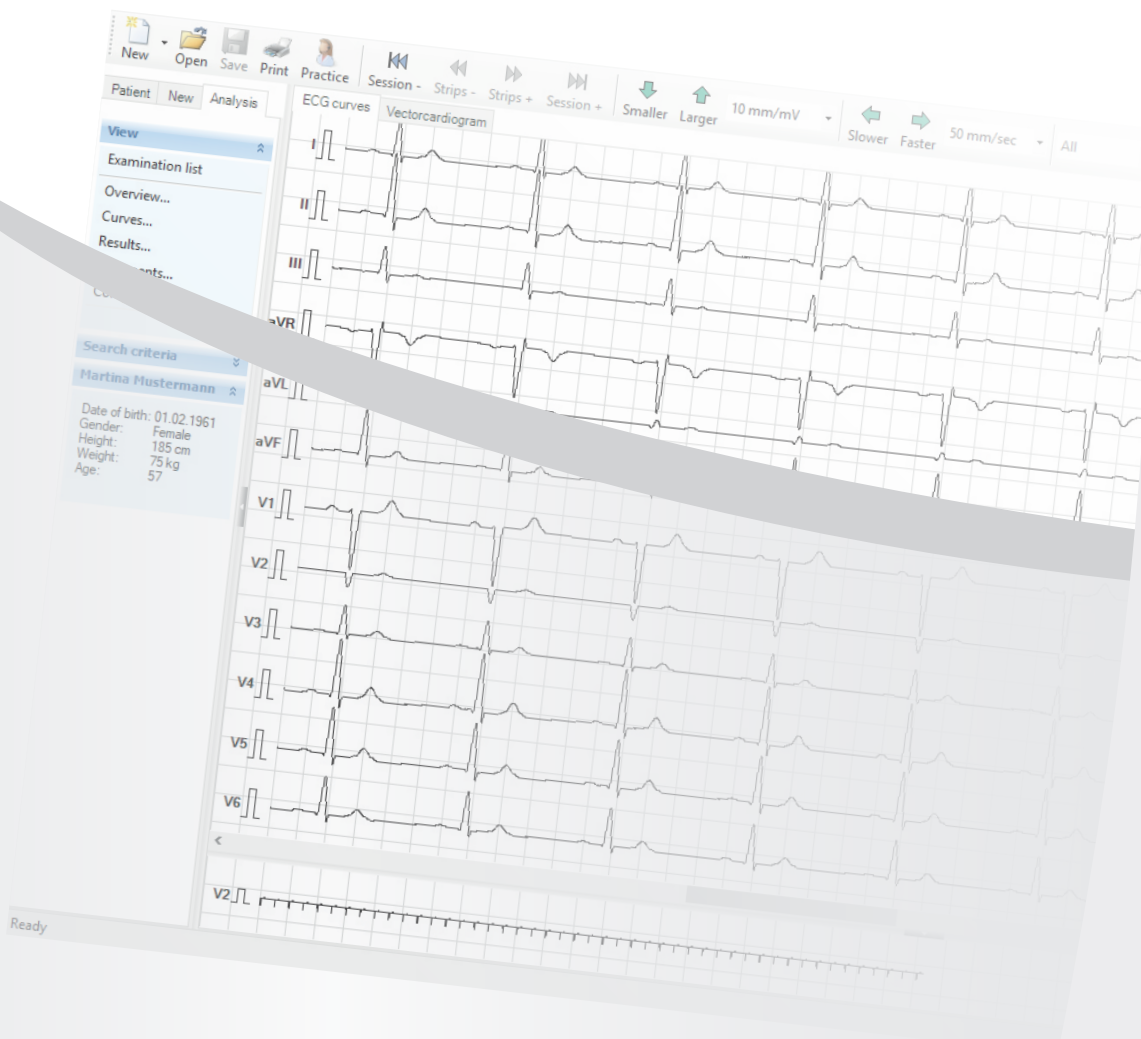


Instructions for Use

Diagnostik*Suite*

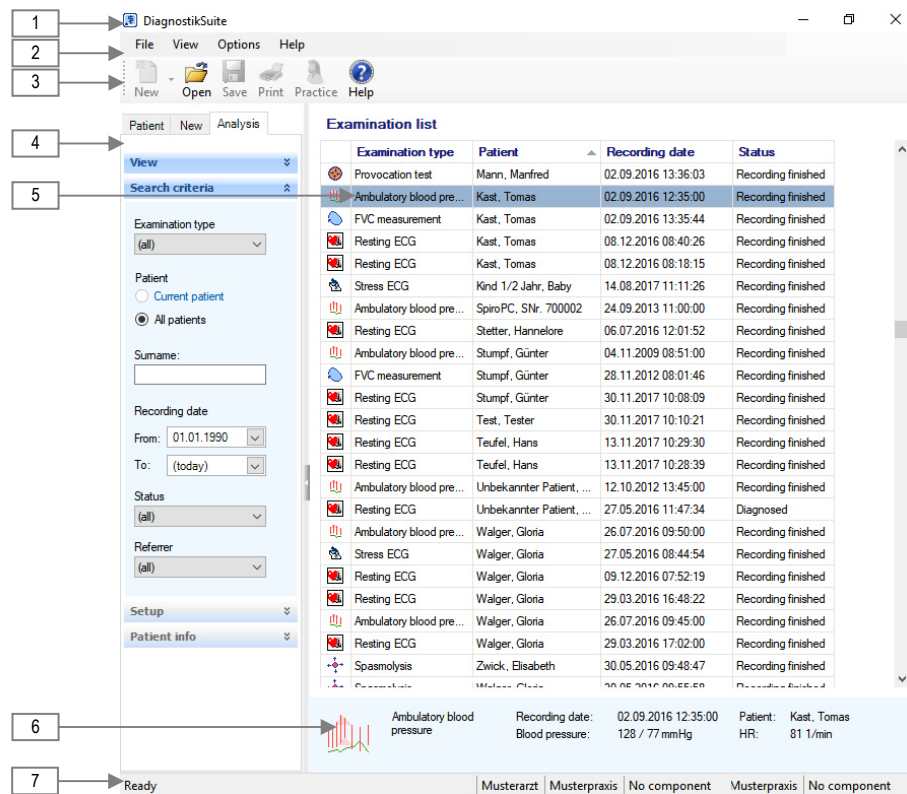
ECG



Illustrations

View/Toolbar

View



Operating elements

- | | | | |
|---|---------------------------|---|------------|
| 1 | Title bar | 5 | Work area |
| 2 | Menu bar | 6 | Info bar |
| 3 | Tool bar | 7 | Status bar |
| 4 | Navigation area with tabs | | |

Toolbar

Symbol Action/command performed

- | | |
|--|---|
| | Starts a new examination which can be selected from a list. |
| | Opens an existing examination for viewing |
| | Saves patient and examination data |
| | Prints the selected examination |
| | Switches to practice management software |
| | Starts online help |
| | End program |

Symbol Action/command performed

- | | |
|--|---|
| | Switches to the previous or next ECG examination |
| | Switches to the previous or next ECG strips |
| | Changes the sensitivity/amplitude of the ECG display |
| | Selection list for adjusting the sensitivity of the ECG display |
| | Changes the speed of the ECG display |
| | Speed adjustment |
| | Adjustment of the leads |
| | Adjustment of the filters |

Brief instructions

Description of symbols

Brief start-up instructions

Assembly

Connect the ECG amplifier and – if available – the sphygmomanometer and the ergometer or treadmill to the computer. If special drivers are needed, install these drivers on the computer.

Switch on the ECG amplifier as well as any other devices needed for ECG examinations. In the case of USB-driven devices, this step can be eliminated since the *DiagnostikSuite* automatically switches these on.

Software installation

Install the database program on a suitable computer.

Install the *DiagnostikSuite* software on all computers provided and perform activation.

Configure the connected devices in the *DiagnostikSuite*.

Select patient

Start the *DiagnostikSuite* and select the “Open” entry in the navigation area. Double-click to select the desired patient.

Perform examination

In the navigation area, open the “**New**” tab and select the desired type of examination (resting ECG, ergometry) there in the “**ECG examination**” panel.

Record data

Now place the ECG electrodes on the patient and start the ECG recording using the “Start” button. Check the ECG signals displayed and start the analysis or the stress test, depending on the type of examination.

Analyse examination

In the “**Analysis**” tab, you can display the individual views of the examination and check the results.

Save examination



After completing the new examination, this is filed in the database using the “Save” button.



If there is a connection, you transfer the examination into the index card of the practice management software using the “Practice” button.

Ending the examination



The *DiagnostikSuite* is ended using the “Close” button.

Description of symbols



In the instructions for use this symbol indicates “Danger”.



In the instructions for use this symbol indicates special information.

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These instructions for use are an integral part of the device and are to be observed in conjunction with the instructions for use of the individual examination modules. They should be kept available near the device at all times. Full compliance is a precondition for proper use and correct handling of the device as well as for the safety of the patient and user which is dependent on this.

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Therefore: Liability claims against Zimmer MedizinSysteme relating to damage

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Version information

These instructions for use are valid for the ECG software as of version 1.1. This is a component of the DiagnostikSuite, version 1.2.

1. Background medical information

Overview

In cardiovascular diseases, the resting and stress electrocardiograms (ECG) play an important role in the diagnosis and verification of the success of therapy. This examination is performed at the discretion of the responsible attending physician.

1.1. Indications/Contraindications

Indications

Resting ECG

- The resting ECG is used for support when clarifying thoracic pain and diagnosing cardiac arrhythmias, damage in the area of the coronary vessels and enlargement of the heart muscle.
- It can additionally help assess the involvement of the cardiovascular system in primary extracardiac diseases.

Stress ECG

A stress examination requires a clear indication by the attending physician. The stress ECG represents the basis in the diagnosis of ischaemia in CHD.

- Stress ECGs are most frequently performed to clarify chest pain in patients with cardiac risk factors, following an infarct, or in patients after revascularisation.
- The stress ECG also enables statements on exertional cardiac arrhythmias to be made.
- Another important indication is the documentation of physical capacity and the training heart rate in athletes or patients as well as the occupational medical monitoring in certain professions, for example, in emergency services.
- In addition, the blood pressure adjustment can be controlled during stress.

Contraindications

If the presence of one of the absolute contraindications listed below is suspected, no stress ECG should be performed.

Absolute contraindications

- Acute myocardial infarct
- Unstable angina pectoris
- Cardiac arrhythmias with symptoms and/or limited haemodynamics, symptomatic severe aortic stenosis
- Decompensated heart failure
- Acute pulmonary embolism, acute myocarditis, acute pericarditis, acute aortic dissection

Relative contraindications

- Left main coronary artery stenosis
- Valve disease of moderate severity
- Known electrolyte imbalances
- Arterial hypertension (BP >200 mmHg_{syst} >110 mmHg_{diast})
- Tachyarrhythmia or bradyarrhythmia
- Hypertrophic cardiomyopathy and other forms of outflow tract obstruction
- High-grade AV block
- Physical and/or mental impairment

Side effects

- An electrode suction system and longer application times with a high vacuum may lead to haematomas or skin damage.
- Performing a stress examination is not free of risks and complications. For this reason, the necessary emergency equipment must be available.

Also take note of the indications, contraindications, side effects and complications listed in the medical literature as well as in the instructions for use of connected devices.

2. General description

2.1. Intended use

The DiagnostikSuite is a software package for diagnostic examinations. It offers components for ambulatory blood pressure, spirometry, ECG. etc. within a uniform interface. The joint patient and diagnostic database as well as the continuous operation of all applications and communication in data networks facilitate daily work.

The ECG software of the DiagnostikSuite is an analysis software which, together with the ECG amplifiers CardioPort, CardioPort Four or the combination devices CardioPlus, CardioAir plus, CardioSys and CardioPro, is used to record resting and stress ECGs.

The ECG software accepts the ECG signals in real time from the ECG amplifier, represents the signals and results in graph and table form, and saves the examinations. The progress of measurements can be observed online. In addition to independent operation, the DiagnostikSuite is able to incorporate patient data from practice management programs and return important results.

The ECG software is prepared for use with various pieces of exercise equipment and blood pressure monitors. A list of supported exercise equipment is provided in the section "Combination devices".

2.2. Range of services

What is the DiagnostikSuite used for?

The DiagnostikSuite integrates various medical examination components in a flexible diagnostic system. It consists of basic software as well as one or more examination components, such as the ECG software. The DiagnostikSuite works with Windows™.

Where is the DiagnostikSuite primarily used?

The DiagnostikSuite is primarily intended for use in the physician's office and in the hospital. The use of mobile computers enables use at different locations.

The ECG software is used to record and analyse resting and stress ECGs.

What does the DiagnostikSuite do?

The DiagnostikSuite can be connected to a variety of functional diagnostic devices and operated as a system. These include, for example, ECG devices, spirometers and ambulatory blood pressure monitors.

The modular construction makes it possible to satisfy a wide variety of requirements and desires.

What does the ECG software do?

The ECG software provides users with the following functions for daily application:

- Electrocardiographic resting and stress examinations
- Online display of the ECG signals
- Optional measurement and interpretation of resting ECGs according to HES
- Ergometry with automatic sequence control, real-time average beat, ST and arrhythmia detection with HES stress analysis
- Continuous saving of the ECG signals
- A variety of views of the information obtained
 - Overview display of all important data
 - View of the ECG curves with additional rhythm display and average beats as well as additional information
 - Vector cardiogram in the case of a resting ECG
 - Graphic display of the load profile and ST values in the ergometry
 - Session values, global measurements, measurement results and interpretation in the case of a resting ECG.
 - Session values, physical work capacity, values at maximum load, load table, ST amplitudes, ST gradient, event distribution and event histogram in the case of ergometries.
 - Comments
- Comparison of ECG examinations

What are the other benefits of the DiagnostikSuite?

- The modern user interface with intuitive operation is easy for the user to become familiar with and it minimises learning time.
- The symbols in the graphic user interfaces are self-explanatory.
- The DiagnostikSuite can be used everywhere - in emergencies and also during house calls, because the system can also be operated with a notebook.
- The DiagnostikSuite has unlimited network compatibility. In a networked office, the examinations can be recorded in the laboratory and opened and viewed again at network workstations.

Overview of operating modes

The DiagnostikSuite provides the user with various operating modes:

- Patient management
- New recording to resting and stress ECGs
- Analysis of examinations

3. Start-up

Note

All components of the *DiagnostikSuite* are installed with the same installation program. This is described in detail in the instructions for use for the basic software.

3.1. System requirements

System requirements

The system requirements of the *DiagnostikSuite* apply to the ECG software.

3.2. Interfaces

Overview

- Devices with serial communication require either a free serial interface directly on the computer or they are connected via a serial USB converter to a USB port of the computer.
- Devices connected via USB require a free USB port on the computer.
- For devices which communicate with the computer via Bluetooth, a corresponding Bluetooth interface is required on the computer. Before start-up, it is necessary to connect these devices to the computer.
- Devices which communicate via WLAN are connected to the WLAN access point. This is either the correspondingly equipped computer, a WLAN router, or a WLAN repeater.
- Computers on which only existing examinations are opened, viewed or further analysed do not require additional interfaces.



To guarantee the reliable function of the *DiagnostikSuite*, only interface converters approved by Zimmer MedizinSysteme may be used.

3.3. Functional test

Prior to initial start-up, perform a function test to check the functionality of the system.

Proceed as follows:

- As described in the previous sections, you assemble the individual components and, if applicable, install necessary drivers as well as the *DiagnostikSuite*. In the case of a connection to a practice management system, you perform this connection accordingly.
- For a new resting ECG, you connect the ECG device to the PC and configure the connection in the *DiagnostikSuite*.
- Launch the *DiagnostikSuite* or, in the case of a connection, the practice management system and select a patient.
- Place the ECG electrodes on the patient and start a new electrocardiographic examination within the *DiagnostikSuite* in the “**New**” tab using “Resting ECG”.
- The *DiagnostikSuite* now establishes communication with the examination device. If this is not connected or is incorrectly configured, the user receives a corresponding error message with the option of correcting the configuration.
- Perform the resting ECG examination.
- Check the examination results in the *DiagnostikSuite*.
- Save the new examination.
- Transfer the reference to the new examination using the “Practice” button on any practice management software which may be connected. Then end the *DiagnostikSuite*.
- In the index card or in the medical data of any practice management software which may be connected, check whether the reference to the new examination is present.
- Depending on the functions of the practice management software, you can open the examination directly from the index card or the medical data. Check in the *DiagnostikSuite* whether the desired examination is opened.
- Print out the examination in the *DiagnostikSuite*.

In the event of malfunction or visible damage, do not use the *DiagnostikSuite*. Contact the service department of Zimmer MedizinSysteme.



4. Screen and program structure

4.1. Program menu

Note

The ECG module expands the menu of the basic software by a series of functions for recording and analysing ECGs.

Menu groups

File Measurement View Options Help

4.1.1. "File" menu group

File

Functions of the "file" menu group.

Patient	This menu item opens a submenu group with functions for patient management.
New	Lists all possible types of examinations in a submenu group. Is used to start a new examination.
Open ...	Opens an existing examination.
Save	Saves new examination data in the database.
Next session	Opens the next examination
Last session	Opens the last examination
Delete ...	Deletes the selected examination from the database.
Assign...	Assign examinations to other patients.
Import	Opens a submenu group to import examinations.
Export	Opens a submenu group to export examinations.
Database	Opens a submenu group with database service functions.
Set up page ...	Opens a Windows dialogue box to set up the paper format, the orientation as well as the margins for the selected printer.
Page view ...	Opens a submenu group to select the print area. Then the page view is shown for the selected print area.
Print ...	Opens a submenu group to select the print area. Launching of the Windows dialogue box to select and adjust the desired printer as well as to print the opened examination.
Change user ...	Opens the "Login" dialogue box.
End	Ends the DiagnostikSuite.

4.1.2. “Measurement” menu group

Measurement

Using the “**Measurement**” menu group, you can access functions for performing and analysing the examinations.

Start	This menu item starts the ECG recording and display of the ECG signals from new resting and stress ECGs.
Pause	Pauses the real-time ECG display
Stop	Stops the ECG recording, ends stress ECGs
Larger	Increases the sensitivity/amplitude of the ECG display
Smaller	Decreases the sensitivity/amplitude of the ECG display
Faster	Increases the speed, that is, the horizontal resolution of the ECG display
Slower	Decreases the speed, that is, the horizontal resolution of the ECG display
Analysis	Starts the analysis sequence to measure and interpret a resting ECG
Stress	Starts or ends the stress phase of an ergometry
Blood pressure	Starts an (additional) blood pressure measurement
Load phase ...	This menu item opens a submenu group in which the load phase can be increased or decreased.

4.1.3. “View” menu group

View

Using the “**View**” menu group, you can access the views of the individual data.

Operating elements	This menu item opens a submenu group in which the operating elements Menu, Toolbar, Navigation, Info Line and Status Line can be displayed or hidden.
Patient list	Lists all patients according to selectable search criteria.
Examination list	Lists all available examinations of the patient currently open or all patients according to selectable search criteria.
Practice management	If applicable, saves examination data which have not yet been saved, sends information to the practice management on the examination which has just been newly created, and switches to the practice management view.
Caution ...	Entry and monitoring of caution information in a dialogue box.
Note ...	Opens a dialogue box to view and enter notes on the patient.
Overview ...	Display of all relevant information about the examination with average beats, ECG curves, vector cardiogram, rhythm display, global measurement results, interpretation and comments in the case of a resting ECG as well as average beats, load profile, ST trends, session values, work capacity and values at

maximum load of a stress ECG.

[Curves](#)

Shows ECG curves in graphic form with rhythm display as well as vector cardiogram, load profile and ST trends, depending on the type of examination.

[Results ...](#)

Shows the results of the examination. In the case of a resting ECG, the session values, measurements and the interpretation are displayed; in the case of a stress ECG, the session values, work capacity, values at maximum load, load table, ST amplitudes, ST gradient and events are displayed.

[Comments ...](#)

Opens a dialogue box to display and enter notes and comments.

[Comparison ...](#)

Offers the user the option of comparing measurements from various recording times with each other

[Next strip](#)

Changes to the next ECG strip in an ergometry.

[Last strip](#)

Changes to the last ECG strip in an ergometry.

4.1.4. “Options” menu group

Options

In the “**Options**” menu group, dialogue boxes for configuring the DiagnostikSuite are summarised.

<u>Settings ...</u>	This menu item opens a dialogue box in which general settings for handling the patient number, the procedure when launching a program and the properties of the symbol bar can be set.
<u>Print ...</u>	The dialogue box for setting the printer as well as the printed contents are opened using this menu item.
<u>System ...</u>	Opens the dialogue box with system properties such as import and export path, database information, device configuration and card reader.
<u>Practice management ...</u>	The connection to practice management software is configured in this dialogue box.
<u>Medical systems...</u>	Opens a dialogue box for selection and configuration directly on medical devices connected to the DiagnostikSuite.
<u>Practice ...</u>	<p>This menu item opens a dialogue box in which data from the practice which was just opened can be checked and edited.</p> <p>If the “Practice ...” menu function with administrative rights (for example, as the user “Administrator”) is opened, the “Practice” dialogue box appears in which the list of practices used is displayed. These practices can be added to, edited, or deleted.</p>
<u>User ...</u>	<p>In the “Edit user” dialogue box, the data of the user who is currently working with DiagnostikSuite are displayed. The user data can be modified in this dialogue box, as needed.</p> <p>If the “User ...” menu function with administrative rights (for example, as the user “Administrator”) is opened, the “User” dialogue box appears in which the list of users created is displayed. These users can be added to, edited, or deleted.</p>
<u>ECG...</u>	The settings for electrocardiographic examinations are made in this dialogue box.
<u>Lead</u>	Used to select a group of leads or individual leads.
<u>Filter</u>	In a submenu, mains, muscle and anti-drift filters can be switched on and off.
<u>Load profile ...</u>	Opens a dialogue box to display and configure load profiles.
<u>Calibration ...</u>	Starts a dialogue box to adjust the 1 cm grid on the screen.

4.1.5. “Help” menu group

Help

The DiagnostikSuite offers you various forms of online help. These are grouped in the “**Help**” menu group.

Contents	Under “Help - Contents”, you can view the DiagnostikSuite help system. You can narrow down your subject area from a clear table of contents and select specific help. Detailed texts provide comprehensive information about the selected help topic.
Component	Here the online help of the examination module currently loaded is accessed. For example, if an ECG is currently open, the online help on ECGs is launched.
Protocol	Shows the protocol of the most recent sessions with information about the operating system, the PC hardware, device settings with their interfaces, information about the DiagnostikSuite as well as any irregularities which may have occurred.
Zimmer on the web	Shows the webpages of <i>Zimmer MedizinSysteme</i>
Enter licence key ...	The licensing of the DiagnostikSuite takes place in the “Licence key entry” dialogue box. In addition to the identification of the licensee, with first name, surname and practice name, one or more licence keys are to be entered. Alternatively, the licence keys can also be incorporated from a licence file.
Info about ...	Opens a dialogue box with general program information, such as manufacturing company, copyright, program version, licensing information, etc.

4.2. Toolbar

Functions of the toolbar

The symbols and functions of the toolbar are described on page “A”.

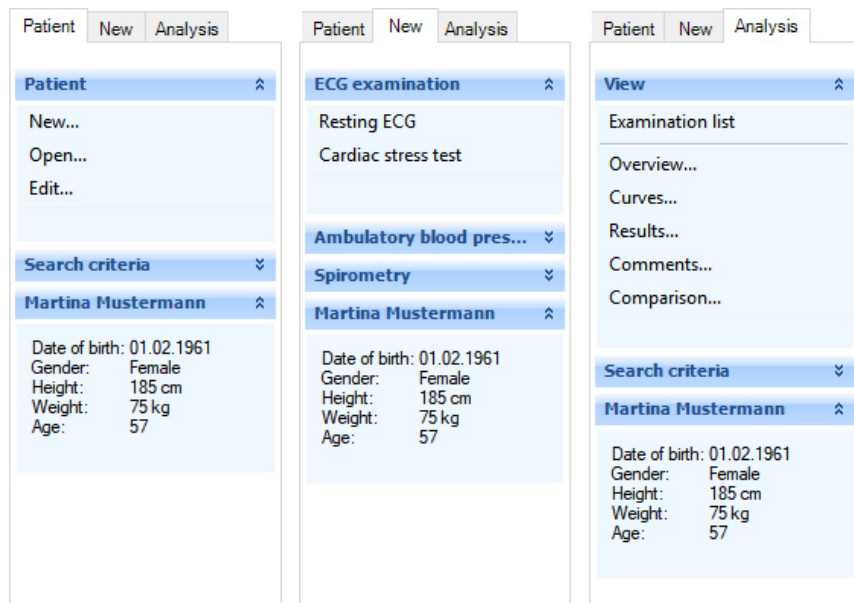
Depending on the functionality of the examination components loaded, these are expanded by the toolbar, if applicable.

4.3. Navigation area

The DiagnostikSuite supports the user with a navigation area in which all daily routine tasks can be performed in the three areas “Patient”, “New” and “Analysis”. These areas are assigned to tabs.

- The “**Patient**” tab contains patient administration.
- The “**New**” tab is used to record new examinations.
- The “**Analysis**” tab is used to analyse examinations.

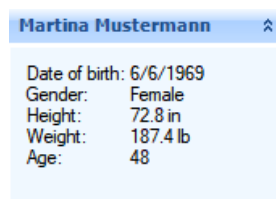
Tab



Panels which group associated functions are available within the tab.

The panels can be opened and closed by a left click on the heading line. Only useful and applicable panels can be opened.

“Patient info” panel



The “Patient info” panel is available in each tab.

The panel displays the patient data of the patient currently open. In addition to the first name and surname, these include the date of birth, sex, height and weight.

4.3.1. “Patient” tab

“Patient” panel

The “**Patient**” panel contains functions for selecting a patient or managing his or her master data.

[New ...](#)

Used to create a new patient.

[Open ...](#)

This function lists the patients available in the database. A patient can then be opened from the patient list.

[Edit ...](#)

This function allows the patient’s master data to be displayed and edited.

“Search criteria” panel

In the “**Search criteria**” panel of the “**Patient**” tab, criteria for filtering the patient list can be entered, if needed.

The screenshot shows a panel titled "Search criteria" with a list of filter criteria, each with a dropdown menu currently set to "(all)":

- Pat. number: (all)
- Surname: (all)
- First name: (all)
- Date of birth: (all)
- City: (all)
- Zip Code: (all)

These filter criteria are available to you:

- Patient number
- Surname
- First name
- Date of birth
- City
- Postcode

Search criteria

- Missing characters can be replaced by “*”.
- If the term “**B***” is entered as a search criterion, all entries starting with “**B**” as the first letter will be listed.
- If the term “***or**” is entered as a search criterion, all entries ending with “**or**” will be listed.
- If the term “***ch***” is entered as a search criterion, all entries which include “**ch**” will be listed.
- If a particular date of birth is entered as a search criterion, all patients who were born on that date will be listed.

4.3.2. “New” tab

The “**New**” tab contains functions for performing new examinations. For each examination component enabled, there is a panel enabled. The desired examination is launched directly via this panel.

A precondition for performing new examinations is that a patient is opened and the desired examination component is enabled.

“New” panel

The function of the “**New**” panel is explained here using the example of an ECG examination. The entries differ for other types of examinations.

Resting ECG	New recording of a resting ECG
Ergometry	New recording of a stress ECG

4.3.3. “Analysis” tab

The “**Analysis**” tab contains functions for analysing examinations.

“View” panel

If no examination is open, the “**View**” panel only shows the “Examination list”.

Examination list	Lists all available examinations of the patient currently open or all patients according to selectable search criteria.
----------------------------------	---

After an examination has been opened, the panel contains all views of the examination opened.

Overview ...	Display of all relevant information about the examination with average beats, ECG curves, vector cardiogram, rhythm display, global measurement results, interpretation and comments in the case of a resting ECG as well as average beats, load profile, ST trends, session values, work capacity and values at maximum load of a stress ECG
Curves	Shows ECG curves in graphic form with rhythm display as well as vector cardiogram, load profile and ST trends, depending on the type of examination.
Results ...	Shows the results of the examination. In the case of a resting ECG, the session values, measurements and the interpretation are displayed; in the case of a stress ECG, the session values, work capacity, values at maximum load, load table, ST amplitudes, ST gradient and events are displayed.
Comments ...	Opens a dialogue box to display and enter notes and comments.
Comparison ...	Offers the user the option of comparing measurements from various recording times with each other.

“Search criteria” panel

In the “Search criteria” panel of the “Analysis” tab, criteria for filtering the examination can be entered, if needed.

These filter criteria are available to you:

- Type of examination
- Current patient/all patients
- Surname
- Recording date from/to
- Status
- Referrer

Search criteria

- Missing characters can be replaced by “*”.
- If the term “B*” is entered as a search criterion, all entries starting with “B” as the first letter will be listed.
- If the term “*or” is entered as a search criterion, all entries ending with “or” will be listed.
- If the term “*ch*” is entered as a search criterion, all entries which include “ch” will be listed.
- If a particular recording date is entered as a search criterion, all examinations created on this date will be listed.

5. Patient data

5.1. Record patient

In addition to automatic inclusion of patient data when there is a connection to practice management software, the *DiagnostikSuite*, in stand-alone mode, also offers the option of manually entering patient data.

In the “**Patient**” tab, click on the “New ...” entry within the “**Patient**” panel.

Tip: Check beforehand whether the patient has already been entered (see section “Examination list”). This avoids unnecessary duplicate entries.



“New patient” view

DiagnostikSuite - Martina Mustermann

File View Options Help

New Open Save Print Practice Help

Patient New Analysis

Patient

New...

Open...

Edit...

Search criteria

Martina Mustermann

Date of birth: 06.06.1969
Gender: Female
Height: 185 cm
Weight: 85 kg
Age: 48

Edit patient

Patient number: 1

Surname: Mustermann Title:

First name: Martina Suffix:

Gender: Female Date of birth: 06.06.1969

Size (cm): 185.0 Age (Years): 48

Weight (kg): 85.0 BMI (kg/m²): 24.8

Street: Junkersstrasse 9 Home phone: 0731/9761-100

Zip Code: 89231 Business phone: 0731/9761-0

City: Neu-Ulm Mobile: 0731/9761-200

Email: Fax: 0731/9761-118

Ins. number: IK:

Ethnic group: Chinese Smoker: Unknown

Notes:

Remarks of the patient

Caution:

CAVE!!!

Martina Mustermann Street: Junkersstrasse 9 Private tel.: 0731/9761-100
Zip Code: 89231 Business tel.: 0731/9761-0
City: Neu-Ulm Mobile tel.: 0731/9761-200

Ready Musterarzt Musterpraxis No component

Enter the patient data in the fields provided. Fields for information which must be available are highlighted in colour.



After entering the patient data, the “Save” button is used to save the information in the database.

Plausibility check

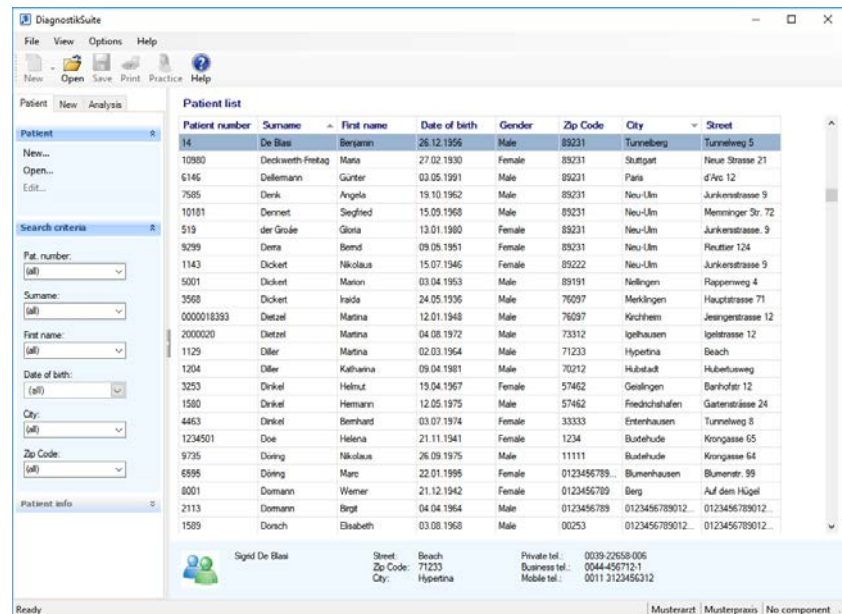
When patient data are saved, they are checked with regard to plausibility. If necessary data are missing or if these are not plausible, saving will not be performed. The implausible data will instead be marked.

5.2. List patients

Patient list

To search for a patient or check whether a particular patient has already been recorded or also to open a patient, use the “List patients” function.

In the “**Patient**” tab, click on the “Open ...” entry within the “**Patient**” panel. You will then obtain the patient list.



- The search can be refined using the search criteria.
- The patient list can be sorted by a left click on one of the column headings. Another left click on the column heading alternates the sorting sequence between ascending and descending.
- In the context menu, you can select the information displayed.
- A left click on a patient in the patient list shows advanced patient data in the info line.
- Double-clicking on a patient in the list of patients selects this patient for further processing and loads his or her patient data.
- The data on the opened patient are displayed in the “**Patient info**” panel.

5.3. Open patient file

Open patient file

- To perform a new examination for a patient, it is necessary for the patient file to be opened. This is done via the patient list.
- The patient list is accessed in the “**Patient**” tab within the “**Patient**” panel via the entry “Open ...”. You will then obtain the patient list.
- Now select the desired patient in the patient list. A double click on the list entry opens the patient file.

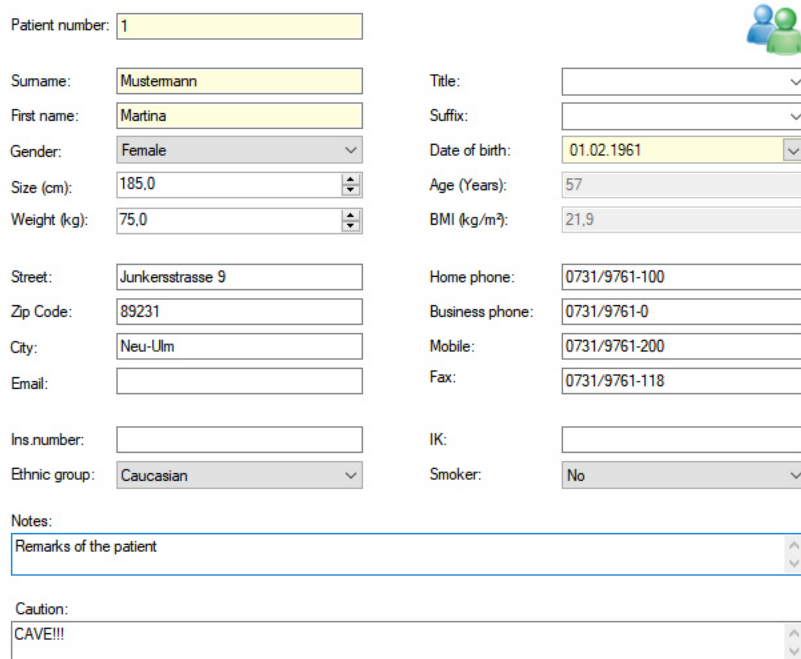
5.4. Change patient data

Edit patient

To display and change the data of a patient who has been entered, his or her data must be loaded. If this is not the case, this is performed via the “**Patient**” panel, via “Open ...” and via the patient list (see section “Open patient”).

In the “**Patient**” tab, the data of the loaded patient are displayed via the entry “Edit ...” within the “**Patient**” panel. There the patient data can be changed.

Edit patient



Patient number: 1

Surname: Mustermann Title:

First name: Martina Suffix:

Gender: Female Date of birth: 01.02.1961

Size (cm): 185,0 Age (Years): 57

Weight (kg): 75,0 BMI (kg/m²): 21,9

Street: Junkersstrasse 9 Home phone: 0731/9761-100

Zip Code: 89231 Business phone: 0731/9761-0

City: Neu-Ulm Mobile: 0731/9761-200

Email: Fax: 0731/9761-118

Ins number: IK:

Ethnic group: Caucasian Smoker: No

Notes: Remarks of the patient

Caution: CAVE!!!

Save changed patient data




Use the “Save” button in the toolbar to permanently save changes in the database.

Plausibility check

When patient data are saved, they are checked with regard to plausibility. If necessary data are missing or if these are not plausible, saving will not be performed. The implausible data will instead be marked.

Example:

Date of birth: 01.02.2961 

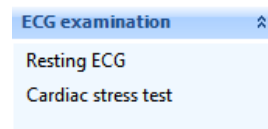
Correct or amend your entries and then save the patient data.

6. Perform new examination

Preconditions

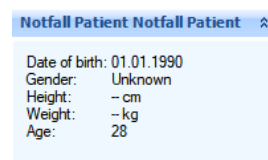
- New examinations are launched in the “**New**” tab.
- A precondition for performing new examinations is that a patient is opened and the desired examination component is enabled. (See section “Open patient file”)
- If the “Automatic measurement” (article “I”) is available, the HES analysis module performs the automatic measurement and interpretation of the ECG.
- If the “Ergometry” option (article “E”) is available, stress ECGs can be performed.
- If the ECG module or the options listed were not enabled, the associated functions are not available.

Select examination type



- (1) Switch on the ECG amplifier, the blood pressure monitor, if applicable, and in the case of stress ECGs, the ergometer or treadmill.
- (2) Open the “**New**” tab in the navigation area. There you will find the “**ECG examination**” panel.
- (3) Click on the desired examination type.

6.1. Record emergency ECG



If there are no patient data available, the so-called “Emergency patient” can be selected as the patient and an ECG can be recorded for this patient. In this case, the automatic interpretation of the ECG can be evaluated to only a very limited extent, since variables, such as age and sex, which are important for a valid interpretation are missing.

6.2. Record resting ECG

6.2.1. “New resting ECG” view

“New resting ECG” view

While a resting ECG is being recorded, the following information is displayed on the screen:

- Display of the ECG signals in real time with individual choice of leads, speed, sensitivity and filter.
- Reduced display of the ECG rhythm with up to three leads, individual speed, sensitivity and filter adjustment.
- Readings panel with enlarged display of heart rate, blood pressure and session duration.
- Indication of additional information about the ECG recording in the status bar.








Readings panel

Important measured parameters are visualised in the readings panel.

HF 1/min	72	▪ Current heart rate
BP mmHg	120/80	▪ Current blood pressure
Time Min	00:24	▪ Total session duration
	00:02	▪ Duration of the analysis and progress of the analysis as graph

Chronological sequence

1. Place the electrodes on the patient and start the ECG recording using the “Start” button .
2. Check the ECG quality on the screen.
3. If needed, correct the electrode positioning to obtain a high-quality ECG.
4. If an important ECG episode occurs, the display can be interrupted using the Pause button .

5. If needed, the  button can be used to start a blood pressure measurement or blood pressure values can be entered in the dialogue box.
6. Using the Stop button , the ECG recording can be ended at any time.
7. The "Analysis" button  starts the recording of a 10-second ECG segment and its automatic measurement and interpretation. Thereafter the ECG recording stops.
8. After the ECG recording has ended, all important information is displayed in an overview.

6.3. Record stress ECG

6.3.1. "New ergometry" view

6.3.1.1. "ECG curves" tab

"ECG curves" tab

While a stress ECG is being recorded, the following information is displayed on the screen in the "ECG curves" tab:

- Display of the ECG signals with individual choice of leads, speed, sensitivity and filter.
- Representation of the average beats with information on the ST amplitude as well as ST gradient.
- Reduced display of the ECG rhythm with up to three leads, individual speed, sensitivity and filter adjustment.
- Readings panel with enlarged display of heart rate, blood pressure, session duration, load as well as additional information.
- Display of arrhythmic events with information on the type, start time as well as duration.
- Display of a load profile with progression of heart rate and blood pressure display.
- Display of the ST trend.
- Indication of additional information about the ECG recording in the status bar.

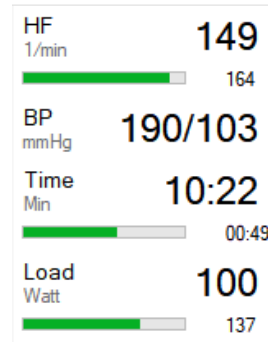
Perform new examination

6

Record stress ECG



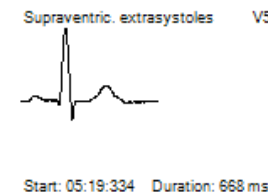
Readings panel



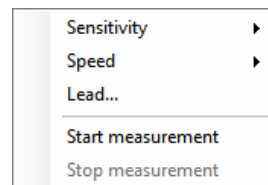
Important measured parameters are visualised in the readings panel.

- Current heart rate
- Exhaustion heart rate and percentage achievement of the exhaustion heart rate as a graph
- Current blood pressure
- Total session duration
- Duration of the current load phase and progress within the phase as a graph
- Current load
- Target load and percentage achievement of the target load as a graph

Event display

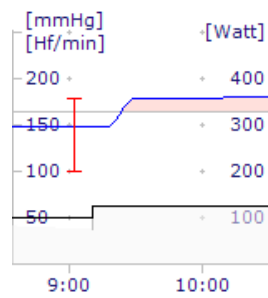


If arrhythmic events occur during the ergometry, these are shown on the screen with information about the type, start time as well as duration.



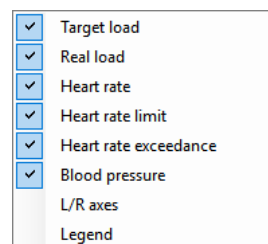
The sensitivity, speed, lead and filter can be freely selected via a context menu.

Load profile



Another window shows a segment of the currently active load profile with the variables:

- Heart rate
- Load
- Blood pressure



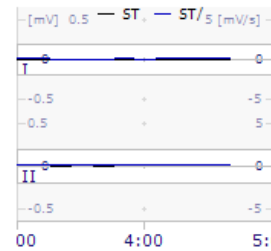
In a context menu, the display of the target load, the real load, the heart rate, the heart rate limit, the exceedance of the heart rate as well as the blood pressure can be switched on and off.

Perform new examination

6

Record stress ECG

ST trends



Another window shows a section of the ST amplitude and ST gradient progressions.

<input checked="" type="checkbox"/>	ST-Amplitude
<input checked="" type="checkbox"/>	Grenzwerte ST-Amplitude
<input checked="" type="checkbox"/>	Überschreitung ST-Amplitude
<input checked="" type="checkbox"/>	ST-Steigung
<input checked="" type="checkbox"/>	Null Line
<input type="checkbox"/>	Ableitung ...

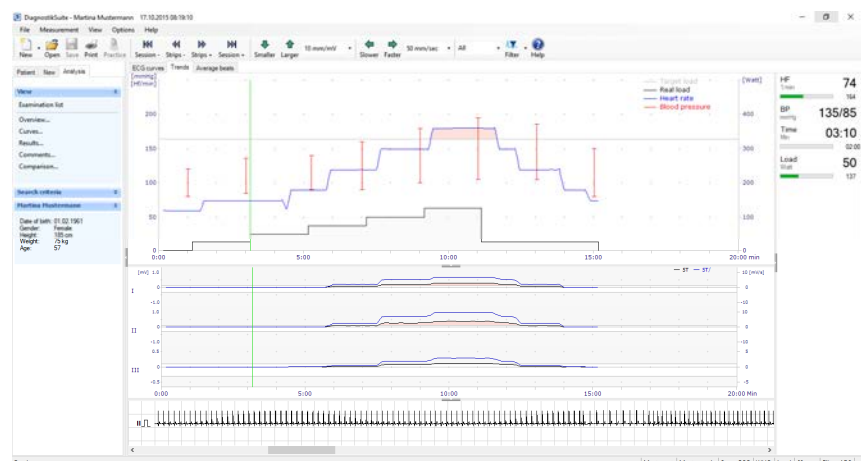
In a context menu, the display of the ST amplitude, its limits, its exceedance, the ST gradient, and the null line can be switched on and off. In addition, the lead can be selected.

6.3.1.2. "Trends" tab


"Trends" tab



The chronological progression of the examination can be monitored in the "Trends" view. The following information is displayed:




- Display of the load profile with heart rate, blood pressure, target load and real load in the case of bicycle ergometries and speed and gradient in the case of treadmill ergometries.
- Continuous display of the ST amplitudes and ST gradient.
- Readings panel with enlarged display of heart rate, blood pressure, session duration, load as well as additional information.
- Indication of additional information about the ECG recording in the status bar.



Chronological sequence

1. Place the electrodes on the patient and start the ECG recording using the "Start" button .
2. Check the ECG quality on the screen.
3. If needed, correct the electrode positioning to obtain a high-quality ECG.
4. At the start of a new ergometry, a reference ECG is recorded to support the real-time measurement.
5. The actual stress begins when

- the patient begins to walk or pedal,
 - the selected rest time has expired or
 - The "Load" button  is pressed.
6. If an important ECG episode occurs, the display can be interrupted using the Pause button  .
 7. Depending on the setting in the load profile, one or more automatic blood pressure measurements can be performed for each load phase.

You can initiate additional measurements using the  button.
 8. During a stress test, it is possible to switch between the display of the ECG curves and the trends.
 9. The load is ended
 - using the  button or
 - when the selected load profile has reached the recovery phase.
 10. The ergometry session is ended when the recovery period set in the load profile is reached or when the stop button  has been pressed.
 11. After the ECG recording has ended, all important information is displayed in an overview.

7. Analyse examinations

Examinations are viewed, checked and diagnosed in the “**Analysis**” tab.

7.1. List examinations

Examination list

To search for a particular examination and check whether it was already performed or also to open an examination, use the “**Examination list**” view.

In the “**Analysis**” tab within the “**View**” panel, click on the entry “**Examination list**”. This will provide you with a list of available examinations.

Examination type	Patient	Recording date	Status
Provocation test	Mann, Manfred	02.09.2016 13:36:03	Recording finished
Ambulatory blood pre...	Kast, Tomas	02.09.2016 12:35:00	Recording finished
FVC measurement	Kast, Tomas	02.09.2016 13:35:44	Recording finished
Resting ECG	Kast, Tomas	08.12.2016 08:40:26	Recording finished
Resting ECG	Kast, Tomas	08.12.2016 08:18:15	Recording finished
Stress ECG	Kind 1/2 Jahr, Baby	14.08.2017 11:11:26	Recording finished
Ambulatory blood pre...	SpiroPC, SNr: 700002	24.09.2013 11:00:00	Recording finished
Resting ECG	Stetter, Hannelore	06.07.2016 12:01:52	Recording finished
Ambulatory blood pre...	Stumpf, Günter	04.11.2009 08:51:00	Recording finished
FVC measurement	Stumpf, Günter	28.11.2012 08:01:46	Recording finished
Resting ECG	Stumpf, Günter	30.11.2017 10:08:09	Recording finished
Resting ECG	Test, Tester	30.11.2017 10:10:21	Recording finished
Resting ECG	Teufel, Hans	13.11.2017 10:29:30	Recording finished
Resting ECG	Teufel, Hans	13.11.2017 10:28:39	Recording finished
Ambulatory blood pre...	Unbekannter Patient, ...	12.10.2012 13:45:00	Recording finished
Resting ECG	Unbekannter Patient, ...	27.05.2016 11:47:34	Diagnosed
Ambulatory blood pre...	Walger, Gloria	26.07.2016 09:50:00	Recording finished
Stress ECG	Walger, Gloria	27.05.2016 08:44:54	Recording finished
Resting ECG	Walger, Gloria	09.12.2016 07:52:19	Recording finished
Resting ECG	Walger, Gloria	29.03.2016 16:48:22	Recording finished
Ambulatory blood pre...	Walger, Gloria	26.07.2016 09:45:00	Recording finished
Resting ECG	Walger, Gloria	29.03.2016 17:02:00	Recording finished
Spasmolysis	Zwick, Elisabeth	30.05.2016 09:48:47	Recording finished

Ambulatory blood pressure Recording date: 02.09.2016 12:35:00 Patient: Kast, Tomas
 Blood pressure: 128 / 77 mmHg HR: 81 1/min

- The search can be refined using the search criteria.
- The examination list can be sorted by a left click on one of the column headings. Another left click on the column heading alternates the sorting sequence between ascending and descending.
- In the context menu, you can select the information displayed.
- A left click on an examination in the patient list shows extended information in the info line.
- A double click on a list entry opens the examination and selects the patient in question for further processing.

7.2. Open examination

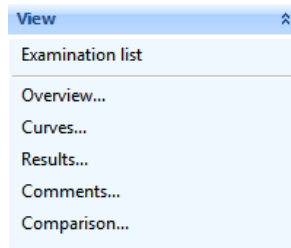
Open examination

- To analyse an examination, it is necessary for the examination to be opened. This is done via the examination list.
- The examination list is accessed in the “**Analysis**” tab via the “Examination list” entry within the “**View**” panel.
- Now select the desired examination in the examination list. A double click on the list entry opens the examination and the patient in question.

7.3. Analyse resting ECG

Different views of the data are available in the “**Analysis**” tab, in the “**View**” panel for in-depth analysis of examinations.

Select examination views

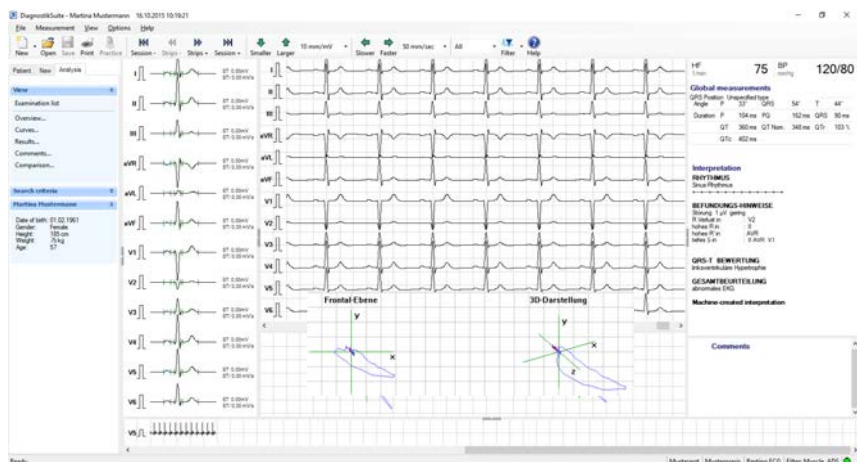


Open the “**Analysis**” tab in the navigation area. There you will find the “**View**” panel.

A left click on a list entry opens the desired view.

7.3.1. “Overview” view

The “Overview” summarises all important information of a resting ECG.



Average beats

In the case of the resting ECG, a dominant average beat is formed and measured. In addition to the morphology of the average beat, the display shows the relevant measurement positions with green markers, the ST amplitudes in mV and the ST gradient in mV/s.

ECG curves

The ECG curves are shown in the centre of the view. On the left-hand margin, in addition to the lead designation for each lead, a 1mV reference pulse is displayed for size comparison. Sensitivity, speed, leads and filters can be adjusted via the toolbar and a context menu. A slider allows the time period displayed to be changed. Significant ECG passages can be printed using the "Print screen" context menu.

Vectorcardiogram

The vectorcardiogram is displayed below the ECG curves in various projections: as a 3D display as well as optionally in the frontal, left sagittal and horizontal plane. The sensitivity can be varied using the mouse scroll wheel.

The vectorcardiogram is based on the average beat of the ECG. The orthogonal leads X, Y and Z are calculated approximately via the inverse Dower transformation from the 12 standard leads.

For better orientation, the individual loops of the vectorcardiogram are shown in different colours.

Rhythm display

To monitor the ECG rhythm, the ECG signal progression is shown with reduced sensitivity and speed for up to three selectable leads. A context menu enables individual settings to be made. The time period displayed can be adjusted using the slider.

Global measurements

In addition to the heart rate and blood pressure, the QRS position, the P, QRS and T angle, the P, PQ, QRS, QT, QTc, QT_r and QT target time as well as, optionally, the Sokolow index are indicated.

Interpretation

The automatic interpretation of the HES module is displayed in this field. The automatic interpretation provides information on the ECG rhythm, diagnostic information, a QRS-T evaluation, as well as an overall evaluation. The QT dispersion can also be optionally displayed.

Comments

If desired, comments on the measurement currently being analysed can be entered.

Status bar

The status bar informs the user of the type of the examination currently being performed, the status, as well as the filter settings.

Analyse resting ECG

7.3.2. “Curves” view

The “Curves” view provides a detailed graphic display of the ECG curves as well as the vectorcardiogram.

7.3.2.1. “ECG curves” tab

“ECG curves” tab



This view includes the following information:

- Large-size visualisation of the ECG signal progression with lead designation, 1mV reference pulse, selectable sensitivity, speed, leads and filters as well as variable time segment.
- Display of the dominant average beats with wave points, ST amplitudes in mV and ST gradient in mV/s.
- Display of the ECG rhythm of a longer selectable time period with individual settings for sensitivity, speed, leads and filters.
- Measurement panel with heart rate, blood pressure and total duration.

7.3.2.2. “Vectorcardiogram” tab

“Vectorcardiogram” tab

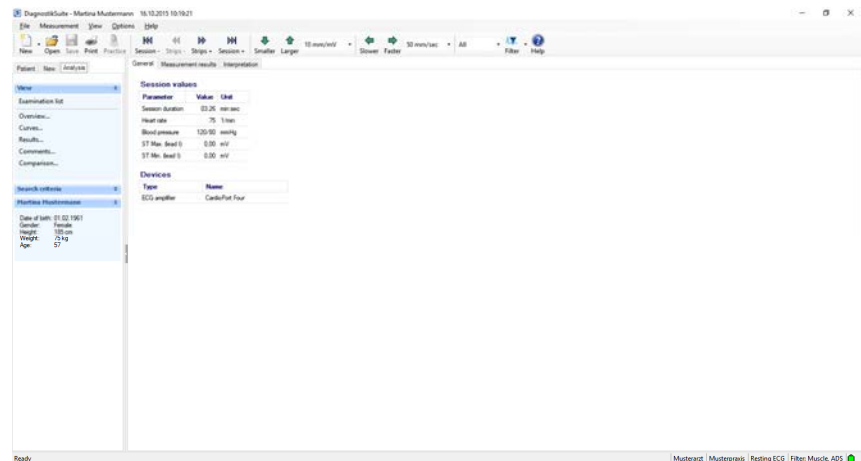
The following information is displayed in this tab:

- Vectorcardiogram as a 3D projection, frontal, left sagittal and horizontal projection. The sensitivity can be varied using the mouse scroll wheel.
- Average beats of the three orthogonal leads X, Y and Z which are calculated via an inverse Dower transformation from the 12 standard leads.
- Display of the ECG rhythm of a longer selectable time period with individual settings for sensitivity, speed, leads and filters.
- Measurement panel with heart rate, blood pressure and total duration.

7.3.3. “Results” view

7.3.3.1. “General” tab

The “Results” view provides general information about the examination, the measurement results as well as the interpretation of the ECG.



Session values

The “Session values” table contains general data on the ECG examination and provides information on

- Session duration
- Heart rate
- Blood pressure
- Maximum ST amplitude indicating the respective lead
- Minimum ST amplitude indicating the respective lead

Devices

Information about the device used in this examination.

7.3.3.2. “Measurement results” tab

“Measurement results” tab

This summary displays the measurement results.

Global measurements

- QRS position,
- P, QRS, T angle,
- P, QRS interval, PQ, QT interval,
- Frequency-corrected QT interval “QTc”,
- The QT target value corresponding to the frequency according to Hegglin & Holzmann “QT Nom.”,
- Relative QT interval “QTr” in %

Measurement results with the following measurements per lead:

- P amplitude,
- Q amplitude, Q duration,
- R, R' amplitude, R, R' interval,
- S, S' amplitude, S, S' interval,
- J amplitude,
- ST amplitude, ST gradient,

Analyse resting ECG

- T amplitude

7.3.3.3. “Interpretation” tab

“Interpretation” tab

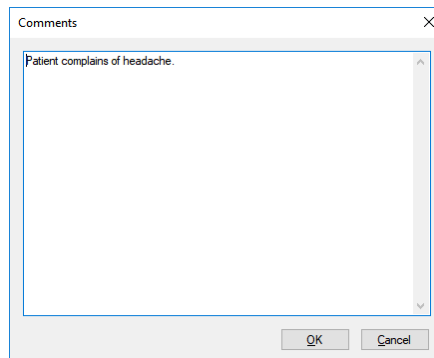
The automatic interpretation of the HES module is displayed in the “Interpretation” tab.

The automatic interpretation provides information, including

- the ECG rhythm,
- a symbolic rhythm chart with typing of individual beats,
- diagnostic information,
- optionally the QT dispersion,
- a QRS-T evaluation as well as
- an overall assessment.

7.3.4. “Comments” view

Add comment to examination



A dialogue box can be opened using the “View-Comments” menu function in which comments on the measurement currently being analysed can be entered.

While the “Comments” dialogue box is open, the views of the ECGs currently open can be switched.

7.3.5. “Comparison” view

The DiagnostikSuite allows two similar recordings from the same patient to be compared. In this way, recordings which were made at different times can be compared to each other. In addition, different ECG passages from the same examination can be compared to each other.

Starting from the measurement currently open, the examination to be compared is selected in the “View” panel via the “Compare” entry. Then both measurements are shown.



Compare examinations

In a comparison, the two ECGs are displayed one below the other.

This information and these methods are available for each ECG:

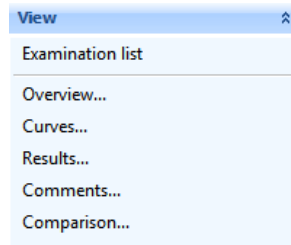
- Indication of the recording date and time.
- Visualisation of the ECG signal progression with lead designation, 1mV reference pulse.
- Display of the dominant average beats with wave points, ST amplitudes in mV and ST gradient in mV/s.
- Measurement panel with heart rate, blood pressure and current time within the ECG examination.
- Individual selection of the time point compared using its own slider.

The sensitivity, speed, lead and filters are adjusted simultaneously for both ECG examinations.

7.4. Analyse stress ECG

Different views of the data are available in the “**Analysis**” tab, in the “**View**” panel for in-depth analysis of examinations.

Select examination views

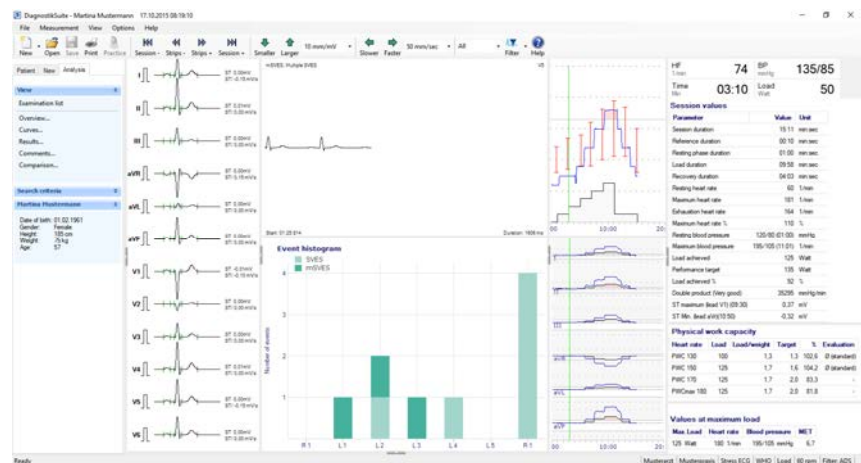


Open the “**Analysis**” tab in the navigation area. There you will find the “**View**” panel.

A left click on a list entry opens the desired view.

7.4.1. “Overview” view

The “Overview” summarises all important information of a stress ECG.



Average beats

For each stress level of the ergometry, a dominant average beat is generated and measured. In addition to the morphology of the average beat, the display shows the relevant measurement positions with green markers, the ST amplitudes in mV and the ST gradient in mV/s.

Events

In the centre of the view, arrhythmic events which occurred are displayed with information on the event type, start time as well as duration. Sensitivity, speed and leads can be adjusted via a context menu.

Event histogram

In this graphic, the number of events which occurred are displayed in the form of a vertically tiered bar graph for each load phase.

Load profile

Another window shows the complete progression of the load profile with heart rate, blood pressure and load as well as speed and gradient. A context menu enables individual settings to be made.

ST trends

Another window shows the complete progression of the ST amplitudes and ST gradients during the ergometry. The parameters displayed can be adjusted in a context menu.

Rhythm display

To monitor the ECG rhythm, the ECG signal progression is shown with reduced sensitivity and speed for up to three selectable leads. A context menu enables individual settings to be made. The time period displayed can be adjusted using the slider.

Session values

The “Session values” table summarises general information on the ergometry:

- Total duration, duration of rest, loading and recovery phase
- Resting heart rate, maximum heart rate, exhaustion heart rate
- Resting blood pressure, maximum blood pressure
- Load achieved, target load and max. speed and gradient, respectively
- Double product (heart rate * systolic blood pressure)
- Maximum ST amplitude and minimal ST amplitude

Work capacity

Indication of cardiopulmonary and physical work capacity during bicycle ergometry for the heart rates 130, 150 and 170 or the maximum heart rate. The work capacity achieved is compared to the target values and evaluated.

Values at maximum load

In the case of bicycle ergometries, this table indicates the heart rate, blood pressure and metabolic equivalent MET associated with the time point at which the maximum load was achieved.

7.4.2. “Curves” view

The “Curves” view provides a detailed graphic display of the ECG curves as well as the trends.

7.4.2.1. “ECG curves” tab

“ECG curves” tab



This view includes the following information:

- Display of the ECG signals with individual choice of leads, speed, sensitivity and filter.
- Representation of the average beats with information on the ST amplitude as well as ST gradient.
- Reduced display of the ECG rhythm with up to three leads, individual speed, sensitivity and filter adjustment.
- Readings panel with enlarged display of heart rate, blood pressure, session duration, load as well as additional information.

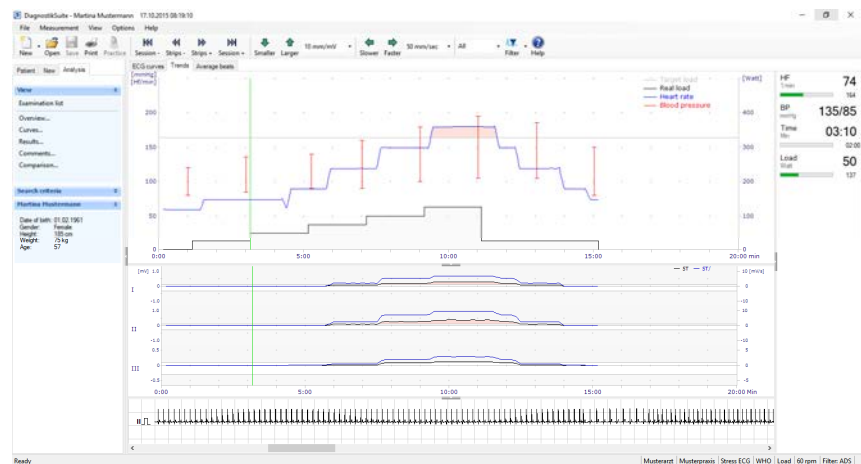
Analyse examinations

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Analyse stress ECG

- Display of arrhythmic events with information on the type, start time as well as duration.
- Display of a load profile with progression of heart rate and blood pressure display.
- Display of the ST trend
- Indication of additional information about the ECG recording in the status bar.

“Trends” tab



The chronological progression of the examination can be monitored in the “Trends” view. The following information is displayed:

- Display of the load profile with heart rate, blood pressure, target load and real load in the case of bicycle ergometries and speed and gradient in the case of treadmill ergometries.
- Continuous display of the ST amplitudes and ST gradient.
- Readings panel with enlarged display of heart rate, blood pressure, session duration, load as well as additional information.
- Indication of additional information about the ECG recording in the status bar.

“Average beats” tab



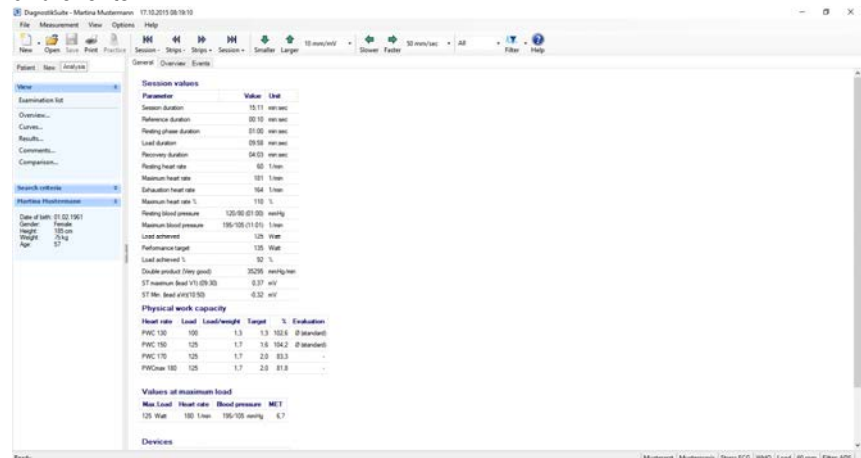
The change in average beats during the examination can be monitored in the “Average beats” view. The following information is shown per phase:

- Name of the phase
- Start time of the phase, load or speed and gradient, heart rate, blood

- pressure
- Average beat of the selected leads

7.4.3. “Results” view

The “Results” view provides you with general information about the examination, work capacity, values at maximum load, load results, ST values and events.



7.4.3.1. “General” tab

The “General” tab provides session values, information about work capacity as well as values for maximum load.

Session values

The “Session values” table summarises general information on the ergometry:

- Total duration, duration of rest, loading and recovery phase
- Resting heart rate, maximum heart rate, exhaustion heart rate
- Resting blood pressure, maximum blood pressure
- Load achieved, target load or max. speed and gradient, respectively
- Double product (heart rate * systolic blood pressure)
- Maximum ST amplitude and minimal ST amplitude

Work capacity

Indication of cardiopulmonary and physical work capacity during bicycle ergometry for the heart rates 130, 150 and 170 or the maximum heart rate. The work capacity achieved is compared to the target values and evaluated.

Values at maximum load

In the case of bicycle ergometries, this table indicates the heart rate, blood pressure and metabolic equivalent MET associated with the time point at which the maximum load was achieved.

Devices

Information about the devices used in this examination.

7.4.3.2. “Overview” tab

The “Overview” tab contains a tabular summary of the load, the “ST amplitudes” as well as the “ST gradient”.

Load table**Bicycle stress test**

In a bicycle stress test,

- the start of the phase,
- the duration of the phase,
- the load in watts,
- the heart rate in beats/min.,
- the blood pressure in mmHg with indication of the time of the blood pressure measurement,
- the ergometer speed in rpm,
- the double product (heart rate * systolic blood pressure),
- as well as the metabolic equivalent are displayed for each phase of the session.

The duration, load, speed, double product and MET can optionally be switched on and off via a context menu.

Treadmill stress test

In a treadmill stress test,

- the start of the phase,
- the duration of the phase,
- the speed in km/h,
- the gradient in %,
- the acceleration in m/s²,
- the heart rate in beats/min.,
- the blood pressure in mmHg with indication of the time of the blood pressure measurement,
- the double product (heart rate * systolic blood pressure),
- the metabolic equivalent as well as
- the distance covered in km are displayed.

The duration, acceleration, double product and MET can optionally be switched on and off via a context menu.

ST amplitudes and ST gradient

In both of these tables, for each phase

- the start of the phase,
- the duration of the phase, and
- the ST amplitudes of all leads are shown in mV and the ST gradient is shown in mV/s.

The duration can be optionally configured in the context menu.

7.4.3.3. “Events” tab

The events which occurred are summarised in the “Events” tab.

A list of event abbreviations used can be found in the “HES evaluation” section.

Event distribution

The “Events distribution” table lists the events which occurred for each phase.

Analyse stress ECG

Event distribution

Phase	Time	Load	VES	SVES	BIG	DIST
Rest 1	00:10	0	--	--	--	--
Load 1	02:10	50	--	2	--	--
Load 2	04:10	75	2	--	--	--
Load 3	06:10	100	1	1	--	2
Load 4	08:10	125	--	--	--	--
Load 5	10:10	150	--	--	--	--
Relaxation 1	12:09	50	33	--	8	--
Relaxation 2	14:10	25	--	--	--	--
End*	14:10	--	--	--	--	--
Total	--	--	36	3	8	2

Event histogram

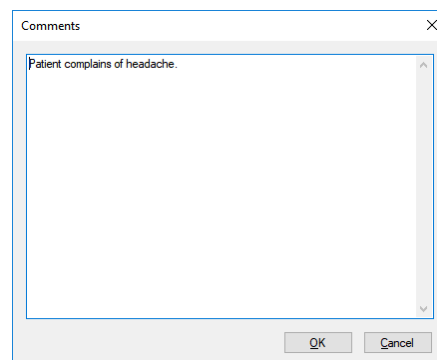
In this graphic, the number of events which occurred are displayed in the form of a vertically tiered bar graph for each load phase.

Rhythm display

To monitor the ECG rhythm, the ECG signal progression is shown with reduced sensitivity and speed for up to three selectable leads. A context menu enables individual settings to be made. The time period displayed can be adjusted using the slider.

7.4.4. “Comments” view

Add comment to examination



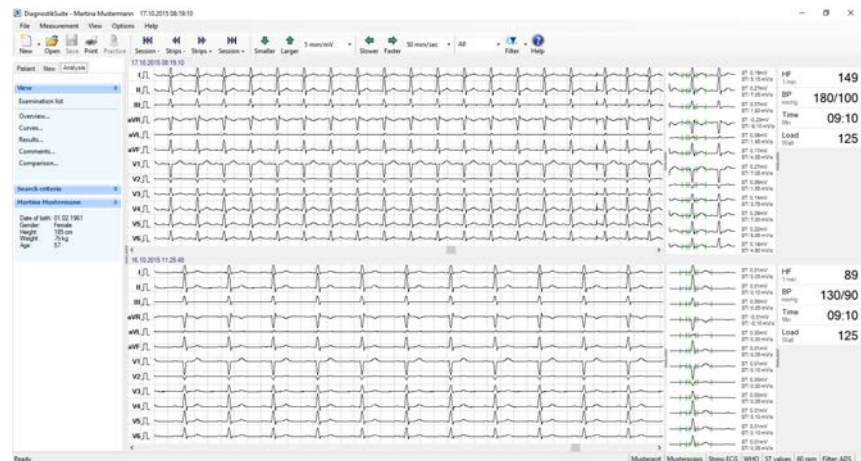
A dialogue box can be opened using the “View–Comments” menu function in which comments on the measurement currently being analysed can be entered.

While the “Comments” dialogue box is open, the views of the ECGs currently open can be switched.

7.4.5. “Comparison” view

The DiagnostikSuite allows two similar recordings from the same patient to be compared. In this way, recordings which were made at different times can be compared to each other. In addition, different ECG passages from the same examination can be compared to each other.

Starting from the measurement currently open, the examination to be compared is selected in the “View” panel via the “Compare” entry. Then both measurements are shown.



Compare examinations

In a comparison, the two ECGs are displayed one below the other.

This information and these methods are available for each ECG:

- Indication of the recording date and time.
- Visualisation of the ECG signal progression with lead designation, 1mV reference pulse.
- Display of the dominant average beats with wave points, ST amplitudes in mV and ST gradient in mV/s.
- Measurement panel with heart rate, blood pressure, current time within the ECG examination and load.
- Individual selection of the time point compared using its own slider.

The sensitivity, speed, lead and filters are adjusted simultaneously for both ECG examinations.

7.5. Graphically measure examination manually

The manual graphic measurement provides the user with the simple option of determining amplitudes and time differences of the displayed ECG directly on the screen. A rectangle is placed between the start and end position and this serves as a ruler.

The manual graphic measurement of an ECG is possible in the case of a resting and stress ECG if the ECG recorder has been stopped.



Start manual measurement

The manual measurement is started and ended via the context menu.

An active manual measurement is displayed to the user through a crosshair cursor.

Set starting and target position

Pressing the left mouse button defines the starting position. The left mouse button now remains held down until the mouse cursor is over the target position. The target position is defined by releasing the left mouse button.

The next click on the left mouse button deletes the two previous positions and displays and restarts the process with the specification of the next starting position.

Changing the positions

The starting and target position can be subsequently changed. To do this, the square itself as well as all four side lines of the square can be moved at right angles. The measurements are then updated.

Function overview

Function	Display symbol
Selection of degree of precision	+
Vertical resizing	↑↓
Horizontal resizing	↔
Diagonal resizing 1	↖↘
Diagonal resizing 2	↗↙
Move	↕↔

Measure times and amplitudes

When the target position is selected, the time and amplitude difference of both positions is displayed. If the time difference is between 0.25 seconds and 2 seconds, a heart rate (HR 30 to 240) calculated from this is additionally

indicated.

Rhythm analyses

To check rhythm deviations, for example, of the RR interval, the time period set on the right next to the measurement square is repeated a total of five times.

Note:

- Measurements and positions are not saved.
- Operations which change the ECG display in any way delete the measurement displays: filter, sensitivity, speed and lead settings, scrolling, start of the ECG recorder, mode change, modifying the window size, etc.

7.6. Save examination

Save examination



After the new examination is completed, it is saved in the database using the "Save" button.

7.7. Print out examination

There are various configuration options available for printing out examinations.

Preparation

1. Under "*Options – Print*" in the "General" area, use the "Printer settings" button to specify the printer which is to be used to print out the examinations. Other printer-dependent properties can be accessed using the "Properties" button. Here, among others, the paper source, paper size and its orientation are specified.
2. On the same page, you configure whether the advanced patient data as well as the name of the physician and the facility are to also be printed.
3. In the other pages of the "Print setup" dialogue box, you individually compile the information which you require when printing out your examinations.
4. As needed, a Windows dialogue box can be opened via the "*File – Set up page*" menu function in which the margins can be adjusted, in addition to the paper size and the orientation.
5. As desired, a preview of the paper printout can be opened using the "*File – Page preview*" menu function. The printout can be checked, scaled in various enlargements, and examined page by page.



Tip: Since the printer settings are saved in the *DiagnostikSuite*, you do not need to set the settings described here again with each printout.

Print examination



Using the "Print" button in the tool bar, the examination which is currently open is printed out.

If no examination is open, the "Print" button is locked.

Print screen

Significant ECG passages can be documented using the “Print screen” function. This prints the ECG passage currently displayed on the screen. Depending on the screen or paper width, the printed ECG duration may deviate somewhat from the ECG duration displayed.

The screen printout is started via the context menu of the ECG curves or via the “File | Print | Screen” menu.

8. Settings and configuration

Settings are made in the *DiagnostikSuite* in the “Options” menu.

The settings are saved and are also available following a restart of the *DiagnostikSuite*.

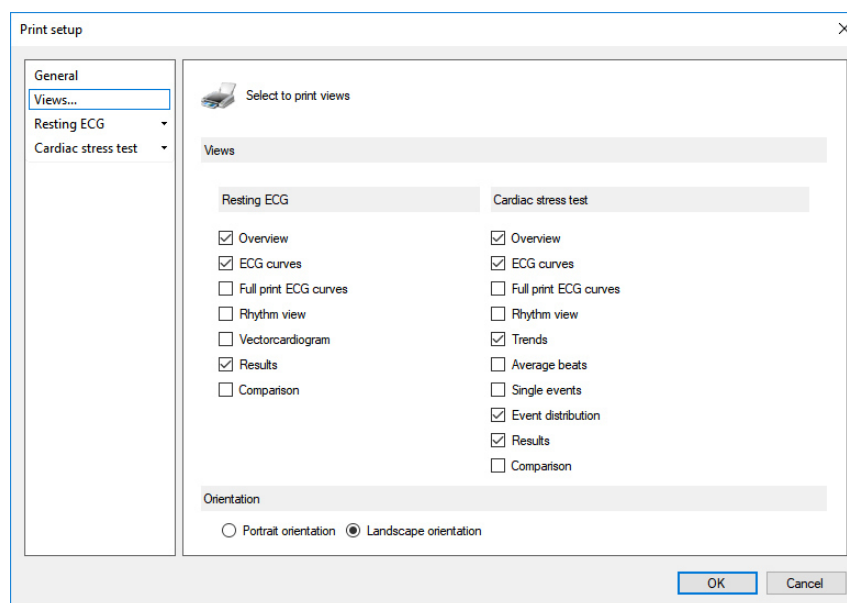
8.1. Set print options

General

The print options are set in the “Print setup” dialogue box. Basic print settings as well as the selection of the printer can be made on the “General” page.

Views

Each type of examination has its own print settings. The contents of the ECG report for resting ECGs as well as stress tests are defined on the “Views” page. In addition to the overviews, the ECG curves, rhythm view, results, comparison and other views can be included in the design of the report.



Resting ECG, ergometry

The design of the individual print views can be individually configured. Using the “Resting ECG ▼” menu item, the contents and properties of the resting ECG printouts can be defined, and those of the stress ECG printouts can be defined using the “Ergometry ▼” menu item.

Overview, trends, results, comparison

On the “Overview”, “Trends”, “Results” and “Comparison” pages, the printout of these pages is individually configured.

Global settings ECG curves, average beats, vectorcardiogram, rhythm display

Many print elements, such as ECG curves, the average beats, the vectorcardiogram and the rhythm display, are printed on multiple pages. The display of these print elements can be configured via the menu item “Global settings”.

8.2. Define system properties



Make changes to the system properties only after consulting your service partner.

General

On the “General” page, general system properties such as the import and export path are defined.

Database

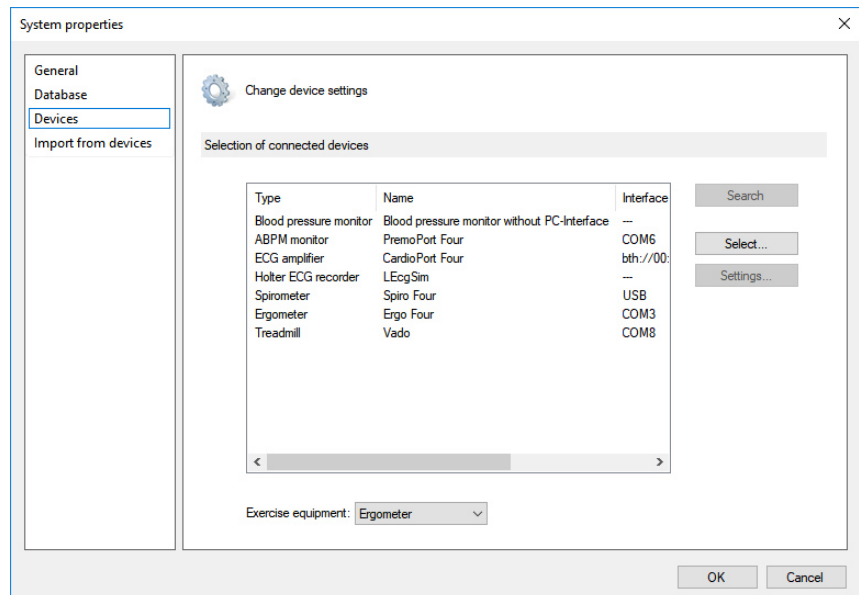
On the “Database” page, the connection with the database program is configured and the path to the examination data is specified.



Tip: Remember to include the database in your data backup concept and to regularly back up the data.

Devices

On this page the devices connected are listed and can be changed, if needed. In addition, the interface used can be selected.



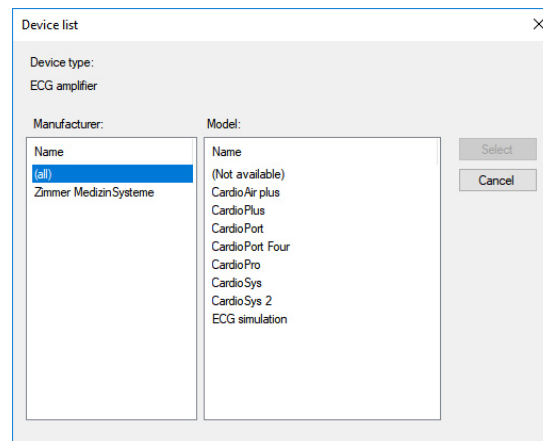
Exercise equipment

In this field, you define which type of stress examination is to be performed and which type of exercise equipment is to be used. The type of stress examination influences the type of load profile and the load parameters used.

Selecting the connected devices

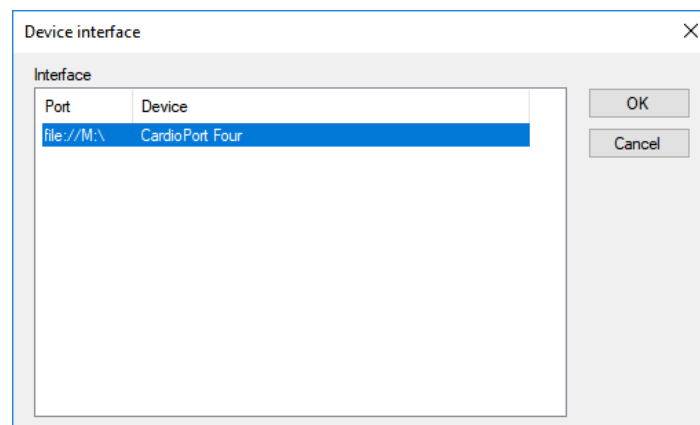
Device type

To set or change a device, select the device type and use the “Select” button to launch a dialogue box in which all examination devices of this type which are supported are listed according to manufacturer. Select the desired model and confirm the setting with “Select”.



Interface

To change the interface of a device, select the device type and use the “Settings” button to launch a dialogue box in which all possible interfaces are listed. There you will also see which interfaces are already being used. Select the desired interface and end the dialogue box with the “OK” button.



8.3. Define ECG options

8.3.1. ECG settings

The ECG options are set in the “ECG settings” dialogue box which is reached via the “Options – ECG...” menu.

General ECG settings, electrode placement

The general ECG settings are adjusted on the “General” page.

Advanced electrode control

Here you select whether non-contacting electrodes are displayed graphically during an ECG recording in a separate control window. This is particularly helpful if not all electrodes were selected as a lead in the display. The electrode control window can be placed anywhere on the desktop.

Resting ECG, measurement

Sokolow index, QT dispersion

Here you select whether the Sokolow index or QT dispersion are to be displayed during a resting ECG. The Sokolow index is listed as another variable in the “Global measurements”; the QT dispersion is a part of the ECG interpretation.

QTc interval

There are different calculation specifications available for calculating the frequency-corrected QT interval “QTc”. Bazett, Fridericia, Framingham, Hodges, Nomogram.

Ergometry, average beat, ergometric parameters

Exhaustion heart rate

In the stress test, the DiagnostikSuite guides the exhaustion heart rate. It is calculated according to the formula $HF_{\text{Exhaustion}} = \text{starting value} - \text{age} - \text{deviation}$. The starting value and the deviation can be entered in the dialogue box. Common calculation formulas are:

$$HF_{\text{Exhaustion}} = 220 - \text{age} \pm 0 \text{ or}$$

$$HF_{\text{Exhaustion}} = 200 - \text{age} \pm 0$$

Physical capacity in MET during a stress test

The metabolic equivalent is used to determine the energy consumption during maximum load. Determination according to the practice guidelines of the Austrian Cardiology Society (ÖKG) or the American College of Sports Medicine (ACSM) may be selected.

Treadmill load calculation

Various calculation specifications are available for calculating the load on the treadmill: CardioData, Nowacki, Schulz and Eschenbacher.

While a stress ECG is being performed, the heart rate, blood pressure and ST amplitudes are monitored. If limit values are exceeded or undershot, a visual warning appears on the screen. The monitoring of the individual parameters can be individually activated or switched off. The limit values to be monitored can be specifically set in the dialogue box. The respective reference values are measured before the start of the rest phase.

Warnings

Heart rate

In addition to monitoring the absolute level of the heart rate, the drop as compared to the reference value of the resting phase and the drop compared to the previous phase can be activated.

Blood pressure

As in the case of the heart rate, not only the absolute level of the heart rate but also the drop as compared to the reference value of the resting phase and the drop as compared to the previous phase can be monitored. Individual settings are available for the systolic and diastolic blood pressure.

ST amplitude

The height of the ST amplitude can also be monitored. Here, separate settings are available for the decrease and increase as compared to the reference value.

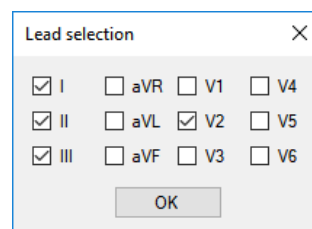
8.3.2. Adjust leads**Leads**

The ECG leads can be adjusted for the ECG curves at various points: via the context menu, the space bar, the tool bar and – as described here – via the menu.

The leads for the rhythm display can only be defined via the context menu for the rhythm display.

The following lead systems are available. Einthoven, Goldberger, Wilson, Nehb, Cabrera, Cabrera2 and all 12 standard leads.

In addition, the leads shown can be individually selected.

**8.3.3. Adjust filters****Filters**

The adjustment of the ECG filters for the ECG curves, like the adjustment of the lead, can be performed at various points: via the context menu, the toolbar and – as described here – via the menu.

The filters used for the rhythm display can only be defined via the context menu of the rhythm display.

There are three filter types available.

- Mains filter to suppress 50 Hz and 60 Hz disruptions in mains power
- Muscle filter to remove muscle tremors
- Antidrift system to reduce baseline fluctuations

Note:

- A precondition for high-quality ECGs is the optimal placement of the ECG electrodes.
- Filters should be used only if all other measures for eliminating faults have been exhausted.
- No filter improves the ECG; only the display of the ECG is optimised.
- The automatic ECG measurement is performed with unfiltered ECGs.

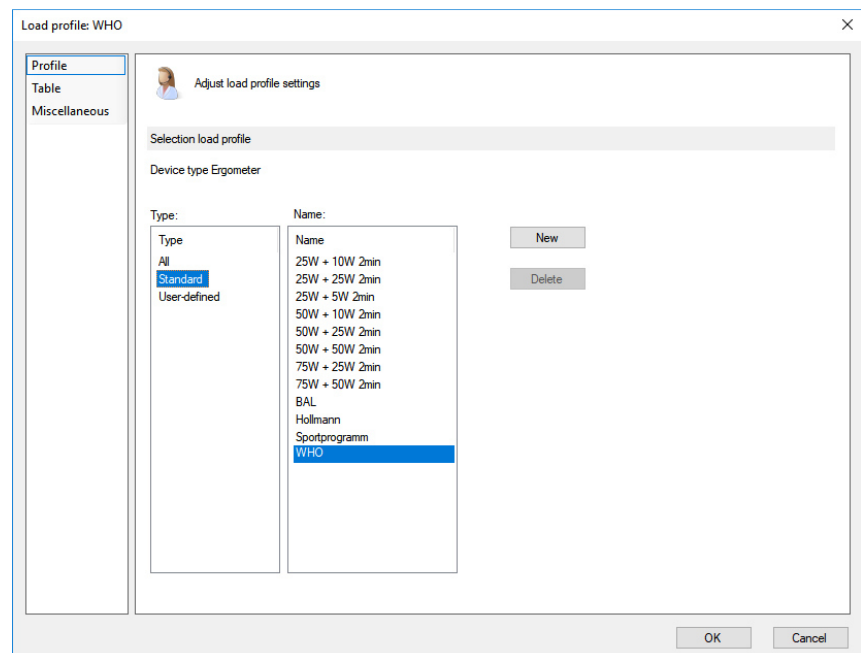
8.3.4. Create and select load profile

Load profile

The load profiles for bicycle and treadmill stress tests can be selected or created according to individual factors in the “Load profiles” dialogue box which can be accessed via the “Options – Load profiles” menu.

Only the stress test program of the current session can be retrospectively viewed.

Profile



After the “Load profiles” dialogue box is brought up, the load profile currently set is marked and selected in the “Profile” view.

By selecting a certain type (all, user-defined or standard), the list of available load profiles is filtered.

[Left click with mouse](#) Selects a load profile from the list.

[New](#) Starts another dialogue box to create a new load profile.

[Delete](#) Removes the selected load profile. Only user-defined load profiles can be removed.

Table

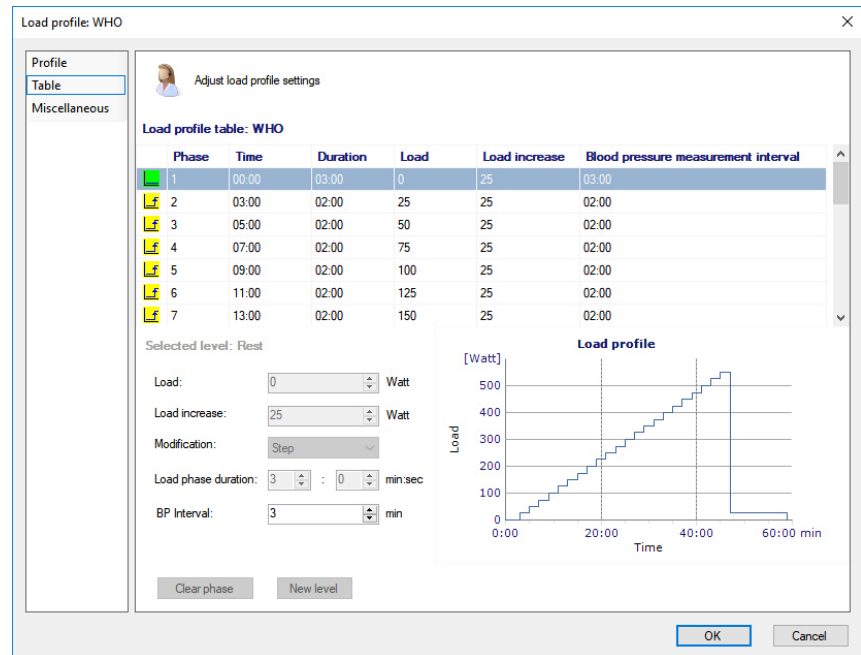
The selected load profile is displayed in the “Table” view. The table lists the individual phases of the load profile, indicating the phase type (resting, stress and recovery), start time, load and load increase in the case of bicycle stress

Define ECG options

tests, as well as speed and gradient in the case of treadmill stress tests, and the blood pressure measurement interval.

All settings can be manually adjusted for a selected phase in the table.

For visualisation of the load profile, this is displayed in the form of a graphic.



[Left click with mouse](#) Selects a load phase from the list.

[Clear phase](#) Clears the selected load phase.

[New level](#) Prior to the selected load phase, inserts a level of the same type (resting, stress, recovery).

Other

The other settings of the load profiles can be adapted in this view.

Blood pressure

If the "Perform measurement" option is selected, blood pressure measurements are performed during the stress ECG according to the load profile. If the option is deselected, no blood pressure measurements are fundamentally performed.

Stress test speed

For bicycle stress tests, define the limit values here for which the user is to be warned in the event these values are exceeded or undershot.

Create new load profile

The creation of new load profiles is launched in the "Profile" view after pressing the "New" button. By doing so, the "Create new load profile" dialogue box opens.

Create new load profile

Name:

Description:

Type	Repose	Stress	Recovery
Quantity:	<input type="text" value="1"/>	<input type="text" value="20"/>	<input type="text" value="2"/>
Initial load:	<input type="text" value="0"/>	<input type="text" value="25"/>	<input type="text" value="50"/> watt
Load increase:	<input type="text" value="25"/>	<input type="text" value="25"/>	<input type="text" value="-25"/> watt
Modification:	<input type="text" value="Step"/>	<input type="text" value="Step"/>	<input type="text" value="Step"/>
Duration:	<input type="text" value="3"/> : <input type="text" value="0"/>	<input type="text" value="2"/> : <input type="text" value="0"/>	<input type="text" value="2"/> : <input type="text" value="0"/> min.sec.
BP measuring interval:	<input type="text" value="3"/> min.	<input type="text" value="2"/> min.	<input type="text" value="2"/> min.

Number

For the three load phase types (resting, stress and recovery phase), it can be indicated how many load phases the "Create new load profile" dialogue box should generate.

Base load

Base load of the first phase

Load increase

Change in the load from one phase to the next phase

Change

Indication whether the load change takes place in the form of steps or as a ramp.

Duration

Duration of the phase in minutes and seconds

Blood pressure measurement interval

Interval duration between two blood pressure measurements

Create

The load profile is created using the button and the dialogue box is closed.

Cancel

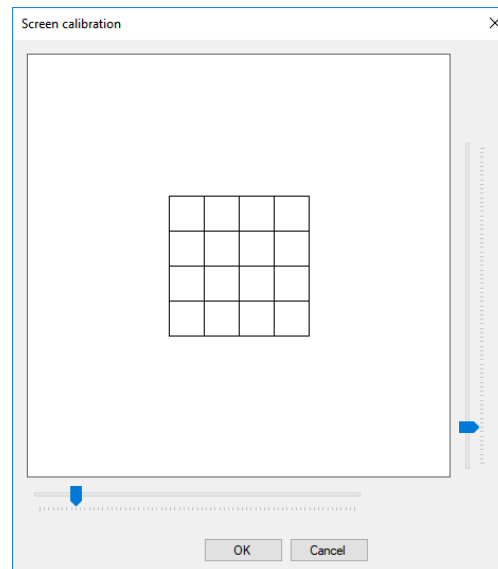
Cancels the dialogue box without creating the profile.

In the case of treadmill stress tests, the starting speed, speed increase, initial gradient and gradient increase are entered instead of base load, load increase and change.

8.3.5. Calibrate screen

Screen

Sensitivity and speed information from ECGs refer to metric lengths. To ensure a correct display even in the case of different screen sizes and resolutions, the screen can be calibrated. To do this, the 1-cm grid is horizontally and vertically controlled and adjusted, if necessary.



- In the dialogue box, 4 fields in each case, each 1 cm wide and 1 cm tall, are shown.
- Move the slider horizontally or vertically to change the scaling and then use a ruler to measure the size of the fields.
- If the desired scaling has been adjusted, exit the dialogue box with "OK".

9. Reference

9.1. Safety

General safety information

The DiagnostikSuite may only be operated in accordance with these instructions for use. All other applications are the responsibility of the operator.

Prior to each use, the user must ascertain the functional safety and proper operating condition of the DiagnostikSuite.

For maintenance measures, expansions, readjustments or modifications, the provisions of the German Medical Devices Act (MPG) and the Medical Device Operator Ordinance (MPBetreibV) apply.

According to the Medical Device Operator Ordinance, medical devices may be set up, operated and used only by persons who have the necessary training or knowledge and experience to do so.

Performing a technical safety check (TSC) is not necessary in the Federal Republic of Germany.

9.2. Questions, technical problems, faults

If questions, technical problems or faults arise, observe the explanations, descriptions and solutions listed here (see section "Answers to frequently asked questions") and those described in the documentation of connected combination devices.

If you require further support or if there is interference which cannot be corrected, please contact your sales consultant or, for matters of urgency, please contact the factory directly.

Zimmer MedizinSysteme GmbH
Junkersstraße 9
89231 Neu-Ulm
Germany
Telephone +49 0731/9761-0

Diagnostic hotline: Telephone 0731/9761-115 (Mon. - Fri., 8 a.m. - 5 p.m.) or fax 0731/9761-4443

You can also receive support via email: support@zimmer.de
Visit us online at: <http://www.zimmer.de>

You will help us solve the problem if you have the following information at hand:

- Version number, serial number
- Computer configuration
- Accurate description of the problem
- Printout of the protocol file (menu function: "Help – Protocol")

9.3. Combination devices

ECG amplifier

Name	Description
CardioPort	Real-time ECG recording with 12 leads, electrode control, pacemaker detection and power-saving function.
CardioPort Four	Real-time ECG recording with 12 leads, electrode control, pacemaker detection.
CardioPlus	Integrated ECG system with ECG device for signal recording plus application system for suction electrodes.
CardioAir Plus	Integrated ECG system with ECG device for signal recording plus application system for suction electrodes.
CardioSys CardioSys 2	Mobile ECG system with ECG device for signal recording plus application system for suction electrodes on a device cart.
CardioPro	Mobile ECG system with ECG device for signal recording plus application system for suction electrodes on a device cart.
ECG simulation	Driver for the simulation of a real-time ECG for demonstrations, tests and presentations.

Ergometer

Name	Description
Ergo 3	Seated bicycle ergometer from 0–400 W, with integrated stress programs.
Ergo 4	Seated bicycle ergometer from 25–999 W (firmware version 2.9/8.9 needed).
Ergo 5	Seated bicycle ergometer from 25–999 W, with integrated blood pressure monitor (firmware version 7.52 needed).
Ergo 6	Seated bicycle ergometer from 25–600 W.
Ergo K	Seated bicycle ergometer from 10–1000 W, with integrated stress programs and optional blood pressure monitor.
Ergo SL	Seated/recumbent bicycle ergometer from 10–1000 W, with integrated stress programs and blood pressure monitor.
Ergo Four	Seated bicycle ergometer from 10–1000 W, with optional blood pressure monitor.
EGL 2000	Recumbent bicycle ergometer (elmed) from 10–150 W, integrated stress programs and blood pressure monitor.
EGT 1000	Seated bicycle ergometer (elmed) from 25–600 W, with integrated stress programs and blood pressure monitor.
EGT 1500	Seated bicycle ergometer (elmed) from 25–600 W, with optional blood pressure monitor.
EGT 2100	Seated bicycle ergometer (elmed) from 10–1000 W, with blood pressure monitor.
EGT 2200	Seated bicycle ergometer (elmed) from 10–1000 W, with integrated stress programs and optional blood pressure monitor.
EC 2000	Seated bicycle ergometer (custo med) from 10–1000 W, with blood pressure monitor.

EGT 2100	Seated bicycle ergometer (Delmar Reynolds) from 10-1000 W, with blood pressure monitor.
Ergo 3000	Seated bicycle ergometer (Dr. Vetter) from 10-1000 W, with blood pressure monitor.
EGT 2100 ge	Seated bicycle ergometer (GE) from 10-1000 W, with blood pressure monitor.
EC 3000	Seated bicycle ergometer (Groz)
ergo control 3000	Seated bicycle ergometer (Groz)
EGT 2200	Seated bicycle ergometer (Nihon Kohden) from 10-1000 W, with integrated stress programs and blood pressure monitor.
EGT 2100 s	Seated bicycle ergometer (Schiller) from 10-1000 W, with blood pressure monitor.
ER800	Seated bicycle ergometer (Ergoline) from 25-999 W (firmware version 2.9/8.9 needed)
ER900	Seated bicycle ergometer (Ergoline) from 25-999 W, with blood pressure monitor (firmware version 2.36 or 4.36 needed)
ERG 900 EL	Bicycle ergometer (Ergoline)
ERG 900 S	Bicycle ergometer (Ergoline)
ERG 900 SL	Bicycle ergometer (Ergoline)
Variotrainer 500	Seated bicycle ergometer (Ergoline), compatible with the Ergo 6 driver, PC operation by pressing the "End" button once
Variobike 500	Seated bicycle ergometer (Ergoline), compatible with the Ergo 6 driver, PC operation by pressing the "End" button once
Variobike 550	Seated bicycle ergometer (Ergoline) from 25-600 W
ergoselect 100	Seated bicycle ergometer (Ergoline) from 20-1000 W, with integrated stress programs.
ergoselect 200	Seated bicycle ergometer (Ergoline) from 20-1000 W, with integrated stress programs.
ergoselect 1000L	Bicycle ergometer (Ergoline)
ergoselect 1200L	Bicycle ergometer (Ergoline)
Examiner	Seated bicycle ergometer (Lode)
Without PC interface	Driver for manual ergometer control. Requires an ergometer with manual load phase change or integrated ergometry programs.
Ergometer simulation	Driver for the simulation of a stress test for demonstrations, tests and presentations.

Treadmills

Name	Description
Vado	Treadmill using lamella technology, from 0–20 km/h and 0–10% gradient
PPS 55 med	Treadmill using lamella technology, from 0–20 km/h and 0–10% gradient (Woodway)
Trackmaster TMX425	Treadmill (Full Vision)
Coscom v3	Treadmill (h/p/cosmos)
Treadmill without PC interface	Driver for manual treadmill control. Requires a treadmill with manual speed change or integrated ergometry programs.
Treadmill simulation	Driver for the simulation of a treadmill stress test for demonstrations, tests and presentations.

Blood pressure monitors

Name	Description
Premo	Blood pressure measurement up to 300 mmHg according to Riva-Rocci-Korotkow or oscillometric. With integrated measurement memory and PC control.
EBM503D	Blood pressure monitor (Bosch, Dimeq)
Blood pressure device without PC interface	Driver for manual blood pressure measurements, adjustment option on the PC.
Blood pressure simulation	Driver for the simulation of automatic blood pressure measurements for demonstrations, tests and presentations.

Note

- Device and driver settings as well as their interfaces can be changed under *Option - System - Devices*.
- A current list of connectable ergometry devices is available from Zimmer MedizinSysteme.
- All information supplied without guarantee!

9.4. Evaluations**9.4.1. HES evaluation****HES general**

HES® stands for Hannover ECG system and contains a computer-aided ECG analysis for the resting ECG and stress ECG.

The DiagnostikSuite offers the user the HES ECG analysis as an option.

Note:

- The computer-aided ECG analysis uses qualitative and quantitative methods for detecting patterns and measuring intervals as well as amplitudes. The interpretation of the results is based on typical parameters of shape, amplitude and frequency analysis. However, despite its high success rate, it does not replace the independent assessment by the physician, since errors in the lead and special physiological features can



HES resting ECG evaluation

influence the results.

- In the case of absolute arrhythmia as well as blockages of the impulse conduction, the list of individual events is not practical and cannot be used for diagnostic purposes.
- Interested users can obtain information from Zimmer MedizinSysteme on the method for determining amplitude values, the treatment of isoelectric segments within a QRS complex, the acceptance criteria of smaller waves, the ECG diagnosis groups and the accuracy measurements.

In an HES evaluation of a resting ECG, the last 10 seconds of the ECG recording are examined. The HES evaluation determines the shape and position of QRS complexes and from this, it determines the heart rate as well as a "Representative cycle" (average beat) for each lead. This average beat is measured.

Global measurements over all leads

In the measurement of resting ECGs, common, valid measurements, that is, global measurements, are determined for all leads.

P interval (P), PQ interval (PQ), QRS interval (QRS), QT interval (QT), frequency-corrected QT interval (QTc), QT target value corresponding to frequency QT Nom. (according to Hegglin and Holzmann), relative QT interval QTr in %, Sokolow index SI.

The global durations are determined in that the first start and last end of a wave is searched for in all leads. The time difference between the first start and the last end determined as a result corresponds to the global duration.

Spatial values

Frontal vectors P, QRS and T.

QRS position type

Marked right axis deviation, right axis deviation, vertical heart position, normal heart position, left axis deviation, marked left axis deviation, QRS angle < -90 degrees, sagittal type, SI/QIII type, QI/SIII type, QIII left type

Table of measurements

Detailed for each lead, the waves and peaks (P, Q, R, S, ST, ST/, T, etc.) are measured in the report and displayed in a table. The ST segment refers to the j+60ms position in the case of the HES measurement.

Atrial diagnostics

Based on the conventional criteria, information on the P-sinistro-, P-dextro- and P-biatrial or on an atrial conduction disorder is provided.

Interpretation

All ECG measurements which are important for the diagnosis are checked for normalcy. Reference is made in particular to special morphological features such as Q waves, R loss, delta waves, ST changes, etc. if these are not within normal limits.

Specific references are made to delays, complete and incomplete bundle branch blocks, pre-excitation disorders (WPW), hemiblocks, and nonspecific intraventricular conduction disorders.

In the case of an abnormal ST-T progression, reference is made to repolarisation disturbances of the inner or outer layer type, classified according

to grade 1 ... 4.

QRS-T evaluation

The ECG recorded is checked for similarities with normal and pathological ECGs from a "learning collective".

Interpretation groups

The various interpretation algorithms are divided into the following groups:

- Normal
- Right ventricular hypertrophy
- Left ventricular hypertrophy
- Biventricular hypertrophy
- Anterior myocardial infarct
- Infarct (large infarct or infarct with nonspecific localisation)

HES rhythm analysis

Rhythm statements from a recording of only 10 s in length require an analysis of any ECG complex available and any prior and subsequent RR interval. For the plausibility check of the rhythm data and as an aid for quality control, the HES ECG program displays a rhythm and typing diagram which represents the beat sequence of the ECG cycles in short form. Each ECG complex is marked by a symbol; the interval between the symbols represents – in the simplified grid – the RR interval.

Rhythm and typing diagram for a regular sinus rhythm:

+--+--+--+--+--+--+--+--+

This display means that 9 ECG cycles with the same morphology were found in the ECG recording and were averaged for the "Representative cycle". The interval of the cycles was equal (regular interval --).

Rhythm and typing diagram for a sinus rhythm with two compensating ventricular and one compensating supraventricular extrasystole:

+--+2---+--+2---+P---+--+

Here, 10 ECG cycles were found. Cycles 1,2,4,5,7,9,10 (+) form the main type from which the "Representative cycle" was determined for the diagnosis. Cycles 3 and 6 (designated with "2") deviate from the main type in the QRS morphology and have a shortened interval to the previous and a prolonged RR interval to the next normal complex (+). This constellation indicates two monomorphic ventricular extrasystoles.

Cycle 8 (P) once again has a shortened interval to the previous (+) and a prolonged interval to the subsequent (+) normal beat.

The P means that only the P wave, however not the QRS-T of the cycle in question, deviates from the normal beat. In context with the prematurity and the subsequent prolongation of RR, an atrial extrasystole is suggested.

The following table provides an overview of the symbols which may appear in the rhythm and typing diagram and their meaning:

Symbol	Meaning
+	The cycle belongs to the representative cycle (main type) and was used for averaging.
2, 3, 4	The cycle belongs to type 2, 3, or 4. (Morphologically different from the representative cycle: VES (monomorphic and polymorphic), SVES, aberrant QRS beats)
!	Pacemaker-triggered complex
P	Exclusion from the main group due to deviating P contours
T	Exclusion from the main group due to deviating T contours
O	Exclusion from the main group due to deviating P and T contours
B	Exclusion from the main group due to baseline fluctuations
R	Exclusion from the main group due to an excessively short interval to the previous or subsequent cycle (measurement error possible)
U	Incomplete ECG complex
V	Peripheral position; parts of the complex are missing
X	Exclusion for technical reasons, e.g. fault, unexplained aberrant form

The brief visual review of the rhythm and typing diagram should be a fixed component of the quality control of the computer ECG evaluation, as should the examination of the wave point marks.

Paediatric ECGs

Based on the special physiological and anatomic conditions in children, as compared to adults, the HES module does not interpret any paediatric ECGs, but rather performs a measurement of specific characteristics. These measurement results are compared with age- and sex-dependent normal values according to André Davignon et. al., 1980 and displayed in table form. In this case, the confidence interval from 2% to 98% is considered; this corresponds to twice the standard deviation. Measurements which are outside of the confidence interval are marked with an asterisk “*”.

Age groups

The HES module divides children up to the age of 16 years into a total of 12 age groups.

0 – 1	days	7 – 12	months
2 – 3	days	1 – 3	years
4 – 7	days	4 – 5	years
8 – 30	days	6 – 8	years
1 – 3	months	9 – 12	years
4 – 6	months	13 – 16	years

Sinus rhythm

V-----+-----+-----+-----+-----+-----+-----+-----T

Age group/years	13 - 16	2%	98%
HR	: 66	62	120 /Min.
* PQ vs age:	204	93	175 ms
QT vs HR	: 388	310	393 ms
QT vs age:	388	292	390 ms
QRS axis	: 85	10	127 °
QRS duration	: 94	75	108 ms
R/S V1	: 0.00	0.00	1.70
R amp V3	: 0.11	0.02	0.72 mV
S amp V3	: 1.21	0.06	1.62 mV
R/S V3	: 0.09	0.00	1.20
* R/S V5	: --	1.00	44.50
* R/S V6	: --	1.40	38.50
RV6 + SV1 :	1.50	1.15	4.15 mV
RV5 + SV2 :	4.18	1.95	6.25 mV
T amp V1+	: 0.07	-0.38	0.30 mV
T amp V2+	: 0.74	0.04	0.93 mV

In the HES evaluation of a stress ECG, a 10-second reference ECG is initially recorded. Using the reference ECG, it is checked whether a real-time analysis of the ECG under stress conditions is possible. This test is repeated a maximum of three times. If the ECG of HES can be analysed in real time, 2-second intervals are continuously evaluated during a stress ECG and from this the heart rate is calculated and arrhythmic events are determined. Every 10 seconds, a representative cycle (average beat) is formed and the ST values are measured.

HES stress analysis identifies the following events:

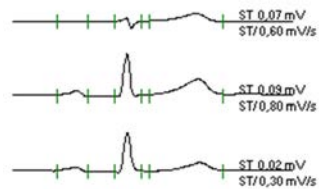
Event	Abbreviation
Asystole	ASYS
Fibrillation or flutter	FF
Check fibrillation or flutter	CFF
Ventricular tachycardia (> 3 VES)	VT
Polyform ventricular extrasystoles	pVES
Salvo (3 VES)	SALV
Bigeminy	BIG
Couplet (2 VES)	COUP
Intermittent bundle branch block	BB
Ventricular extrasystole	VES
Pacemaker error	PME
Pause of two QRS complexes	P2

Pause of a QRS complex	P1
Supraventricular tachycardia (≥ 2 SVES)	SVT
Supraventricular extrasystole	SVES
Disturbance	DIST
Artifact	ART

In addition to the regular events, extrasystoles which are detected during the real-time ECG analysis but are still undefined are temporarily displayed as irregular.

Representative cycles, average beats

The representative cycles corresponding to the dominant, that is, typical ECG complex, which is formed by averaging.



During the evaluation of the average beats, their morphology and the correct placement of the wave positions must be checked.

9.4.2. Electrode control

Electrode control

The electrode placement is monitored by the ECG amplifier currently in use. It continuously checks whether all electrodes are attached to the patient and provides this information to the DiagnostikSuite. The DiagnostikSuite itself displays non-contacting electrodes lead-wise by a red horizontal line in place of the ECG signals.

ECG with non-contacting electrodes V2 and V3:

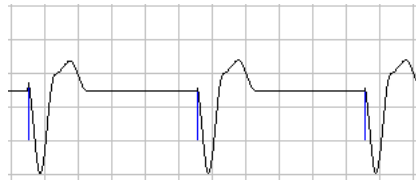


Non-contacting electrodes can also optionally be displayed in "Advanced electrode control".

**Cardiac pacemaker
pulses****9.4.3. Cardiac pacemakers**

In a patient with a cardiac pacemaker, there are needle pulses in the ECG before the respective QRS complex, depending on the type of pacemaker.

The ECG amplifier used in each case checks the ECG signal for pacemaker pulses and transmits this information to the *DiagnostikSuite*.



The *DiagnostikSuite* marks these signals in the ECG display as blue pulses. However, the display does not represent the actual pulse width and height, rather, it symbolises only the pacemaker action. Detecting the pacemaker pulses avoids misinterpretations and errors in the heart rate calculation.

9.5. Answers to frequently asked questions



Here you will find frequently asked questions about the technology, updating and handling of the DiagnostikSuite.

Medical devices, interfaces, etc.

■ How do I set my examination device in the DiagnostikSuite?

- ! Select “Options – System – Devices”. In the list of connected devices, select the device type which you would like to set. Click on the “Select” button to display the “Device list” dialogue box. This box lists the models, sorted by manufacturer, which the DiagnostikSuite can control. Select the appropriate examination device and confirm your entries with the “Select” button. Now start the “Device interface” dialogue box using the “Settings” button and select the communication connection there. Then press the “OK” button to accept the communication connection and then press “OK” once again to accept the settings of the “System properties” dialogue box.

■ My examination device is not listed in the device list!

- ! If your examination device is not on the list of connectable devices, there is no device driver available for it. However, there may be a compatible device driver for it. For more help, please contact the diagnostic hotline.

■ What is a simulation driver and how is it adjusted?

- ! A simulation driver makes simulated operation of the DiagnostikSuite possible without a connected examination device. Thus, for example, a spirometer can be simulated and a virtual spirometry can be performed as a result without a spirometer being connected.

You can select the simulation driver under “Options – System – Devices”. Select the device type to be simulated and click on “Select”. In the next dialogue box, you will find a simulation device available for this device type.

■ How do you shift the DiagnostikSuite from simulation back to normal status?

- ! Select “Options – System – Devices”. Select the device type simulated and click on the “Select” button. In the “Device list” dialogue box, select the desired model. The dialogue box is acknowledged with “OK”. Now use the “Settings” button to select the communication connection and confirm the dialogue box with “OK”. Thereafter close the “System settings” dialogue box with “OK”.

■ “Simulation” is in the background of the ECG curves although the ECG amplifier “CardioPort Four” is set. Why is this the case?

- ! When recording new ECGs, the DiagnostikSuite checks whether one of the devices needed for this is a simulation device. If so, “Simulation”

appears as background text in some graphs.

- ! Since a blood pressure measurement is possible while performing a resting ECG, no simulation device may be stored as a blood pressure monitor in the case of real resting ECGs. Change the configuration, if necessary, under “Option – System – Devices”.

- **Why are no interfaces seen under “Option – System – Devices” (“Settings – Resources”) although several COM interfaces are installed in the PC?**

- ! Once the interfaces are physically occupied, that is, during an ongoing examination, for example, these are no longer available to the system and are also not displayed. End active sessions or change the operating type to control the COM ports or reallocate them.

- **Where must the interface parameters, such as baud rate, data bits, parity, and the like be adjusted for the examination devices?**

- ! These interface parameters are permanently set and controlled by the *DiagnostikSuite*. The user thus has no option for changing these values. COM settings which you set in the system control also do not take effect.

- **When starting a new ECG examination, the *DiagnostikSuite* reports “ECG driver: The connection to the ECG device could not be established!”. What is the reason?**

- ! This message appears when an ECG device operated via USB is not connected to the PC.

- **Why does the *DiagnostikSuite* report “buffer overflow” during a real-time examination?**

- ! If the examination data cannot be read quickly enough from the buffer of the physical interface, a buffer overflow occurs.

The reasons may include:

- The interface is incorporated in the energy-saving functions (power management). Switch all energy-saving functions of the computer off.
- The computer is overloaded. End all other applications. Minimize the programs and drivers which are also running in the background.
- Install a high-performance graphics card with a sufficient amount of its own RAM.

- **Why does the message “Timeout” appear during a real-time examination?**

- ! The *DiagnostikSuite* cannot receive any data from the examination device. The connection between the computer and examination device may be broken.

The reasons may include:

- The connection cable or a converter which may be connected between them is inserted in the wrong COM port. Check the assignment of the interfaces.
- The connection cable is damaged. Check the connection cable for kinked, crushed areas and replace it if needed.
- The batteries of the examination device are depleted. Check the batteries and replace them, if needed.
- The device interface is incorporated in the energy-saving functions. Switch all energy-saving functions of the computer off.
- When connecting the examination device to a notebook, special cables, converters and interface adapters may be necessary. Contact the diagnostic hotline for more information.

■ **There is no transfer of examination data. The DiagnostikSuite reports “Data could not be received!”.**

! The PC does not receive any data from the examination device.

Check the connection between the computer and the medical device.

■ **In the middle of a real-time examination, the DiagnostikSuite is terminated with an error message.**

! The reasons may include:

- During the examination, data are regularly stored on the hard drive. If the hard drive is in energy-saving mode, it takes a few seconds before it is responsive once again. This can cause timeouts within the DiagnostikSuite. Switch off the energy-saving function of your hard drive.
- The batteries of the examination device are depleted. Check the batteries and replace them, if needed.

■ **What does the “Initialization error” message mean?**

! An examination device cannot be initialized.

- Check under “*Option – System – Properties*” of the examination device whether the correct driver and correct interface are set.
- Check the cable for a proper connection.
- Is the examination device switched on and in the correct mode?
- Check whether the examination device used is set to the correct baud rate.

■ **How can I switch off the power-saving function at the notebook?**

! The power-saving functions of your computer must be switched off at several places.

Information on how to do this can be found in the instructions for your computer.

DiagnostikSuite Update

- **Following a program update of an already-licensed DiagnostikSuite version, is relicensing necessary?**
 - ! No, because the update or installation program applies all previous settings of the installed version. In addition to the licensing information, other presets are thus also maintained.
- **Does deinstallation need to first be performed in the case of a program update to the DiagnostikSuite?**
 - ! **Certainly not!** Install a program update over an existing version. In a deinstallation, all licensing information and settings would be lost.

Patient management

- **Although the last session was saved, there are no ECG results in the index card or the medical data from the practice management system.**
 - ! When there is a connection, the results are only transferred to the practice management system if you begin a new session or access the practice management system with the "Practice" button. A rapid task change (via Windows menu bar or "ALT" + "Tab") does not transfer any data.
- **When a new examination is selected in the practice management software, the DiagnostikSuite starts but it remains in the background. How can I continue working?**
 - ! Depending on the functionality of the practice management software, this may be configured such that the practice management software puts the DiagnostikSuite in the foreground.
 - ! Using the Windows task change (via Windows menu bar or "ALT" + "Tab"), it is possible to switch from one program to another.

DiagnostikSuite application

- **The DiagnostikSuite is not launching! What can I do?**
 - ! Check whether the database program is running and its database service has started.
 - ! In the case of a network installation, check whether the database server has started.
 - ! The DiagnostikSuite application is on a network server which is currently not active or to which there is no network connection. Check whether the server in question is running properly and whether there is a network connection to the server.
- **When launched, the DiagnostikSuite reports: "The database cannot be accessed."**
 - ! Check whether the database program is running and its database service has started.
 - ! In the case of a network installation, check whether the database server has started.
- **Printing does not work. What could be the reason for this?**

- ! No printer is configured in Windows.
- ! The printer is not switched on.
- ! The connection to the printer is interrupted. The printer cable is not connected.
- ! The printer is out of paper.
- ! The toner or ink is empty.

Other

- **Other programs (such as Word) disappear behind the DiagnostikSuite.**
 - ! During the real-time display, the DiagnostikSuite always has priority over all other applications. Stop the real-time display to work with other applications.

9.6. Accessories

To ensure reliable function of the diagnostic system, only original accessories from Zimmer MedizinSysteme may be used.

Scope of delivery

Number	Item no.	Description
1		Digital medium DiagnostikSuite installation
1	9205	Licence DiagnostikSuite, ECG
1	10 102 738	Instructions for use DiagnostikSuite, ECG

Subject to technical changes

List of accessories

Item no.	Description
9205-01	Measurement and interpretation of the resting ECG
9205-02	Ergometry

Subject to technical changes

Additional accessories are available from Zimmer MedizinSysteme.

9.7. DiagnostikSuite components

The DiagnostikSuite has a modular design and consists of various program parts:

Item no.	Component
9202	DiagnostikSuite, basic software
9203	DiagnostikSuite, ambulatory blood pressure
9204	DiagnostikSuite, spirometry
9205	DiagnostikSuite, ECG

The basic software is a prerequisite for being able to operate examination components, because the basic software includes the respective examination components.

If basic software is already on hand, it does not need to be repurchased when additional examination components are purchased.

9.8. Copyright trademarks

DiagnostikSuite, ECG

Copyright © 2018

Zimmer MedizinSysteme GmbH, all rights reserved.

Unauthorised copying or sales of this program or individual parts is punishable!
This will lead to both civil and criminal legal action and may result in severe penalties and claims for damages.

The licence terms listed apply to use.

Trademarks

All trademarks named and shown are brands of their respective owners and are considered to be protected.

9.9. Disposal

The installation media of the DiagnostikSuite software are disposed of with household waste.

9.10. Licence terms

END USER LICENCE AGREEMENT

for the DiagnostikSuite software from Zimmer MedizinSysteme GmbH, Junkersstraße 9, 89231 Neu-Ulm (hereinafter referred to as “Zimmer”).

Please read the following licence terms carefully and in detail before you install the diagnostic program DiagnostikSuite (hereinafter referred to as “software”) on your computer.

By installing or using the software, you declare your consent with the licence terms below.

1. General – Area of application

- a)
These licence terms apply exclusively; Zimmer does not recognise any terms by the customer which are contrary to or which deviate from these licence terms unless Zimmer has expressly agreed in writing to the validity of such terms. Zimmer’s licence terms also apply if Zimmer conducts delivery of the software to the customer without reservation, with knowledge of terms by the customer which are contrary to or which deviate from Zimmer’s sales licence terms.
- b)
Zimmer’s licence terms also apply to all future business with the customer, in particular for any updates or expansions of the software delivered.

2. Subject of the licence

The software is not sold, but rather licensed. Upon purchase of the software, the customer receives only ownership of the physical data storage medium, the packaging and the manual as well as any other associated written material.

3. Granting of a licence

Zimmer grants the customer a nonexclusive right to use the software on the designated hardware in connection with the examination device purchased from Zimmer.

This licence allows the customer to install a copy of the software on various individual computers or on a generally accessible storage medium (such as a server). A copy of the software may be made for backup purposes. The customer is to carefully observe all information in the manuals (in their respective latest version) for the programs.

4. Copyright law

This software is protected by copyright. If Zimmer itself does not have property rights to the software or parts thereof, Zimmer has the rights to pass it on to and permit use by third parties. Zimmer is entitled to all rights resulting from copyright law. Any duplication, use, transfer or change to the software which is not expressly approved is prohibited and will lead to civil and criminal prosecution. The manual as well as written material belonging to the software are protected by copyright. Any copying of, change to, or forwarding of the written material is prohibited. The customer must store the software such that unlawful use by third parties is excluded.

- 5. Duration of the licence** The licence is granted for an unlimited period of time. In the event of termination of the licence granted, the customer is obligated, at Zimmer's request, to destroy the software and any copies of it or to return it to Zimmer. The licence automatically loses its validity, without requiring a notice of termination, if the customer violates any provision of this agreement.
- 6. Preconditions for operation** The following preconditions must be met for use of the software:
- Adherence to the hardware and software requirements
 - Properly performed installation of the operating system
 - Properly performed network installation for use in the network
 - Properly working computer system – hardware, BIOS, operating system, third-party software, network, connected devices, etc.
 - Properly performed installation of the software
 - Properly established connection to third-party programs if these programs are connected to accept personal data and diagnoses
 - Proper handling of the computer hardware and any software used on it
- 7. Guarantee**
- a)
The guarantee for the correct function of the software is excluded if third-party software or third-party software not approved by Zimmer is installed on the same computer, unauthorised changes have been made to the software or data backup was not performed regularly at suitable intervals. A condition for the acceptance of a guarantee is adherence to the preconditions for operation of the software (see no. 6).
- b)
Malfunctions caused by the subsequent installation of or changes to any software or settings for software, such as applications, operating system, driver, system settings, BIOS, etc. are excluded from the guarantee. Malfunctions due to third-party negligence, particularly in the case of defective hardware, incorrectly working drivers or other software as well as application errors are also excluded from the guarantee.
- c)
In addition, unless expressly guaranteed in writing, there is no guarantee for the compatibility of this software with any other programs or hardware components.
- d)
Information in the manual/documentation and/or advertising material which relates to currently available expansion options of a product or to currently available accessories are not binding for the future, in particular because the products undergo continuous adaptation.
- e)
If the customer asks Zimmer to perform troubleshooting within the scope of an alleged warranty claim and if the troubleshooting reveals that the error is not attributable to Zimmer, the user agrees to reimburse the costs of the troubleshooting according to customary hourly rates.

8. Liability for defects

- a)
If there is a software defect, the customer is entitled to subsequent fulfilment at Zimmer's discretion either in the form of correction of the defect or the delivery of new, defect-free software. In the event of correction of the defect, Zimmer is obligated to bear all costs necessary for the purpose of correcting the defect, in particular, transport, road, labour or material costs, provided these do not increase as a result of the software being brought to a location other than the place of delivery.
- b)
If the subsequent fulfilment fails, the customer, at its discretion, is entitled to request a withdrawal or a reduction.
- c)
Zimmer shall be liable according to legal provisions, insofar as the customer asserts claims for damages which are based on intent or gross negligence, including the intent or gross negligence of the representatives or vicarious agents of Zimmer. Unless Zimmer has been accused of an intentional violation of the contract, the liability for compensation is limited to foreseeable, typically occurring damage.
- d)
Zimmer shall be liable in accordance with legal provisions, provided Zimmer has culpably violated a fundamental contractual obligation, however in this case, the liability for compensation is limited to foreseeable, typically occurring damage.
- e)
If the customer is entitled to a claim for compensation of the damage instead of performance, the liability of Zimmer is also restricted within the scope of (b) to compensation for foreseeable, typically occurring damage.
- f)
Moreover, there is – if permitted by law – no liability for lost profit, loss of savings, damage claims by third parties against the customer and others for consequential damage, in particular, damage to the hardware and peripheral equipment as well as for damage to/loss of recorded data and data storage media.
- g)
Justified claims for damages according to (c) to (f) are limited to a maximum of the amount of licence fees paid.
- h)
The installation, configuration and functionality of the hardware used – if not delivered by Zimmer or its agents – are not the subject of this agreement. Liability claims cannot be asserted in this regard.
- i)
The liability for culpable injury to life, the body or health remains unaffected; this also applies for the mandatory liability according to the Product Liability Act.
- j)
Liability shall be excluded in instances not covered in the above provisions.
- k)
The period of limitation for claims for defects is 12 months, calculated from the time of transfer of risk.

9. Total liability

a)

Any further liability for compensation as provided for in no. 8 – regardless of the legal nature of the claim asserted – is excluded.

This applies in particular in the case of claims for damages arising from default upon conclusion of the contract, due to other breaches of duty or due to material damage on account of claims in tort in accordance with section 823 BGB (German Civil Code).

b)

The restriction according to (a) also applies if the customer in lieu of a claim to compensation for damages demands compensation of unnecessary expenditures in lieu of performance.

c)

If the liability for damages vis-a-vis Zimmer is excluded or restricted, this also applies with regard to the personal liability for damage of salaried employees, employees, members of staff, representatives and vicarious agents of Zimmer.

10. Applicable law – Place of jurisdiction – Place of delivery

a)

This licence agreement is subject to the laws of the Federal Republic of Germany.

b)

If the customer is a merchant, the registered office of Zimmer is the place of jurisdiction – however, Zimmer is entitled to select the court competent for the customer's domicile.

c)

Unless not stated otherwise in the order confirmation, the registered office of Zimmer is the place of fulfilment.

11. Severability clause

If any provisions of this licence agreement are or become ineffective, in whole or in part, this does not affect the efficacy of the remaining provisions.

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9.11. CE mark

The device bears the CE mark



in accordance with the EC directive on medical devices 93/42/EEC.

The device meets the essential requirements according to appendix I of this directive.

Manufacturer

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