Beurteilung		
Gemessene Parameter				x	
M-Mode - Mitralsegelspitzen-Ebene	Intraventrikuläre Septumdicke systolisch	IVSs	mm	x	
	Intraventrikuläre Septumdicke diastolisch	IVSd	mm	x	
	linksventrikulärer endokardialer Durchmesser systo	LVEDs	mm	x	
	linksventrikulärer endokardialer Durchmesser diast	LVEDd	mm	x	
	linksventrikuläre posteriore Wand systolisch	LVPWs	mm	x	
	linksventrikuläre posteriore Wand diastolisch	LVPWd	mm		
	rechtsventrikulärer Durchmesser systolisch	RV s	mm		
	rechtsventrikulärer Durchmesser diastolisch	RV d	mm		
	Perikarderguss systolisch	PEs	mm	x	
M-Mode - Aortenwurzel	Aortenwurzeldurchmesser	AoW	mm	x	
	linker Vorhofdurchmesser	LA diam	mm		
	Aortenklappenseparation	AoS	mm		
Berechnete Werte					

Figure 48 DZHK_SOP_ECHO_Parameterliste_V0.9_19NOV2013.xlsx

7.4 eCRF MODULE

Echocardiography

Examination details

I. Was the echocardiography performed?* ◯ yes ◯ no ◯ unknown ◯ not assessed * — Comment Query

II. Date of examination* ___ ___ ___ dd.mm.yyyy
◯ unknown ◯ not assessed (*) — Comment Query

III. Quality level* < Please choose > — Help Comment Query

1. Examination

1.1. Heart rate* ___ /min
◯ unknown ◯ not assessed (*) — Comment Query

1.2. Rhythm — Comment Query
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 *
< Please choose > *
1.2.4 Other rhythm* ◯ yes ◯ no ◯ unknown ◯ not assessed *

2. Image quality

2.1. Parasternal long axis* — Comment Query
◯ performed with good sound quality *
◯ performed with very limited sound quality
◯ no echo window – examination not possible
◯ unknown
◯ not assessed

2.2. Parasternal short axis* — Comment Query
◯ performed with good sound quality *
◯ performed with very limited sound quality
◯ no echo window – examination not possible
◯ unknown
◯ not assessed

2.3. Apical four-chamber view* — Comment Query
◯ performed with good sound quality *
◯ performed with very limited sound quality
◯ no echo window – examination not possible
◯ unknown
◯ not assessed

2.4. Apical three-chamber view* — Comment Query
◯ performed with good sound quality *
◯ performed with very limited sound quality
◯ no echo window – examination not possible
◯ unknown
◯ not assessed

2.5. Apical two-chamber view* — Comment Query
◯ performed with good sound quality *
◯ performed with very limited sound quality
◯ no echo window – examination not possible
◯ unknown
◯ not assessed

2.6. Subcostal*

- ◯ performed with good sound quality *
- ◯ performed with very limited sound quality
- ◯ no echo window – examination not possible
- ◯ unknown
- ◯ not assessed

Comment Query

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

Comment Query

3.2. Aortic root diameter (end-systolic) (AO)*

[ ] mm ◯ unknown ◯ not assessed (*)

Comment Query

3.3. Left atrium (end-systolic) (LA diam)*

[ ] mm ◯ unknown ◯ not assessed (*)

Comment Query

3.4. Interventricular septum (end-diastolic) (IVS_d)*

[ ] mm ◯ unknown ◯ not assessed (*)

Comment Query

3.5. Left ventricular end-diastolic diameter ($LVED_d$)*

[ ] mm ◯ unknown ◯ not assessed (*)

Comment Query

3.6. Left ventricular posterior wall ($LVPW_d$)*

[ ] mm ◯ unknown ◯ not assessed (*)

Comment Query

3.7. Left ventricular end-systolic diameter ($LVED_s$)*

[ ] mm ◯ unknown ◯ not assessed (*)

Comment Query

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

4.1. Left ventricular ejection fraction (LV-EF)*

[ ] % ◯ unknown ◯ not assessed (*)

Comment Query

4.2. Method*

- ◯ Simpson biplane *
- ◯ Simpson monoplane (4CH)
- ◯ visual
- ◯ unknown
- ◯ not assessed

Comment Query

4.3. Left ventricular end-diastolic volume (LVEDV)*

[ ] ml ◯ unknown ◯ not assessed (*)

Comment Query

4.4. Left ventricular end-systolic volume (LVESV)*

[ ] ml ◯ unknown ◯ not assessed (*)

Comment Query

4.5. Left atrium AP longitudinal (end-systolic) ($LA_{S\ (AP\ longitudinal)}$)*	____ mm ○ unknown ○ not assessed (*)	Comment Query
4.6. Left atrium AP transversal (end-systolic)($LA_{S\ (AP\ transversal)}$)*	____ mm ○ unknown ○ not assessed (*)	Comment Query
4.7. Left atrial area 4-chamber view (end-systolic) (LA area (4CH))*	____.____ cm² ○ unknown ○ not assessed (*)	Comment Query
4.8. Left atrial area 2-chamber view (end-systolic) (A2 LA area $(2CH)_S$)*	____.____ cm² ○ unknown ○ not assessed (*)	Comment Query
4.9. Wall motion disorder*	○ yes ○ no ○ unknown ○ not assessed *	Comment Query
4.10. RV dilatation (mid-ventricular)*	○ yes ○ no ○ unknown ○ not assessed *	Comment Query
4.11. TAPSE*	____ mm ○ unknown ○ not assessed (*)	Comment Query
4.12. MAPSE lateral*	____ mm ○ unknown ○ not assessed (*)	Comment Query
4.13. MAPSE septal*	____ mm ○ unknown ○ not assessed (*)	Comment Query
4.14. Pericardial effusion*	○ yes ○ no ○ unknown ○ not assessed *	Comment Query
4.15. Vena cava diameter*	____ mm ○ unknown ○ not assessed (*)	Comment Query
4.16. Vena cava response to breathing (> 50 % decrease on inspiration)*	○ yes ○ no ○ unknown ○ not assessed *	Comment Query
5. *Mitral valve Doppler (PW)*		
5.1. E-wave*	____ m/s ○ unknown ○ not assessed (*)	Comment Query
5.2. A-wave*	____ m/s ○ unknown ○ not assessed (*)	Comment Query
6. *Tissue Doppler (TDI)*		
TDI lat cannot be measured*	☐	Comment Query
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*	☐	Comment Query
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	Comment Query
	◯ unknown ◯ not assessed (*)	
7.2. Pulmonary venous diastolic velocity (PVdVel)*	___ cm/s	Comment Query
	◯ unknown ◯ not assessed (*)	
8. Valves		
Mitral valve		
8.1. Mitral valve*	◯ native *	Comment Query
	◯ post-surgical	
	◯ unknown	
	◯ not assessed	
Status post mitral valve surgery*	◯ mitral valve reconstruction *	Comment Query
	◯ 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 *	Comment Query
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 *	Comment Query
	◯ 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	Comment Query
Aortic valve		
8.2. Aortic valve*	◯ native * ◯ post-surgical ◯ unknown ◯ not assessed	Comment Query
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	Comment Query
8.2.1. Aortic valve morphology*	◯ normal ◯ abnormal ◯ unknown ◯ not assessed *	Comment Query
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	Comment Query
8.2.3. Aortic valve stenosis (AS)*	◯ no AS * ◯ mild AS ◯ moderate AS ◯ severe AS ◯ unknown (cannot be determined) ◯ not assessed	Comment Query
Pulmonary valve		
8.3. Pulmonary valve*	◯ native * ◯ post-surgical ◯ unknown ◯ not assessed	Comment Query
8.3.1. Pulmonary valve morphology*	◯ normal ◯ abnormal ◯ unknown ◯ not assessed *	Comment Query
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	Comment Query
Tricuspid valve		
8.4. **Tricuspid valve***	◯ native * ◯ post-surgical ◯ unknown ◯ not assessed	Comment Query
8.4.1. **Tricuspid valve morphology***	◯ normal ◯ abnormal ◯ unknown ◯ not assessed *	Comment Query
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	Comment Query

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