XRCISE CARE

Software to control
medical exercise equipment

User Manual

Version 3.1

CE 0297

This user manual has been created with greatest possible diligence. Please inform us of any details that do not correspond to your training device so we can take care of this as quickly as possible.

Technical and optical modifications as well as misprints reserved.

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Manufacturer	**Cardiowise GmbH** Blocksbergstraße 165 66955 Pirmasens Tel.: 06331/2461-87 Fax.: 06331/2461-55 Email: contact@cardiowise.com Web: www.cardiowise.com
Authorised dealer	(dealer stamp)
Authorised service technician	(service stamp)
Document version	3.1
Applicable from software version	2.0

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1 General Information

1.1 About this User Manual

The user manual is only valid for the specified product version and only for the original equipment upon delivery of the product.

Changes made to the product later on may invalidate the user manual. In this case, observe the respective applicable manual or additional information.

This user manual is considered to be a component of the **XRCISE CARE Software** and must be kept accessible at all times.

Precisely following this user manual is a requirement for the proper and safe operation of the **XRCISE CARE.**

1.2 Symbols in the document

⚠ **CAUTION!**	Failure to observe this warning can easily lead to slight personal injury or result in damage to the product.

CAUTION!	Indicates a situation which could result in damage to the product.

!	*A hint contains valuable additional information or suggests measures for more efficient and simpler operation of the product.*

1.3 Abbreviations and terminology in the document

PC system	consisting of a PC, monitor, mouse, keyboard, and printer
Therapist	Software user. The therapist is a medical professional.
Borg scale	Scale for evaluating the perceived exertion
Operator	Person who bears the legal responsibility for operation of the product
Slot	Monitoring position in the **XRCISE CARE** software

2 Safety

2.1 Safety information

Observe the applicable legal and official requirements as well as the corresponding guidelines and directives of your local institution when using this device. The operator is responsible for compliance.	**Observe legal regulations**
The **XRCISE CARE Software** may only be used by instructed personnel with medical training! Instruction in use of the software is provided by the manufacturer or one of his authorised dealers following installation. The operator is responsible for educating and training the operating personnel.	**Training**
The PC system may only be set up in rooms which meet the locally applicable installation requirements. Please observe the further applicable documentation for the PC system.	**Setup location**
The product may only be installed by the manufacturer, his authorised dealer, or his authorised service technician. Installation includes configuration of the communication interfaces between the exercise equipment and the **XRCISE CARE Software**. This configuration is performed solely by the installer. The operator cannot perform assignment of the exercise equipment on his own. The user manual doesn't contain any information on the installation of exercise equipment. This information must be taken from the further applicable documentation for the exercise equipment. Both devices have to be turned off before connecting / disconnecting the exercise equipment and the PC. Otherwise communication problems or damage to the devices may result. The PC system must be set up so that it is outside of the patient environment. The patient environment is defined by a radius of 1.5 m around the exercise equipment. The therapist must not touch the patient and the PC system at the same time.	**Installation**
Third-party software on the PC may damage the **XRCISE CARE Software**, for example through viruses. The installation of third-party software on the PC is prohibited. An antivirus program is not included in the scope of delivery. The installation of antivirus software by the operator is only permitted following consultation with the manufacturer or his authorised dealer. The installed text editing software is Notepad.	**Combination with third-party software**
Connecting the PC to a network or to the internet may damage the **XRCISE CARE Software**. The operator bears full responsibility if he connects the PC system to a network or to the internet.	**Network and internet**

The PC system may only be connected to a mains grid with protective conductor. During use of the PC system, the supervising person must never touch the patient and an electrically operated device at the same time. The PC system must be located outside of the patient safety zone of 1.5 m around the exercise equipment.	**Electrical protection**
Only use mobile telephones and other devices that comply with EMC class B. Otherwise malfunctions may occur. The effects of radio signals on medical devices depend on a variety of factors, which means they cannot be predicted. The **XRCISE CARE Software** and the PC system may only be operated according to the intended use.	**Electromagnetic compatibility**
Changes or modifications to the device without the express approval of the manufacturer are not permissible. This could lead to increased electromagnetic radiation or reduced interference resistance of the device or system, and therefore affect the electromagnetic compatibility of the treadmill or other devices.	**Device modifications**
The PC system for the **XRCISE CARE** software may only be connected to medically approved exercise equipment.	**Combination with other devices**
Entry of liquids inside the PC system must be prevented. If liquids get into the device, pull the power cord immediately and contact the authorised service technician.	**Cleaning**
Dispose of the PC system and packaging according to national regulations.	**Disposal**

2.2 Special information for patient safety

CAUTION!	The exercise equipment may only be used by the patient under the instruction of a doctor. Use of the exercise equipment and accessories without instruction and without a supervising person is prohibited. The load applied by the exercise equipment must be set according to the patient's state of health and condition and must not be too high under any circumstances. Both incorrectly performed exercises and excessive stress due to the tests can be harmful to health. The therapist must define a maximum load limit which is matched to the patient. Exercising below this limit must not endanger the patient. Exercising above this limit is prohibited. The therapist must let the patient know about his/her personal perceived exertion (e.g. Borg scale) and encourage him/her to stop the training in case of subjective unpleasant sensations. The values displayed by the **XRCISE CARE** software are provided as guidance and don't replace the individual and direct monitoring of the patient. In order to ensure that the displayed values are correct, they must be double-checked by an independent measurement method. During training, the therapist must monitor the patient and their physiological parameters. The stress on the patient's cardiovascular system intentionally caused by the therapist by way of the training is the full responsibility of the therapist. Patients with restricted mobility must also wear a fall protection belt while training on the treadmill. The stored signals and measured values are intended for informational purposes. The therapist must review this data for plausibility.

2.3 Pictograms on the data media

Pictogram	Meaning
REF	Order number
	Manufacturer and manufacturing date
CE 0297	CE marking with identification number of the notified body. The product meets the fundamental requirements of the Medical Device Directive 93/42/EEC.

3 Description of the XRCISE CARE Software

3.1 Intended Use

The **XRCISE CARE** software is application software used to control medical exercise equipment. It runs on a standard PC according to EN 60950 and a Windows operating system.

The **XRCISE CARE** software is designed for use in medical training rooms or similar facilities.

The **XRCISE CARE** software allows for the simultaneous operation of up to 24 exercise machines.

Medical application of the **XRCISE CARE** software is solely permissible with medical ergometers and treadmills. The use of non-medical exercise equipment is permitted for training purposes. In this case the patient may not wear any sensors which require a cable for data transmission.

The values displayed and stored via the **XRCISE CARE** software are solely for informational purposes. They must be double-checked by the therapist with a measurement method which is independent from the system.

Performing stress tests with the **XRCISE CARE** software is prohibited.

3.2 Contraindications

The following patients must be excluded from training with the **XRCISE CARE** software:

- Patients with hypertrophic obstructive cardiomyopathy (HOCM).
- Patients who suffer from illness, vertigo, nausea, or pain.
- Patients under the influence of substances which may impair alertness (e.g. drugs, alcohol, medications).

3.3 Usage environment

The intended usage environments of the **XRCISE CARE** software are medical training rooms and facilities such as sports clubs, schools, hotels, clubs, rehabilitation centres and studios, where access and supervision is specifically regulated by the operating agency.

3.4 Users

The intended user of the **XRCISE CARE** software is a medical professional. Their practical experience and knowledge forms the prerequisite for patient safety.

3.5 Software - Functions

3.5.1 Overview

The **XRCISE CARE** software can be used to monitor and control up to 24 patients from one PC. Up to 8 patients can be supervised per monitor. Up to 3 monitors can be connected to one PC.

The **XRCISE CARE** software with its open structure offers many opportunities to design and monitor a training sequence.

The patient is able to train on a variety of exercise equipment or free / without equipment support. Exercise equipment which can be controlled via the **XRCISE CARE** software is listed in the section “Allowable combination with other devices". Free training can, for example, be performed on strength training equipment or as gymnastic exercises.

The software supports the following functions:

- Training with up to 24 patients
- Wireless ECG monitoring
- Saving ECGs
- Guideline oriented training
- Multi session training
- Intelli mode
- Pulse, stress, and interval training
- Automatic load adjust
- Analysis and documentation

The **XRCISE CARE** software receives the patient's physiological parameters from other medical products or exercise equipment and uses this information for the on-screen display and to control the exercise equipment.

To support the therapist, the **XRCISE CARE** software displays the physiological data from other medical measuring equipment (e.g. ECG, blood pressure, SpO2).

3.5.2 Data transfer method

Depending on the exercise equipment features, the data transfer between the exercise equipment and the PC can take place via a USB interface or a serial RS 232 interface.

Data transfer between the ECG sensor and the PC takes place wirelessly via Bluetooth®.

3.5.3 Multi session training

The individual design of a multi session training is possible for each patient. This multi session training executes up to five training units one after another, and the type of training and exercise equipment can vary from unit to unit. For example, a patient could start his training on a treadmill, then switch to the ergometer, follow this with free training using gymnastic exercises, and finally conclude his training unit with the ergometer. Thus they have completed 4 training units.

3.5.4 Individual or group training

A patient can either be entered in a slot for individual training or train within a group.

Group training makes sense if the same group of patients always shows up for a training session. These patients are put into a group in the **XRCISE CARE** software. At the start of training, the patients in the group can be assigned to the slots with a few simple mouse clicks. This saves time. The training itself can either be started for all patients at the same time, or individually per patient. As in the individual training, each patient in the group can go through their individual training.

3.5.5 Training on equipment

Training on an ergometer or treadmill is categorically divided into 5-phase training. It is divided into:

- **AP1** Warm-up phase 1
- **AP2** Warm-up phase 2
- **TP** Training phase
- **EP1** Recovery phase 1
- **EP2** Recovery phase 2

A constant load is applied in the phases AP1 and EP2, while the load is slowly increased or decreased in the phases AP2 and EP1. The load can also vary during the actual training phase.

The therapist enters the training parameter settings and adjusts them individually to each patient.

3.5.6 Pulse, load, and interval training as well as Intelli mode

A 5-phase training on equipment is performed under either load or pulse control.

A pulse-controlled training can only be performed with an ergometer training, not with a treadmill training. During a pulse controlled training, the heart rate signal of the applied ECG sensor is included in the ergometer load control. The therapist specifies a patient-dependent target heart rate. The **XRCISE CARE** software compares the current value from the ECG sensor with the specified target value and modifies the ergometer control signal correspondingly. This causes the ergometer to adjust the load to the patient.

During load controlled training, the therapist specifies the patient-dependent maximum load for the exercise equipment. During the 5-phase training, the exercise equipment increases the load up to the specified target value according to the specified training profile.

Interval training is always load controlled and can only be selected for ergometer training. During interval training, very short load phases alternate with short recovery phases. The advantage of interval training is the low stress on the cardiovascular system with simultaneous training of the musculature.

If the Intelli mode is activated during load controlled training, the load in the AP1 and EP2 phases is at a specific ratio relative to the load during the training phase. This ratio is defined in the configuration menu.

4 Commissioning

4.1 Setup conditions

CAUTION!	**Risk of personal injury** **due to electrically conductive connections between the patient and the PC!** Place the PC system outside of the patient environment. The patient environment is defined by a radius of 1.5 m around the exercise equipment. The therapist must not touch the patient and the PC system at the same time.

4.2 Scope of delivery

The **XRCISE CARE** software is installed on a PC system by the manufacturer.

A standard PC system consists of:

- PC
- Monitor
- Mouse
- Keyboard
- Printer
- XRCISE CARE Software
- USB dongle for operating the software

The signals from up to eight pieces of exercise equipment can be displayed on each monitor. Thus one or two additional monitors are required to view signals from 16 or 24 pieces of exercise equipment. These are connected to the existing PC system.

4.3 Installation

CAUTION!	**Risk of personal injury** **due to malfunction in combination with other devices!** The allowable device combinations are listed in the section "Allowable combination with other devices". Further device combinations can be requested from the manufacturer or from one of the manufacturer's authorised dealers.

CAUTION!	**Risk of device damage** **due to unauthorised installation!** The product may only be installed by the manufacturer, his authorised dealer, or his authorised service technician.

CAUTION!	**Risk of damage to the system through the addition or removal of hardware while the system is on!** Turn both devices off before you connect / disconnect the exercise equipment and the PC.

The supplied PC system was pre-configured at the factory. The configuration includes assignment of the exercise equipment to the **XRCISE CARE** software. The operating agency cannot make unauthorised changes to either the configuration or assignment of the exercise equipment. Both the configuration and the assignment can be changed later on by the manufacturer or the manufacturer's authorised dealer.

Specifying limits and training ranges is not part of the configuration. These are defined later on according to the patient.

This user manual doesn't contain any information on the installation of exercise equipment. This information must be taken from the further applicable documentation for the exercise equipment.

4.3.1 Dongle

The **XRCISE CARE** software can only be used in conjunction with the supplied licensing dongle. One dongle is required per PC. You can continue using the existing licensing dongle after a software update.

4.3.2 Operation in a network

The **XRCISE CARE** software is able to transfer data to another PC later on. This review PC is connected to the training PC system via an Ethernet network which can be located in a different room. This review PC is also installed by the installer.

4.4 Prior to Commissioning

Following installation, the manufacturer or the manufacturer's authorised dealer performs a functional test as well as training of the user(s). The training must be documented.

5 Operation

5.1 Overview of the home screen

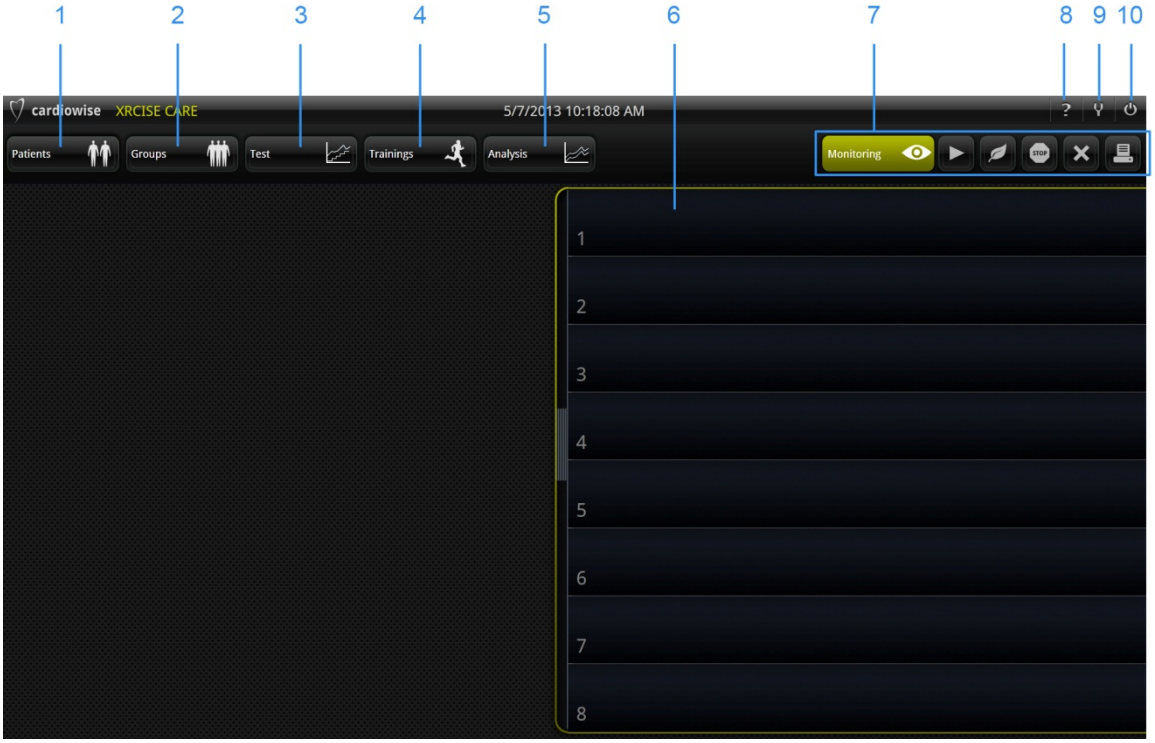
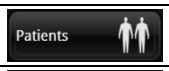
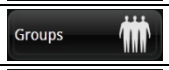
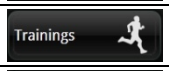
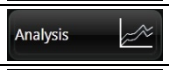
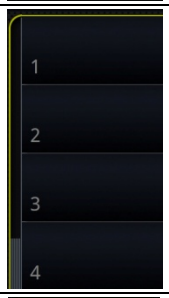


Figure 1 Home screen

1		**Patients** button	Opens the **Patient view** menu
2		**Groups** Button	Opens the **Group view** menu
3		**Tests** button	Opens the **Tests** menu for the individual patient
4		**Trainings** button	Opens the **Trainings** menu for the individual patient
5		**Analyses** button	Opens the **Training analysis** menu for the individual patient
6		List of slots	Shows the monitoring positions (slots) as a list
7		**Monitoring** button	Opens the **Monitoring view** and shows all slots
		**Start** button	Starts the training for all slots simultaneously
		**Recovery phase** button	Initiates the recovery phase EP1 for all active trainings
		**Stop** button	Stops the current training unit in all slots
		**Remove** button	Removes all inactive trainings from the slots
		**Print** button	At the end of the training, prints the completed training for all patients in the slots
8		**About** button	Opens the **Information screen** about the software
9		**Configuration** button	Opens the **Service menu** (only for service technicians)
10		**Exit** button	Closes the program

5.2 Overview of the operating procedure

Due to the large degree of flexibility offered by the **XRCISE CARE** software, the operating procedure can vary according to the requirements in the medical facility. Two examples are provided below for guidance.

5.2.1 Individual training example

	Process	Information and reference to section
1	Enter the patient and define the training sequence for the patient	Section 5.4.3 "Entering patient data" and section 5.6 "Trainings"
2	Select the patient	Section 5.8.1 "Assigning exercise equipment and sensor to a patient"
3	assign an ECG sensor to the patient	This assignment automatically transfers the patient to a slot.
4	Assign the patient to a piece of exercise equipment	Section 5.8.1 "Assigning exercise equipment and sensor to a patient"
5	apply an ECG sensor to the patient	Observe the further applicable documentation for the sensor.
6	Instruct the patient in the use of the exercise equipment	Observe the further applicable documentation for the exercise equipment
7	Check patient dependent training parameters	Section 5.9 "Monitoring menu"
8	Start the training	Section 5.11.1 "Starting the training"
9	Monitor the training	Section 5.11.2 "Monitor the training"
10	Ending the training	Section 5.11.3 "Initiating the recovery phase manually"
11	Remove the patient from the slot	Section 5.11.5 "Removing patients from the slots"

5.2.2 Group training example

	Process	Information and reference to section
1	Enter the patient and define the training sequence for each patient	Section 5.4.3 "Entering patient data" and section 5.6 "Trainings"
2	Create a training group and assign patients	Section 5.5 "Group view menu"
3	Select the training group	Section 5.5 "Group view menu"
4	assign an ECG sensor to each patient	This assignment automatically transfers the patient to a slot.
5	assign a piece of exercise equipment to each patient	Section 5.8.1 "Assigning exercise equipment and sensor to a patient"
6	apply an ECG sensor to each patient	Observe the further applicable documentation for the sensor.
7	Instruct each patient in the use of the exercise equipment	Observe the further applicable documentation for the exercise equipment
8	Check patient dependent training parameters	Section 5.9 "Monitoring menu"

9	Start the training	Section 5.11.1 "Starting the training"
10	Monitor the training	Section 5.11.2 "Monitor the training"
11	Ending the training	Section 5.11.3 "Initiating the recovery phase manually"
12	Remove the training group from the slot	Section 5.11.5 "Removing patients from the slots"

5.3 Starting the XRCISE CARE software

CAUTION!	**Risk** **- of damage to the system through the addition or removal of hardware while the system is on!** Turn both devices off before you connect / disconnect the exercise equipment and the PC. **- of communication problems due to incorrect power-on sequence!** Always turn the exercise equipment and the PC on in the following order: 1. Exercise equipment and sensors 2. PC system and **XRCISE CARE** software.

Process

- Start the PC system.
- Wait a few minutes.
  The system starts up and the background services start.
- Open the software by double-clicking on the symbol.

  The internal configurations are checked while the software starts. This check can take a few minutes. The home screen is displayed once the checks are complete.
  The screen configuration adjusts itself automatically and is dependent on the number of pieces of exercise equipment and the configuration settings.

5.4 Patient view

In this menu you can:

- Search for existing patients
- Edit patient data
- Create a new patient
- Assign a new patient to a device.

Process

- Click on the **Patients** button.
  The **Patient view** menu appears with a list of all entered patients.

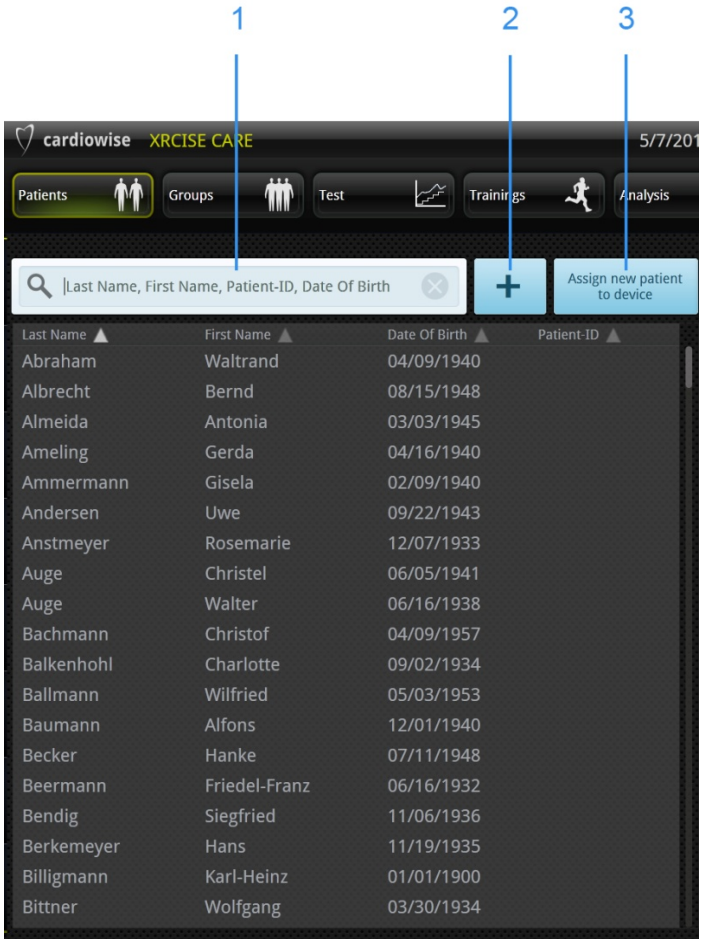


Figure 2 Patient view with a list of the entered patients

1	Patient search field	Entry field for the patient search
2	**New patient** button	Opens the menu to enter patient data
3	**Device assignment** button	Opens the menu for device assignment and creates a new patient.

5.4.1 Searching for a patient

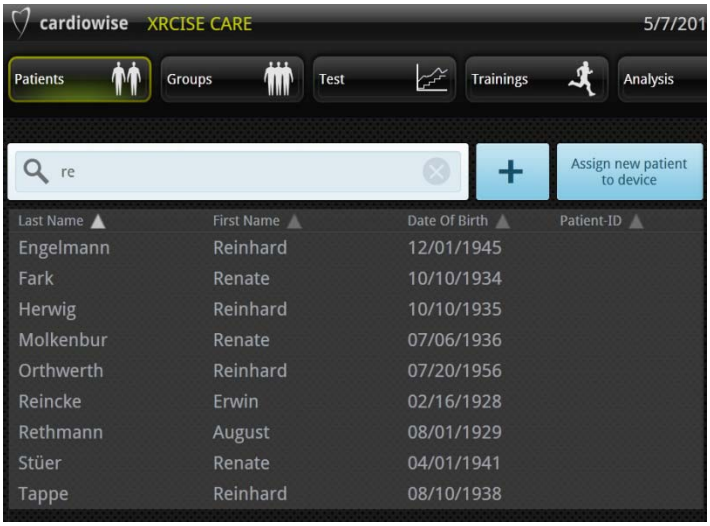


Figure 3 Patient search

You can use the patient search field to search for a specific patient or to filter for specific values.

- Enter the desired value.
  A list of matching patients is displayed.

Example of a filter selection:

%	Lists all listed patients
"r" or "reg"	Entering one or more letters lists all patients whose first or last name starts with this letter or series of letters.
1234567	Entering the patient ID finds the corresponding patient
11.11.1911	Entering the date of birth finds the corresponding patient

5.4.2 Sort by patient data

In the patient view, the patient data can be sorted by the displayed values **name, first name, date of birth, and patient ID**.

- Click on the ▲ symbol to the right beside the term.
  The patient list is re-sorted accordingly.

5.4.3 Entering patient data

CAUTION!	**Risk of health problems due to excessive stress!** Both incorrectly performed exercises and excessive stress due to the tests can be harmful to health. Set the load so that it corresponds to the patient's state of health and condition. It must not be too high under any circumstances. Exercising below this limit must not endanger the patient.

Entering the patient data before beginning a training is not essential. The training can also be started by assigning a new patient to a slot. The patient data can be entered during or after the training.

In this menu you can:

- Create a new patient
- Enter the patient master data
- Assign diagnosis data to the patient
- Define limits for the patient's blood pressure, oxygen saturation, and heart rate

Process

1. Click on the **New patient** button. 
   The "Patient data" input field appears
2. Enter the personal data.
3. Save it.
   The patient's name is displayed beneath the **Patient** button and as "active patient" label.

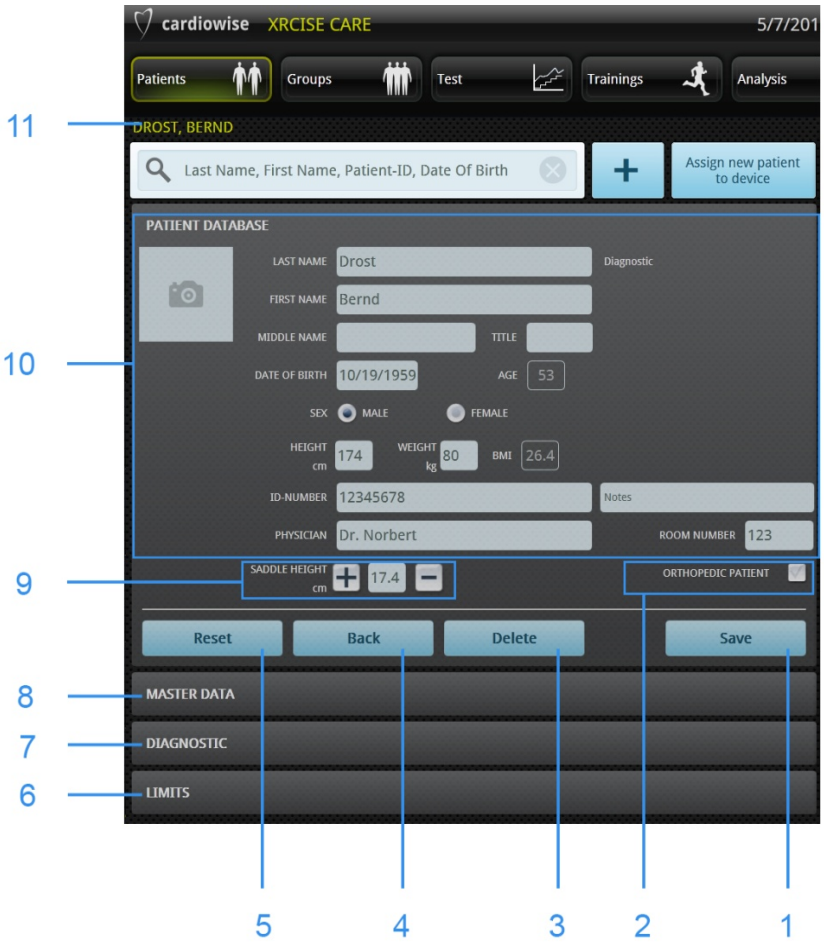


Figure 4 Patient data

1	**Save** button	Saves the entered data
2	**Orthopaedic patient** checkbox	Sets the seat height to 0 for easier mounting, the specified seat height is only adjusted automatically once the training is started
3	**Delete** button	Removes the patient from the **Patient view**
4	**Back** button	Opens the **Device assignment** menu for the selected patient
5	**Reset** button	Resets all entered data
6	**Limits** button	Opens the **limits** input field
7	**Diagnostics** button	Opens the **diagnostics** input field
8	**Master data** button	Opens the **master data** input field
9	Input field for the **seat height**	Used for automatic adjustment of the seat height
10	Input field for the **patient data**	Contains the patient data as well as a summary of the data entered under **diagnostics**
11	"active patient" label	The patient's name appears here after the entered data have been saved

Enter master data

The patient's contact data are stored in the **master data** input field.

Figure 5 Master data

Assign diagnosis

Potential pre-existing conditions are shown in the **diagnostics** list. One or more diagnoses from this list can be assigned to the patient.

This list of pre-existing conditions can help the therapist decide whether or not a patient is allowed to participate in the training and what stress they can be subjected to. However, it must not be the sole source of decision-making information.

Contraindications for training are listed in the section "Contraindications".

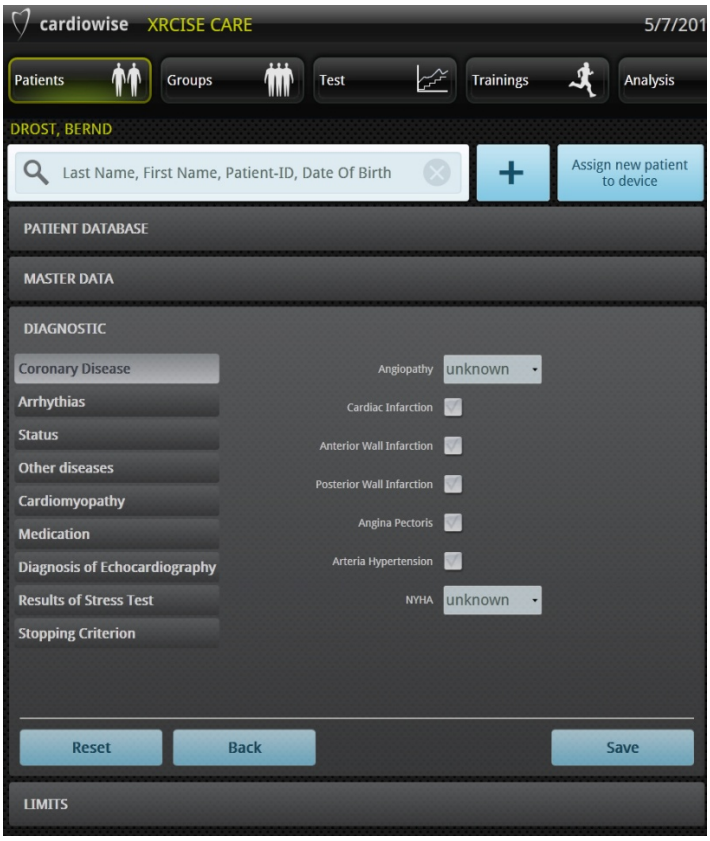


Figure 6 Diagnosis

Define limits

Defining the blood glucose limits provides an overview and can serve as an orientation aid for the therapist.

If the blood glucose values, the heart rate values, and the oxygen saturation values are measured during training, then the values which lie outside of the specified limits are highlighted in red in the **Monitoring** menu. An audible signal can also be specified.

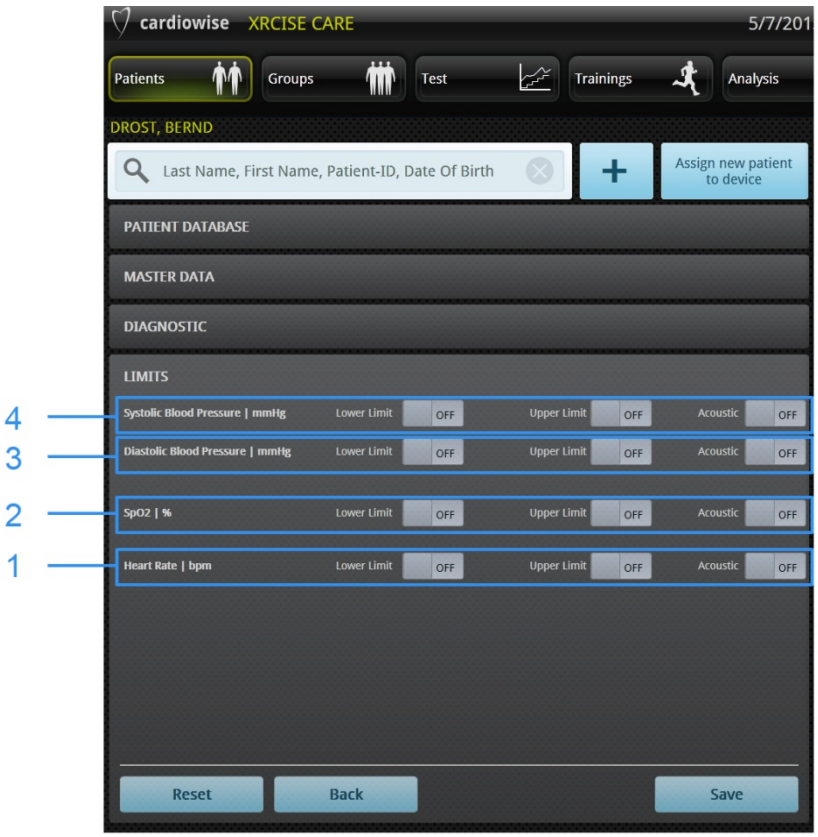


Figure 7 Define limits

1	Nominal heart rate range
2	Nominal blood oxygen saturation range
3	Nominal diastolic blood pressure range
4	Nominal systolic blood pressure range

5.4.4 Edit patient data

The patient data can be edited at any time as soon as you are in the **patient data** input field.

If the patient data need to be modified while a training session is in progress, double-click on the patient name in the **Monitoring** menu. The **patient data** input field appears.

5.5 Group view menu

In this menu you can:

- Search for existing patient groups
- Edit group data
- Create a new group
- Assign a group to slots

Process

- Click on the **Groups** button.
  The **Group view** menu appears with a list of all entered patient groups.

Figure 8 Group view

1	**Groups** Button	Opens the **Group view** menu
2	**New group** button	Opens the menu for creating a new group
3	**Assign group** button	Assigns the patients in the group to the slots
4	Group list	Overview of the created groups

5.5.1 Search for a group

In the group search field, you can search for a specific group or filter for specific values.

- Enter the desired value.
  The list of groups matching the entered values is displayed.

Example of a filter selection:

%	Retrieves all listed groups
"r" or "reg"	Entering one or more letters lists all groups whose name starts with this letter or series of letters

5.5.2 Create a new group

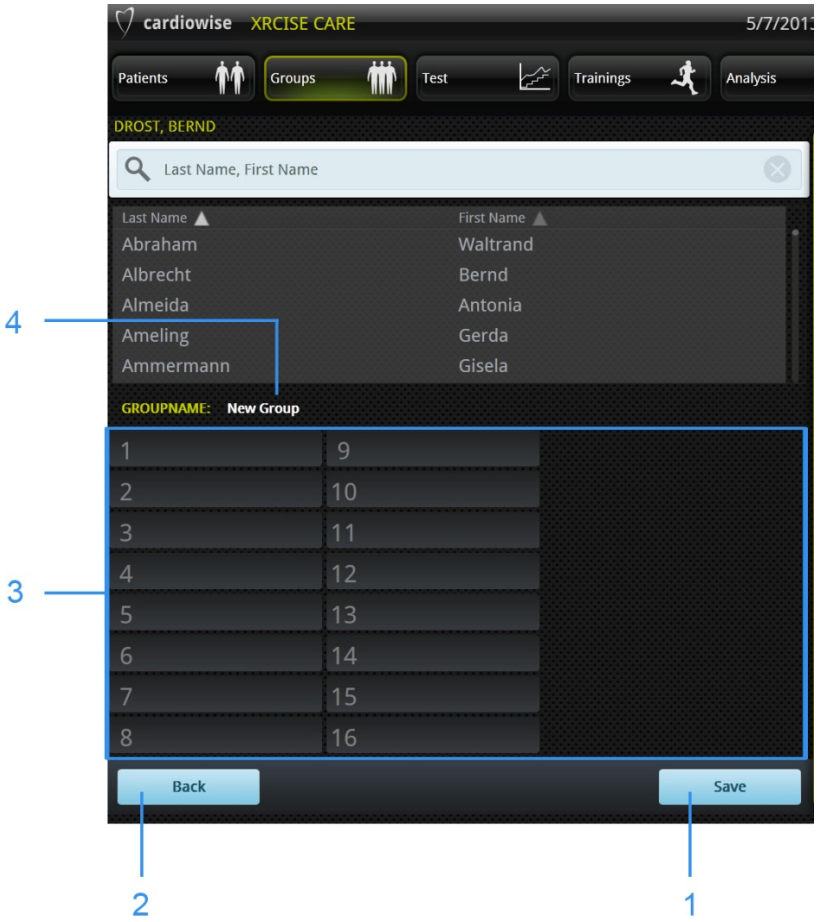


Figure 9 New group

1	**Save** button	Saves the entered values
2	**Back** button	Opens the group view
3	Group members list	Overview of the patients in the group
4	Group name	The name of the group

Process

1. Click on the **New group** button**.**
2. Click on the group name.
3. Rename the group.
4. Select a patient who should be added to this group.
5. Drag & drop to add the patient to the list of group members.
6. Repeat the steps 4 and 5 until the group is complete.
7. Save it.

Each patient can only be added to the current group once. Patients which have already been assigned to this group cannot be selected again. They are indicated by a dark grey font colour.

Removing a patient from a group

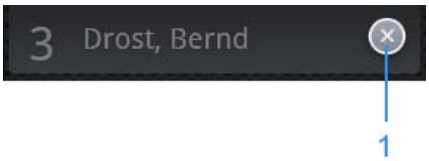


Figure 10 Patient in the list of group members

1	**Remove** button	Removes the patient from the list of group members

- Click on the **Remove** button beside the patient's name.

5.5.3 Assigning a group to slots

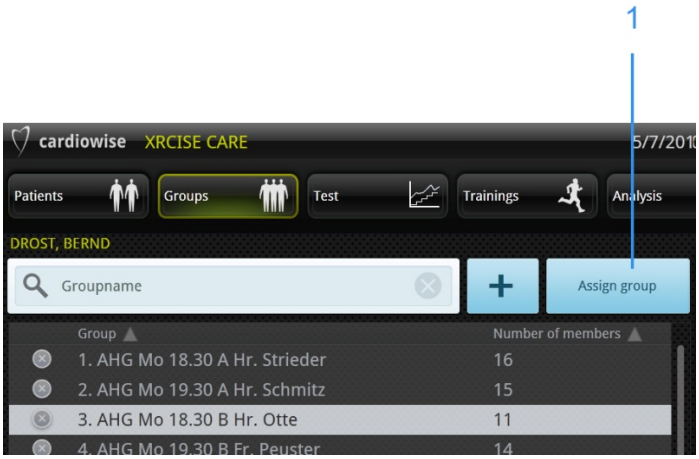


Figure 11 Assigning a group

1	**Assign group** button	Assigns the patients in the group to the slots

In order to perform a training with an existing patient group, the group must be entered in the slots.

Process

1. Select the desired group.
2. Click on the **Assign group** button**.**
3. The patients who were added to this group appear in the slots.
4. Assign the patients in the slots to the devices or the corresponding training room.
   See section 5.8.3 "Changing the assigned exercise equipment" and section 5.8.4 "Changing the assigned sensor”.

5.6 Tests menu

CAUTION!	The tests are not intended for determining the patient's personal limits. Tests during which the patient enters an effort level which requires reliable monitoring of the ECGs must not be performed with the **XRCISE CARE** software (e.g. maximum workout test). Both incorrectly performed exercises and excessive stress due to the tests can be harmful to health. The therapist must let the patient know about his/her personal perceived exertion (e.g. Borg scale) and encourage him/her to stop the training in case of subjective unpleasant sensations. The values displayed by the **XRCISE CARE** software are provided as guidance and don't replace the individual and direct monitoring of the patient. In order to ensure that the displayed values are correct, they must be double-checked by an independent measurement method.

In this menu you can:

- Assign a standard ramp test to a patient
- Create a new test for a patient
- Modify the values for the added tests.

Process

- Select a patient.
- Assign a sensor and a piece of exercise equipment to the patient.
- Click on the **Tests** button.
  The overview of the stress tests is displayed

For diagnostics purposes, the **XRCISE CARE** software provides a range of standard ramp tests from cardiology and sports medicine.

These subject the patient to a stress test according to specified values - this serves to determine the patient's CURRENT performance level. The values are increased incrementally until the patient can no longer generate the requested values (e.g. cadence on the ergometer). Then the **XRCISE CARE** software ends the test and creates a new training in which the performance values are incorporated. The training values are updated correspondingly if the test is performed again.

The standard ramp tests can neither be deleted nor modified.

The **XRCISE CARE** software provides the ability to create your own tests with modifiable values.

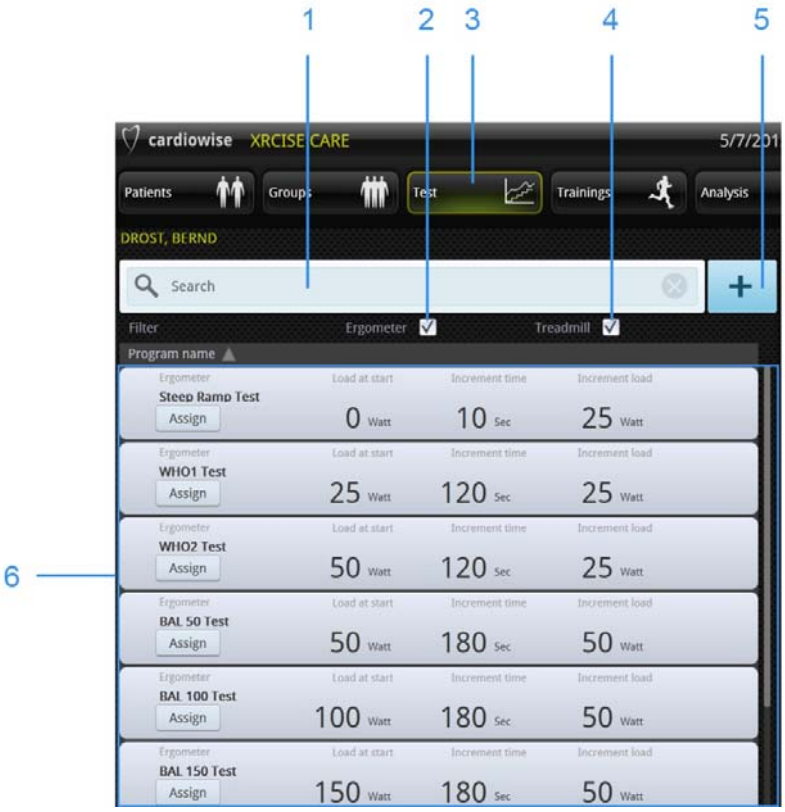


Figure 12 Tests menu

1	Test search field	Input field for search tests
2	Filter "ergometer tests"	When activated, displays all ergometer tests
3	**Tests** button	Opens the **Tests** menu
4	Filter "treadmill tests"	When activated, displays all treadmill tests
5	**New test** button	Creates a new test
6	List of results for a test search	Displays the results of the test search

5.6.1 Searching for a test

In the test search field, you can search for a specific test or filter for specific values.

- Enter the desired value.
  The list of tests matching the entered values is displayed.

5.6.2 Assign test

1. Select the patient in the **patient view** menu.
   The **device assignment** view opens.
2. Assign an ECG sensor and a piece of exercise equipment to the patient.
3. Click on the **Tests** button.
4. Select a test.
5. Assign the patient to the selected test.

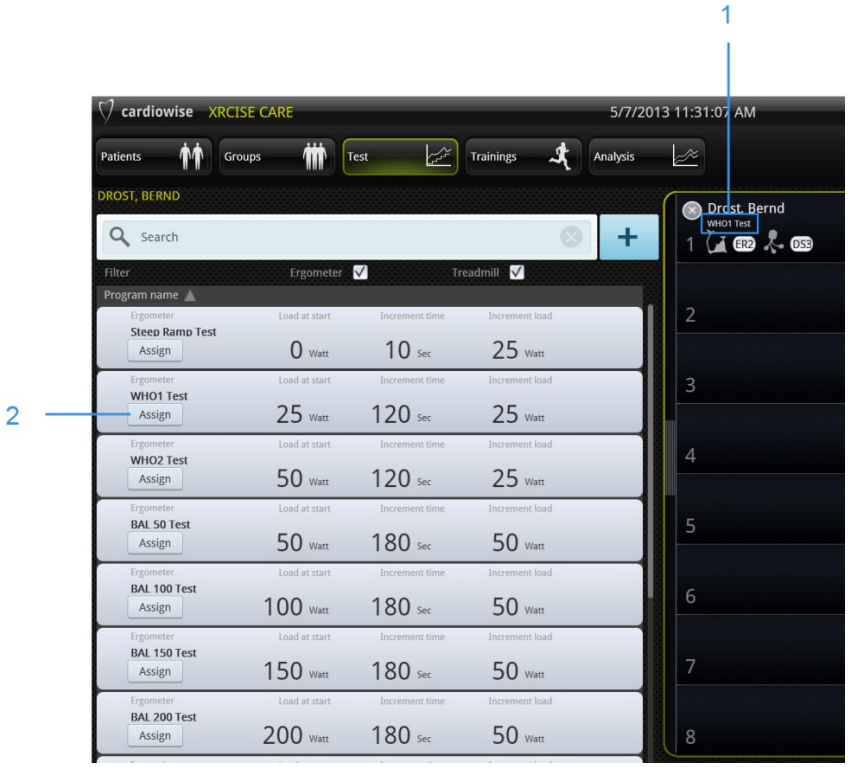


Figure 13 Assigning a test

1	Assigned test or training display field	Shows the name of the assigned test or training
2	**Assign test** button	Assigns the test to the patient

5.6.3 Creating a new test

Process

1. Select a patient.
2. Click on the **Tests** button.
   A test overview with a list of all created tests is displayed.
3. Click on the **New test** button. 
   A selection window opens.
4. Select the type of test.
   A new test opens.
5. Name the test.
6. Enter the values.
7. Save it.

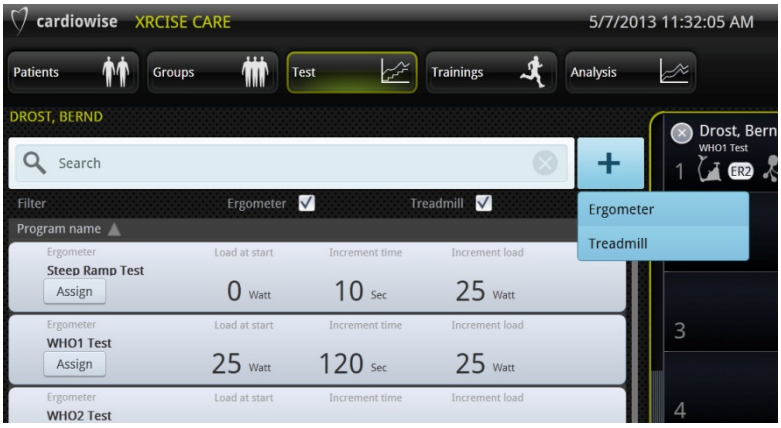


Figure 14 Creating a new test with the test type selection window

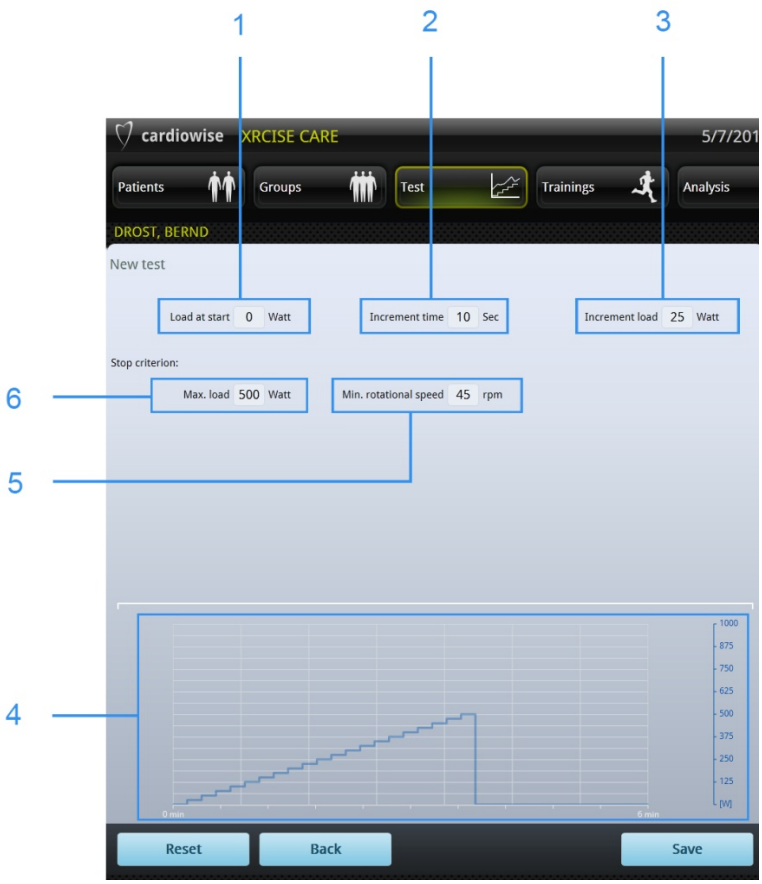


Figure 15 New ergometer test

1	Input field **Starting load**	Shows the starting load for the test
2	Input field **Time interval**	Shows the time interval until the next load increase
3	Input field **Load increase**	Shows the value by which the load is increased
4	Test diagram	Displays the load over the course of the test
5	Input field **Minimum speed**	Shows the minimum speed which must be maintained, the test ends automatically if the speed falls below this value
6	Input field **Maximum load**	Shows the highest load value

5.7 Trainings

CAUTION!

The load applied by the exercise equipment must be set according to the patient's state of health and condition and must not be too high under any circumstances. Both incorrectly performed exercises and excessive stress due to the tests can be harmful to health.

The therapist must define a maximum load limit which is matched to the patient. Exercising below this limit must not endanger the patient. Exercising above this limit is prohibited.

The therapist must let the patient know about his/her personal perceived exertion (e.g. Borg scale) and encourage him/her to stop the training in case of subjective unpleasant sensations.

The values displayed by the **XRCISE CARE** software are provided as guidance and don't replace the individual and direct monitoring of the patient. In order to ensure that the displayed values are correct, they must be double-checked by an independent measurement method.

You can also change a value during the training process. The last specified value is automatically assumed and saved for the patient after the end of the training. When this training is opened again, the patient starts with the last specified values.

In this menu you can:

- Search for existing trainings
- Edit training data
- Create a new training profile for a patient
- Select a training for a patient.

The following training types can be selected:

- Ergometer training
- Treadmill training
- Free training

The following fundamental control methods for training with equipment are distinguished:

Pulse controlled training	During the training, the load produced by the exercise equipment is automatically regulated until the patient has reached their preset maximum heart rate.
Load controlled training	During the training, the load produced by the exercise equipment is automatically increased until the specified maximum load has been reached.
Interval training	Only for the ergometer. During interval training, very short load phases alternate with short recovery phases.

A training categorically consists of five training phases:

- **AP1** Warm-up phase 1
- **AP2** Warm-up phase 2
- **TP** Training phase
- **EP1** Recovery phase 1
- **EP2** Recovery phase 2

Process

- Select a patient.
- Click on the **Trainings** button.
  An overview of the trainings is displayed.

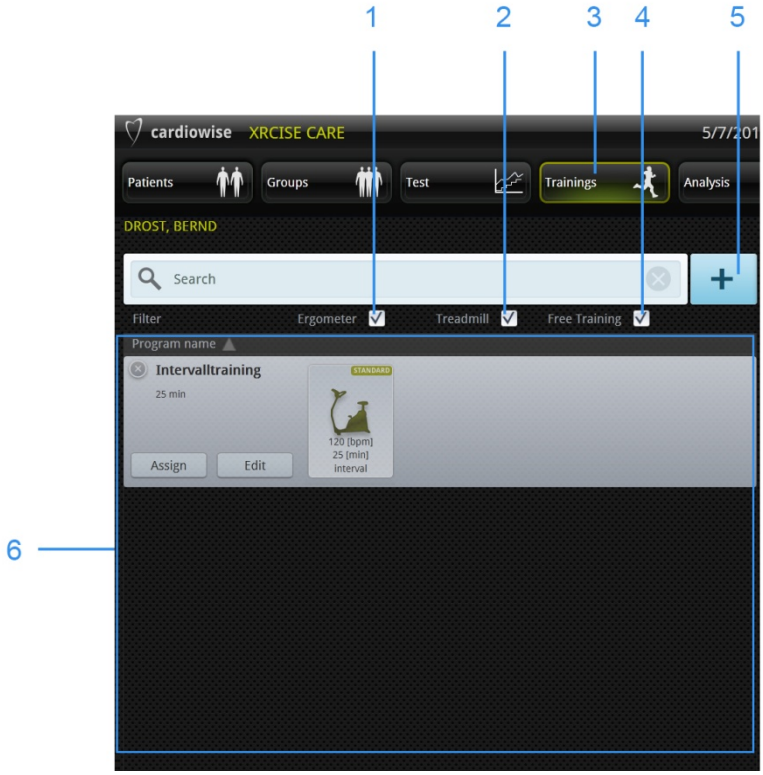


Figure 16 Trainings menu

1	"Ergometer training" filter	When activated, displays all ergometer training types
2	"Treadmill training" filter	When activated, displays all treadmill training types
3	**Trainings** button	Opens the **Trainings** menu
4	"Free training" filter	When activated, displays all free training types
5	**New training** button	Creates a new training
6	Training search results list	Displays the results of the trainings search

5.7.1 Searching for a training

In the training search field, you can search for a specific training or filter for specific values.

- Enter the desired value.
  A list of matching trainings is displayed.

5.7.2 Training in detail

Process

- In the trainings overview, click on the **Edit** button**.**
  A detailed view of the selected training is displayed.

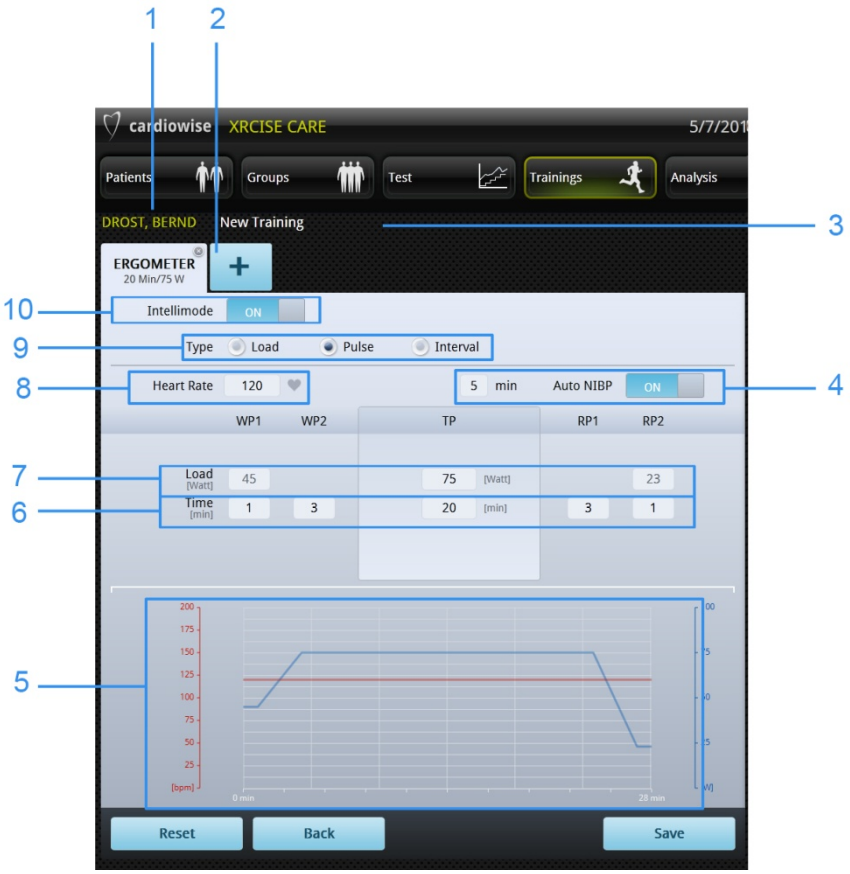


Figure 17 Training on pulse controlled basis

1	"active patient" label	Shows the selected patient
2	**Add training unit** button	Adds an additional training unit
3	Name of the training	Provides an overview
4	Blood pressure measurement	When "ON", sets the time intervals of the automatic blood pressure measurement (BPM) to the specified interval
5	Training diagram	Displays the load during the training and the maximum heart rate
6	Time indicator	Shows the duration of the individual training phases
7	Load indicator	Shows the load for the individual training phases
8	Heart rate	Used as a patient-specific limit during pulse controlled training for automatic control of the load
9	Training control method	Shows the training control method
10	Intelli mode ON/OFF	When "ON", specifies the load during AP1 and EP2 depending on the load values of the training phase TP

Time settings

The duration of a training phase can be specified individually for every phase.

Load settings

The load can only be specified for the phases AP1, TP, and EP2. In the phases AP2 and EP1, the load is regulated automatically by the **XRCISE CARE** software.

If the Intelli mode is active, the **XRCISE CARE** software regulates the load during AP1 and EP2 based on the load values for the training phase.

Heart rate

Defining the maximum heart rate is used during pulse controlled ergometer training to regulate the load automatically. During load controlled training, the heart rate is displayed but doesn't affect execution of the training.

Editing the values

You can edit and save the training values. The values are saved per patient.

Interval training

Interval training is a training type. It is always load controlled and can only be selected for ergometer training. During interval training, very short load phases alternate with short recovery phases.

The Intelli mode is activated during interval training.

The standard software presets provide two cycles during the training phase TP. This setting can be changed in the configuration.

The load and time for each cycle can be defined individually.

The Intelli mode uses the smallest defined load value during the training phase TP for the load values during the warm-up phase AP1 and the recovery phase EP2.

The cycles are repeated until the preset time for the training phase has expired.

During the warm-up phase AP2 and the recovery phase EP1, the duration of the respective phase is controlled by the number of cycles. The Intelli mode adjusts the load.

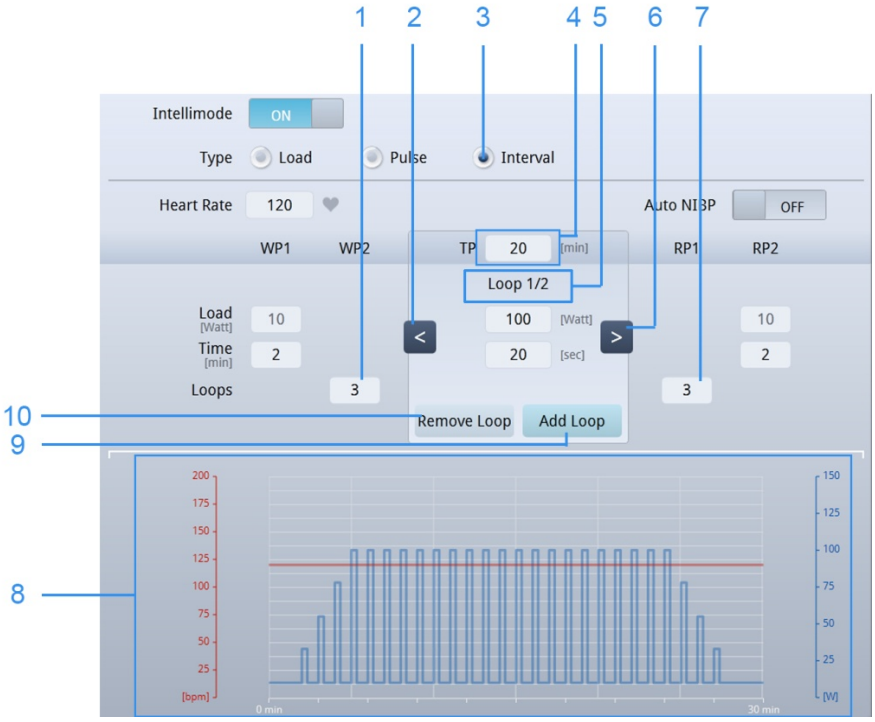


Figure 18 Adjusting the cycles in detail

1	"AP2 cycles" display field	Shows the number of cycles during the warm-up phase AP2
2	"Back" arrow button	Moves to the previous cycle
3	"Interval training" selection	Activates interval training
4	Duration	Shows the duration of the training phase
5	"Current cycle" display field	Shows the current cycle
6	"Forward" button	Moves to the next cycle
7	"EP1 cycles" display field	Shows the number of cycles during the recovery phase EP1
8	Training diagram	Displays the load during the training and the maximum heart rate
9	**Add** button	Adds a cycle
10	**Remove** button	Removes the current cycle

5.7.3 Creating a new training

Process

- Select a patient.
- Click on the **Trainings** button.
  A training overview with a list of all created trainings is displayed.

1. Click on the **New training** button. 
   A selection window opens.
2. Select the training type.
   A new training opens.
3. Name the training.
4. Enter the values.
5. Save it.

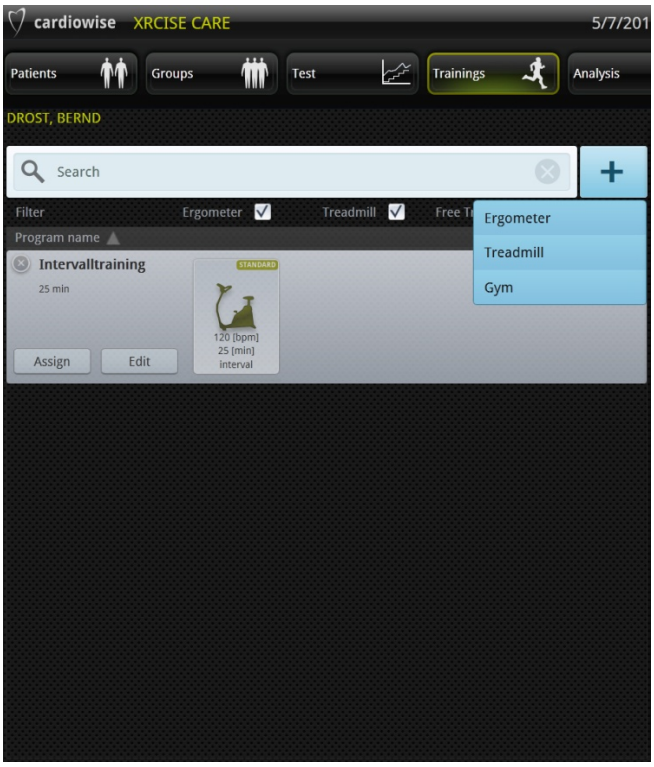


Figure 19 Creating a new training with the training type selection window

5.7.4 Free training

When you create a new training, you have the option of defining a free training.

Example: Gymnastics:

1. Create a new training and select "*Gymnastics"* from the drop down menu.
2. Name the training.
3. Define a training duration.
4. Define the maximum heart rate which the patient should not exceed. The heart rate is measured during the training by an applied ECG sensor.
5. If required, add a description of the training.
6. Save it.

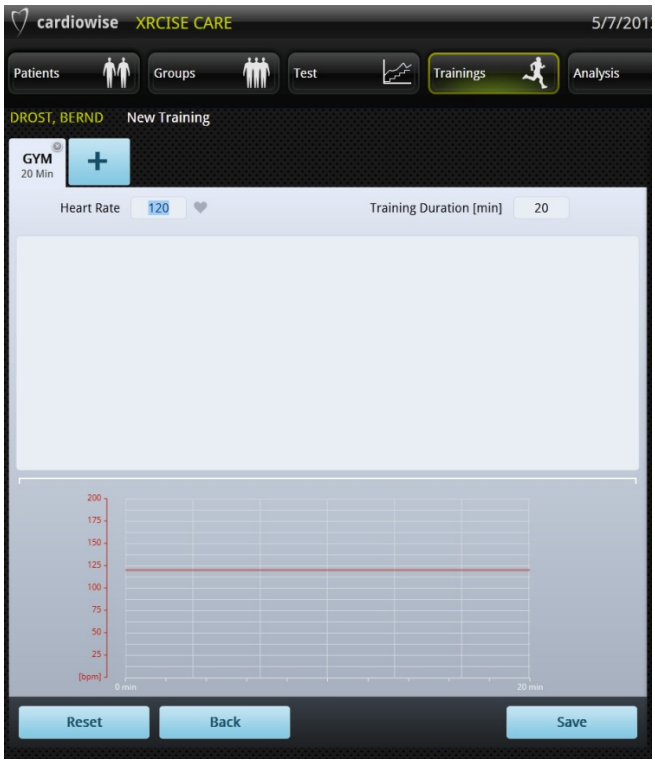


Figure 20 Free training

5.7.5 Creating a multi session training

A training can consist of up to five training units. The training units can be defined individually and independently of one another.

When the training is started from the **Monitoring** menu, the training units are processed according to the current piece of exercise equipment.

- Switch the exercise equipment to change the sequence of the training units.
  See section 5.8.3 "Changing the assigned exercise equipment".
- To remove a training unit, click on the ⊗ button in the tab.

*If a patient was added to a slot and an ergometer, for example, is assigned to this slot but the first training unit for this patient contains a treadmill, then the **XRCISE CARE** software re-sorts all training units accordingly.*
If the sequence of training units needs to be changed during a training, then the patient must switch exercise equipment and the therapist must change the piece of exercise equipment assigned in the slot accordingly.

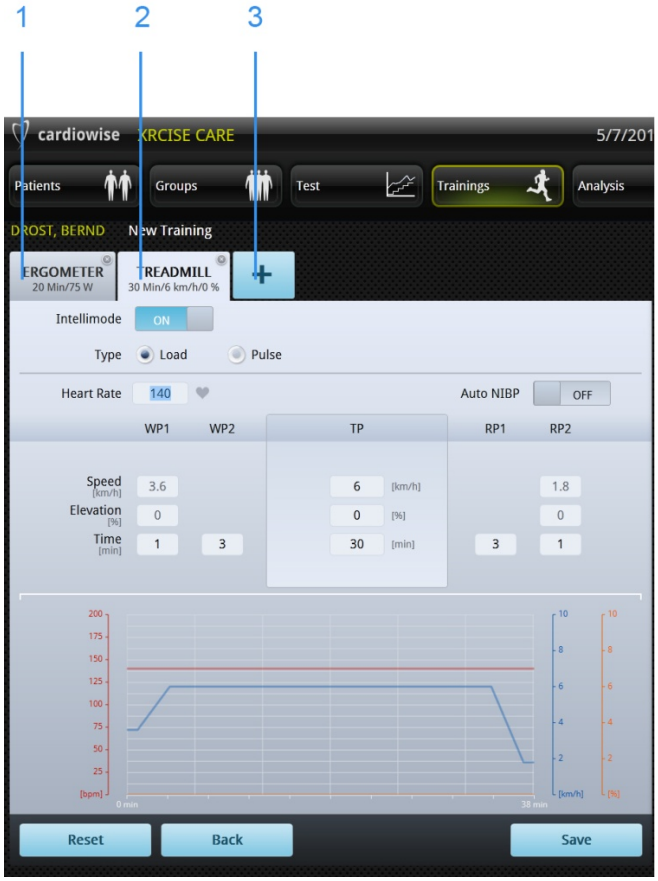


Figure 21 Training with two training units

1	"Training unit 1" tab	Opens training unit 1
2	"Training unit 2" tab	Opens training unit 2
3	**Add training unit** button	Adds an additional training unit

5.8 Assigning a patient to a slot

A slot represents a monitoring position. The following items can be assigned to a slot:

- Patient
- ECG sensor
- Exercise equipment

Assignment of a piece of exercise equipment to a slot is based on the configuration of the **XRCISE CARE** software during installation. During this configuration process, a piece of exercise equipment was either assigned to a fixed slot or you have the option of assigning the exercise equipment freely.

Before a training can be started, a patient must be assigned to the slot and a piece of exercise equipment must be assigned to the patient.

5.8.1 Assigning exercise equipment and sensor to a patient

1. Select the patient in the **patient view** menu.

   The **device assignment** view opens.

2. Assign an ECG sensor and a piece of exercise equipment to the patient by clicking on the corresponding device.

   The entry appears in the slot as soon as a device has been assigned to the patient.

   If the **XRCISE CARE** software was configured so that the exercise equipment is assigned to a fixed slot, then the patient is displayed in the slot for the corresponding piece of exercise equipment.

   If the exercise equipment is assigned freely, then the patient is displayed in the next available slot.

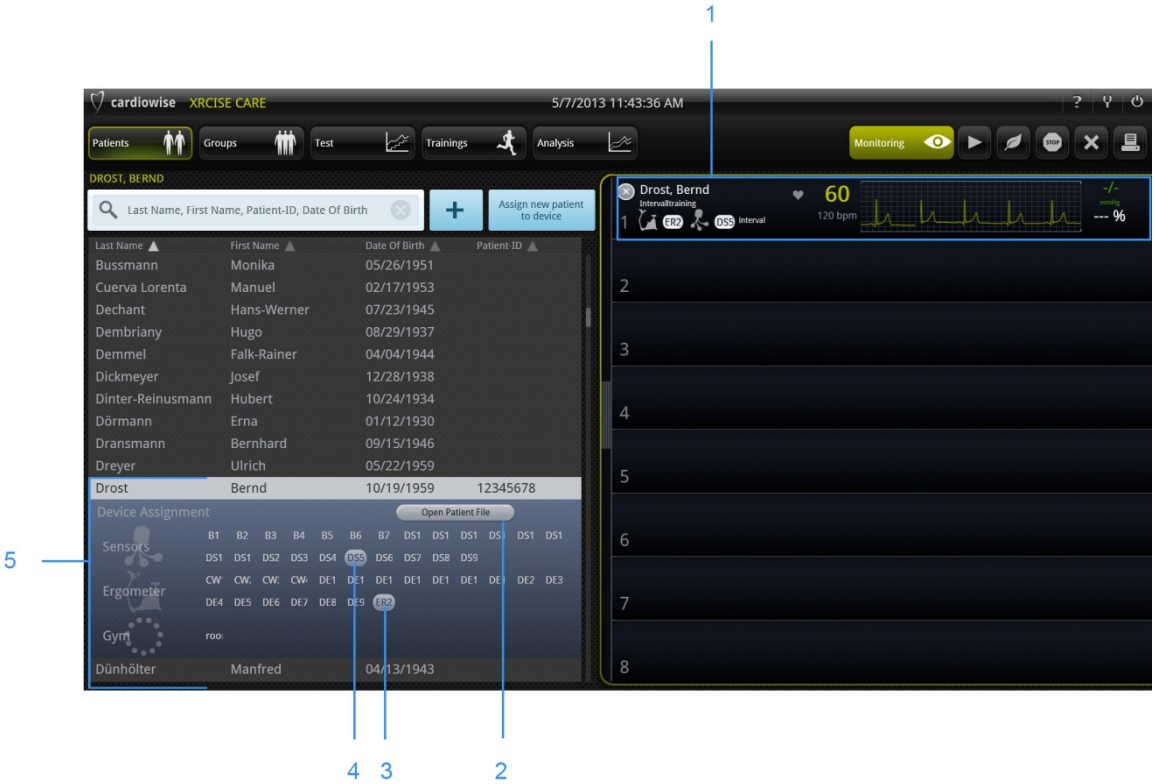


Figure 22 Device assignment view

1	Display of the patient in the slot	The assigned ECG sensor and piece of exercise equipment are displayed. During the training, the ECG signal, heart rate, blood pressure, and SpO2 are also shown if they are available.
2	**Open patient file** button	Opens the patient file for the selected patient
3	Assigned exercise equipment	The patient is shown in the slot with the assigned exercise equipment
4	Assigned sensor	The patient is shown in the slot with the assigned sensor
5	Device assignment view	Overview of the ECG sensors and exercise equipment for assignment to the patient

The last training selected for the patient is the default training for this patient for the next training session.

5.8.2 Removing individual patients from the slot

This function requires that the patient is not currently in a training session.

- Click on the ⊗ **Remove** button in the corresponding slot.
  The patient is removed from the slot.

Figure 23 Occupied slot

1	**Remove** button	Removes the patient from the slot
2	**Sensor** button	Used to change or deactivate the ECG sensor
3	**Exercise equipment** button	Used to change the exercise equipment

5.8.3 Changing the assigned exercise equipment

This function requires that the patient is not currently in a training session.

1. Click on the **Exercise equipment** button in the slot.
   The **Exercise equipment** drop down menu opens. The list of available pieces of exercise equipment is displayed.
2. Click on the desired exercise equipment.
   The number of the selected piece of exercise equipment is shown in the **Exercise equipment** button.

5.8.4 Changing the assigned sensor

1. The assigned sensor can also be changed during an active training session. Click on the **Sensor** button in the slot.

   The **Sensors** drop down menu opens. The list of available sensors is displayed.

2. Click on the desired sensor.

   The number of the selected sensor is shown in the **Sensor** button.

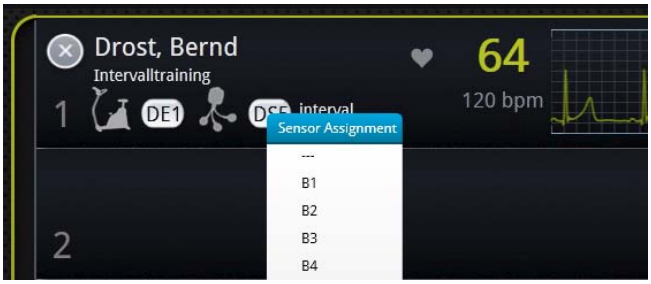


Figure 24 Changing the assigned sensor

5.9 Monitoring menu

The monitoring view is used to monitor the patient data during the training.

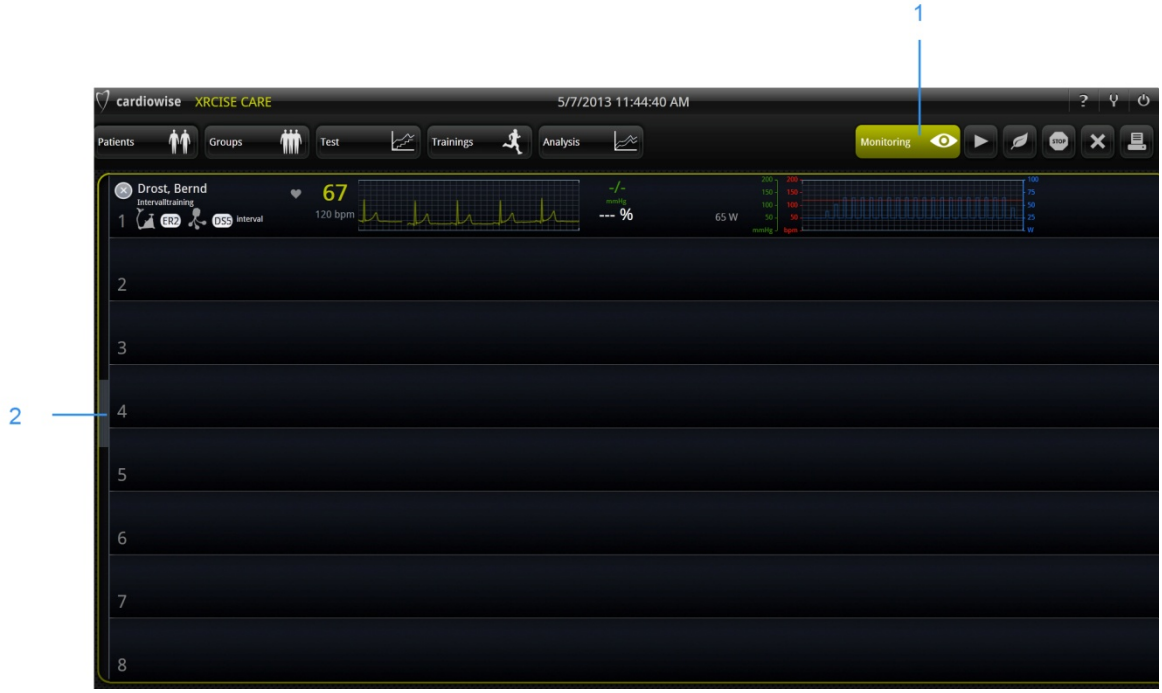


Figure 25 Monitoring

1	**Monitoring** button	Opens the monitoring view
2	**Monitoring** tab	Opens the monitoring view

- Click on the **Monitoring** button or the Monitoring tab.
  The monitoring view can be opened with either method.

5.9.1 Maximise slot

This function requires that at least one slot is occupied.

- Click on the slot.
  The slot expands.

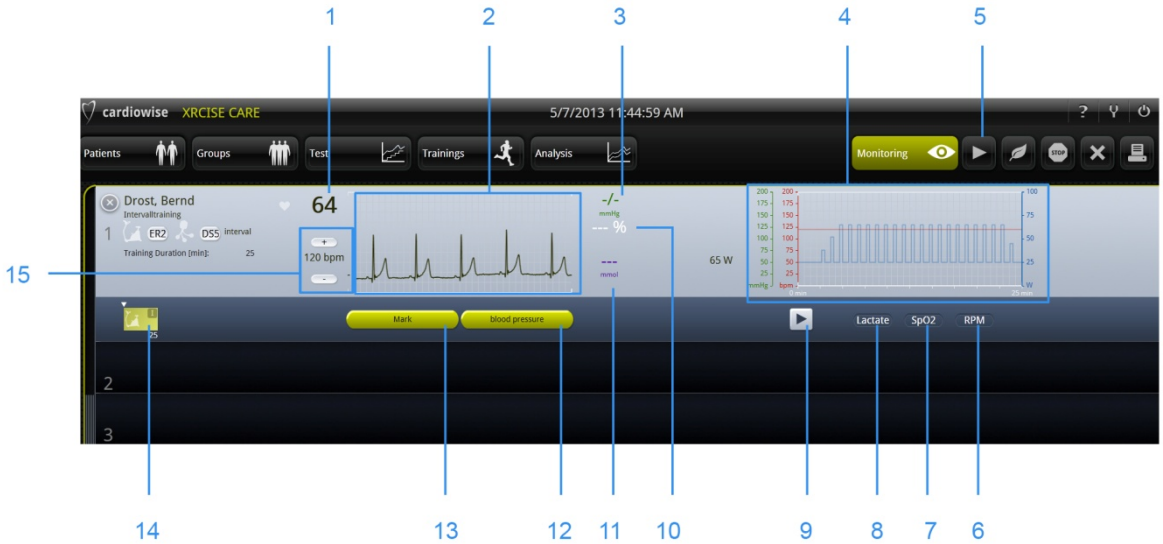


Figure 26 Maximised slot

1	Heart rate display	Shows the current heart rate if it is being recorded by the ECG
2	ECG	Shows the patient's current ECG signal if it is being recorded
3	Blood pressure display	Shows the current blood pressure value if it is being measured
4	Training diagram	Shows the patient's training values
5	**Start** button	Starts the training for all slots simultaneously
6	**RPM** button	Shows the cadence (revolutions per minute)
7	**SpO2** button	Shows the oxygen saturation graph in the training diagram
8	**Lactate** button	Shows the lactate curve in the training diagram
9	**Start** button in the slot	Starts the training for the patient in the slot
10	SpO2 display	Shows the current SpO2 value, if measured
11	Lactate value display	Shows the last entered lactate value
12	**Blood pressure measurement** button	Starts a manual blood pressure measurement (if the exercise equipment is equipped accordingly), independently of the automatic blood pressure measurement
13	**Mark** button	Marks the current section in the ECG
14	"Training" display	Shows the current training
15	HR limit	Lets you change the heart rate limit setting for the current training

5.9.2 Lactate values

Entering lactate values

The lactate value can be entered for informational purposes. It has no effect on the training. The entered values can be shown in the training diagram.

The slot must be maximised for this function.

1. Double-click on the lactate value display.
2. Enter the lactate value.

Displaying lactate values

The slot must be maximised and the lactate values entered for this function.

- Click on the **Lactate** button.
  The entered lactate value is shown as a point in the training diagram.

5.9.3 ECG view

Open detailed view

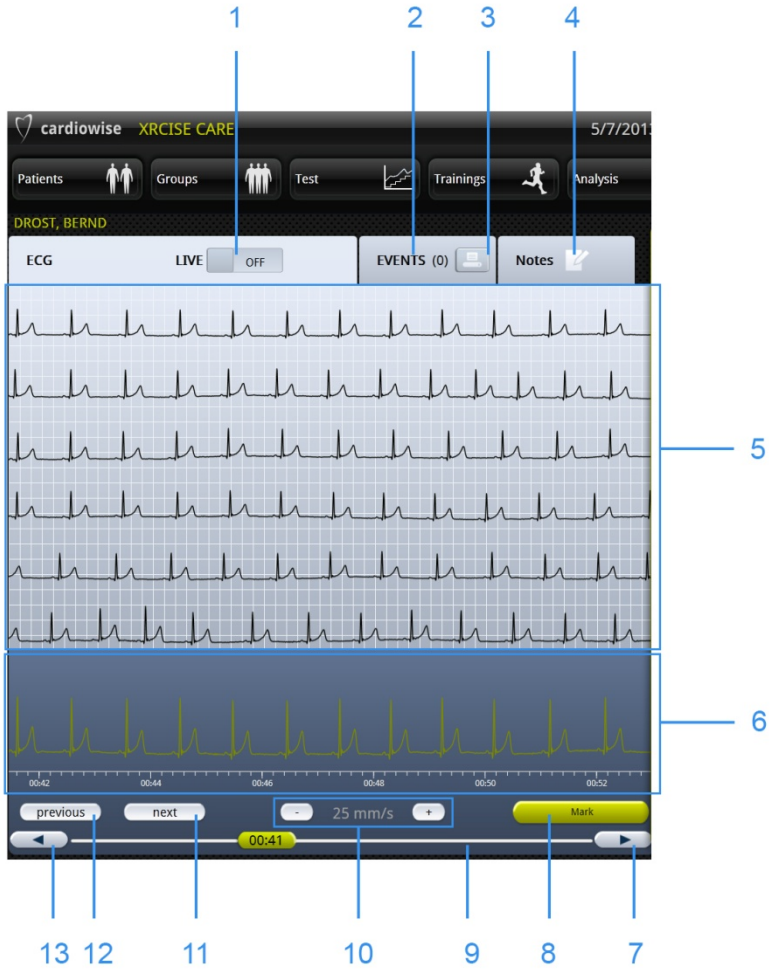


Figure 27 ECG in detail

1	**Live mode** switch	Switches the display of currently recorded data on or off
2	**Events** tab	Opens the "Events" view
3	**Print** button	Prints the events
4	**Notes** tab	Opens the "Notes" view
5	Holter	Shows the recorded ECG values
6	ECG display	Shows the section of the ECG selected with the slider or the live ECG
7	"Forward" button	Moves forward in the record
8	**Mark** button	Marks the displayed section
9	Slider	Selects the section of ECG to display
10	Zoom setting	Determines the length of ECG shown
11	**Next** button	Brings you to the next section marked as an "Event"
12	**Previous** button	Brings you to the prior section marked as an "Event"
13	"Back" button	Moves back in the record

The ECG is recorded continuously.

1. Click on the ECG in the slot to open the ECG detail view.
   The detail view opens.
2. Click on the arrow keys, use the slider, or scroll with the mouse to move back and forth in the data.

Marking events

If the **XRCISE CARE** software is configured accordingly, then points in the ECG record are marked automatically every time the training phase switches (e.g. from the warm-up phase AP2 to the training phase TP).

The therapist can also mark points manually.

These marked points are called "Events".

Process

1. Maximise the slot.
2. Click on the **Mark** button**.**

or

1. Open the ECG detail view.
2. Search for the section you want to mark and click on it.
3. Click on the **Mark** button**.**
   The marked sections are stored under "Events".

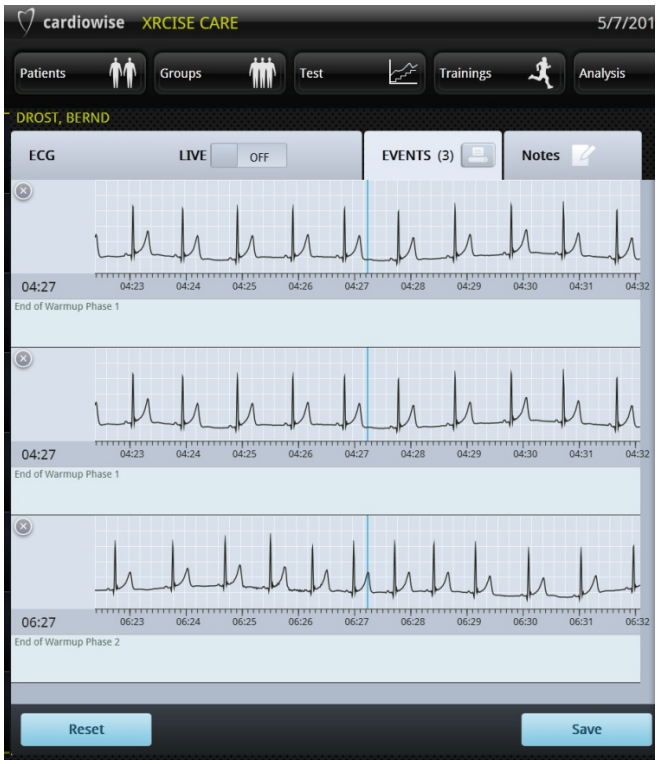


Figure 28 Events

Printing events

A printer must be installed and events must be marked in order to use this function.

- Click on the **Print** button**.**
  The printing window opens.

Figure 29 Printing "Events"

Entering notes

Notes on the training can be entered in the "Notes" tab. These notes are also printed if the events are printed.

Live mode

Live transmission of the ECG data can be switched on or off while viewing the detail view.

- Activate the "Live mode" switch as necessary.

5.9.4 Training diagram

Open detailed view

1. Double-click on the training diagram in the slot.
   The detail view of the current training diagram opens.
2. To display the numerical graph values, move the cursor over the training diagram detail view.

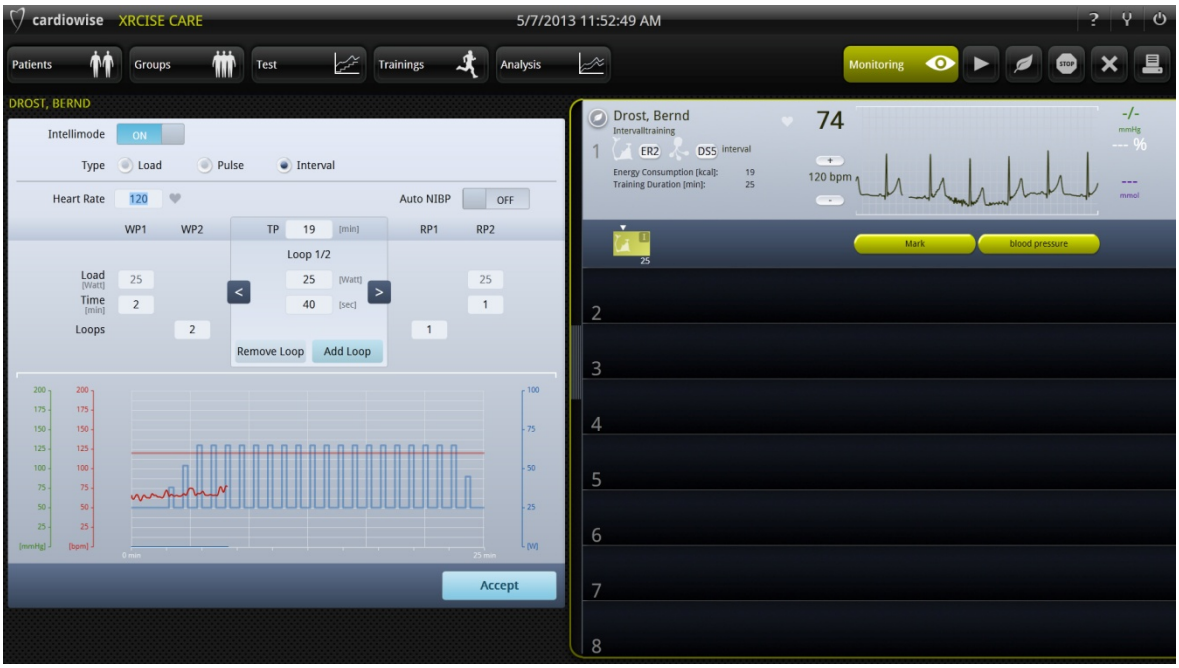


Figure 30 Training diagram in detail

Changing values during the training

The training values can also be changed during the training.

These changes are saved automatically at the end of the training.

These new values are used when the training is opened again.

5.10 Analyses menu

The training values for the individual patients are automatically recorded during a training session and can be retrieved.

5.10.1 Overview tab

1. Select the patient.
2. Click on the "Analyses" button

   A list of all training sessions with a duration of more than one minute is shown for this patient.

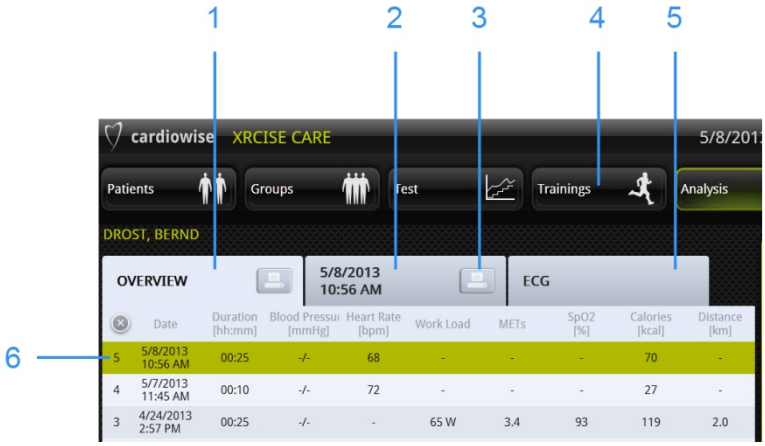


Figure 31 Analysis view

1	"Overview" tab	Opens the list of training sessions
2	"Selected training session" tab	Opens the selected training session
3	**Print** button	Prints the training session
4	**Analyses** button	Opens the analysis view
5	"ECG" tab	Opens the recorded ECG data for the selected training session
6	List of training sessions	When you click on a line, the training details are shown under "selected training session"

5.10.2 Training session in detail

1. Click on the desired training session in the "Overview" tab.

   The date and time of the selected training session is shown on the "selected training session" tab.

2. Click on the "selected training session" tab.

   The values of the selected training session are shown in detail.

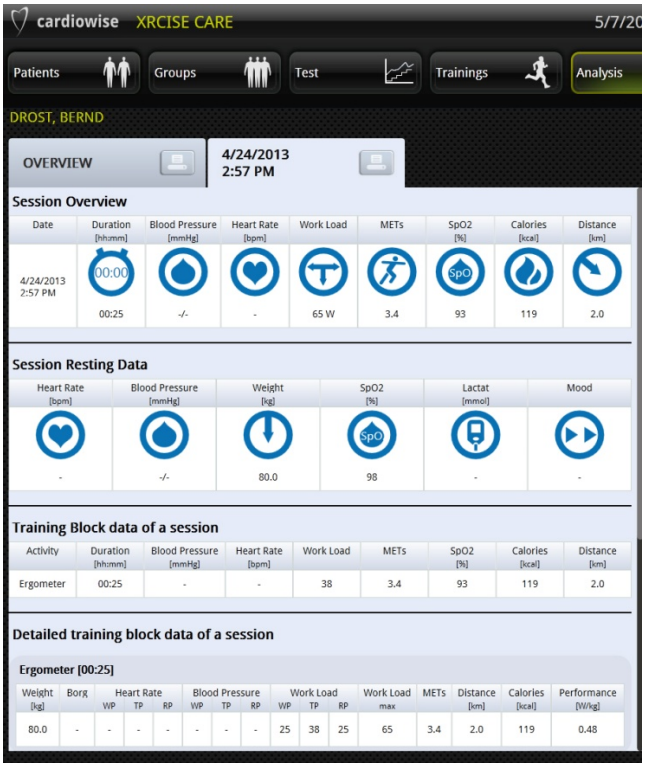


Figure 32 Training session in detail

5.10.3 Display ECG values for the training session

1. Click on the desired training session in the "Overview" tab.
2. Click on the "ECG" tab.
   The ECG values for the selected training session are shown in detail.

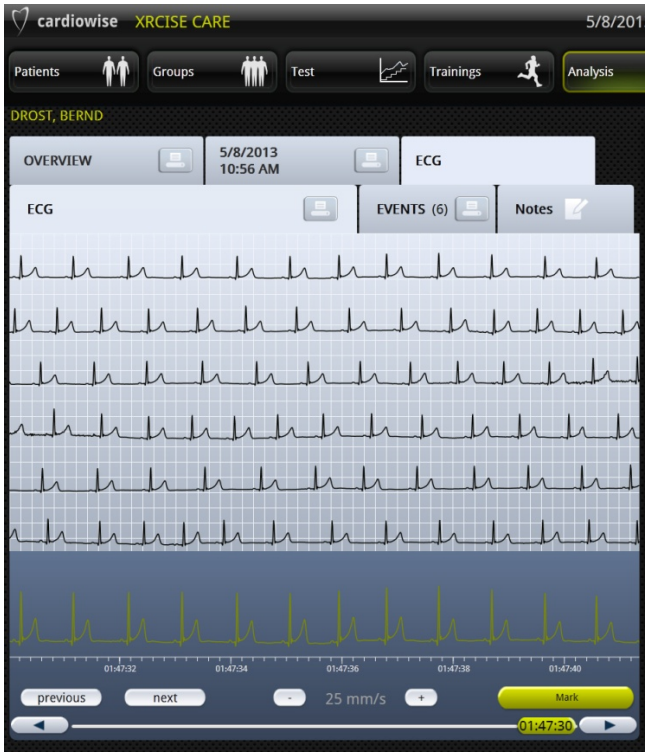


Figure 33 Training session ECG

5.11 Performing a training

5.11.1 Starting the training

This function requires that at least one slot is occupied.

For individual training:

- Click on the **Start** button in the corresponding patient's slot.
  The training for this patient starts.

For group training:

- Click on the **Start** button in the slot control panel.
  All trainings in the slots start if they are ready.

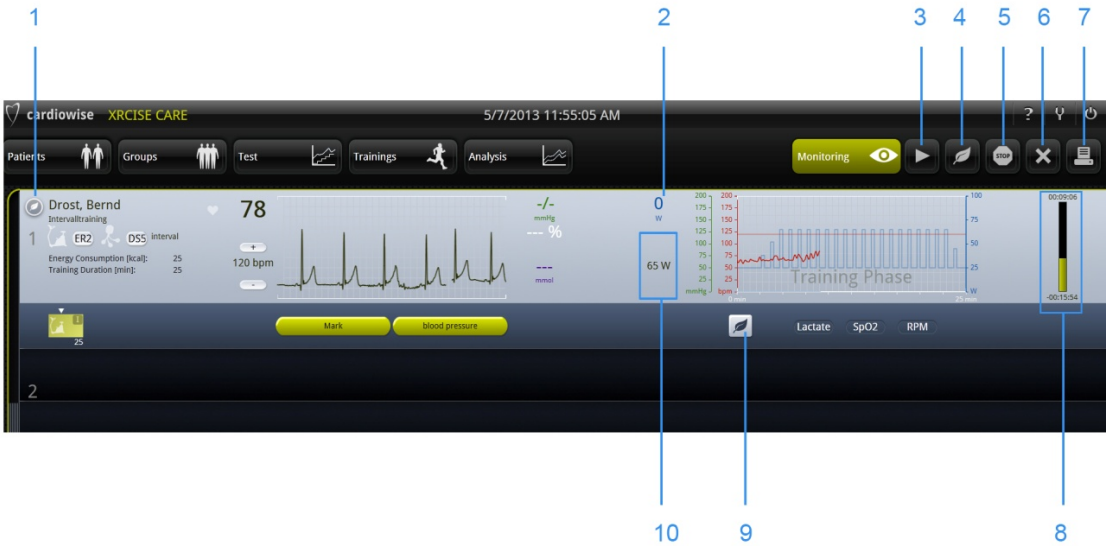


Figure 34 Started training

1	Button	Switches the function after each training phase
2	"Load" display	Shows the current load
3	**Start** button	Starts the training for all slots simultaneously
4	**Recovery phase** button	Initiates the recovery phase (EP1) for all slots
5	**Stop** button	Stops the current training unit in all slots at the same time
6	**Remove** button	Removes all patients from all slots with no currently active training
7	**Print** button	Prints the completed training for all patients in the slots (if the training has ended)
8	"Training times" display	Shows the training times
9	Button	Switches the function after each training phase
10	"Load" settings	Lets you change the load value

5.11.2 Monitor the training

The exercise equipment may only be used by the patient under the instruction of a doctor. Use of the exercise equipment and accessories without instruction and without a supervising person is prohibited.

The therapist must let the patient know about his/her personal perceived exertion (e.g. Borg scale).

The values displayed by the **XRCISE CARE** software are provided as guidance and don't replace the individual and direct monitoring of the patient.

The stress on the patient's cardiovascular system intentionally caused by the therapist by way of the ergometry is the full responsibility of the therapist.

5.11.3 Initiating the recovery phase manually

For individual training:

- Click on the **Recovery phase** button in the corresponding patient's slot.
  The training for this patient switches to the recovery phase.

For group training:

- Click on the **Recovery phase** button in the slot control panel.
  All trainings in the slots switch to the recovery phase.

5.11.4 Ending training manually

This function requires that the corresponding patients are already in the recovery phase.

For individual training:

- Click on the **Stop** button in the corresponding patient's slot.
  The training for this patient stops.

For group training:

- Click on the **Stop** button in the slot control panel.
  All trainings in the slots stop.

5.11.5 Removing patients from the slots

This function requires that no patients are currently in an active training session.

For individual training:

- Click on the **Remove** button in the corresponding patient's slot.
  The slot becomes available.

For group training:

- Click on the **Remove** button in the slot control panel.
  All patients who are not currently in an active training session are removed from the slots.

5.12 Closing the XRCISE CARE software

CAUTION!	**Risk** **- of damage to the system through the addition or removal of hardware while the system is on!** Turn both devices off before you connect / disconnect the exercise equipment and the PC. **- of communication problems due to incorrect power-on sequence!** Always turn the exercise equipment and the PC on in the following order: 1. Exercise equipment and sensors 2. PC system and XRCISE CARE software.

This function requires that no patients are currently in a slot.

Process

- Close the software by clicking on the **Exit** button**.** 
  The software is closed and all settings are saved.

6 Hygiene

Refer to the respective further applicable documentation for information on cleaning the PC system and the exercise equipment and components.

7 Troubleshooting and Fault Correction

Fault	Cause	Corrective action
Unable to communicate with the exercise equipment	No connection between the PC system and the exercise equipment	Check the connections. Try shutting the PC system and exercise equipment down and starting over.
The ECG sensor signals are not displayed	No connection to the PC system. Dead battery in the ECG sensor	Observe the further applicable documentation for the ECG sensor.
Training cannot be started	None or an incorrect piece of exercise equipment was assigned	Check whether a piece of exercise equipment was assigned. See section 5.8 "Assigning a patient to a slot".

8 Disposal

At the end of its useful life, the PC system must be properly disposed of according to national laws.

The operator is responsible for disposal.

PC system	Category: Electronic scrap By customer request, ERGO-FIT GmbH & Co. KG accepts used devices for disposal. Transportation costs are borne by the operator. The device is separated by material type prior to disposal according to the applicable regulations. Of course the system and/or system components can also be disposed of through the clinic's own disposal system. In order to do so, it should be separated by material type prior to disposal according to the local regulations as they apply to clinics.
Packaging material	Category: Recyclable waste By customer request, ERGO-FIT GmbH & Co. KG accepts the return of packaging material. Transportation costs are borne by the operator. The packaging material is separated by material type prior to disposal according to the applicable regulations. Of course the packaging material can also be disposed of through the clinic's own disposal system. In order to do so, it should be separated by material type prior to disposal according to the local regulations as they apply to clinics.

9 Technical Data

Classification of the XRCISE CARE - Software	
Medical device class	IIa
Software safety class	B
Data transfer	
Data transfer between the PC and exercise equipment	USB or serially via RS232
Data transfer between the PC and medical products in order to record physiological parameters (not integrated in the exercise equipment)	Wirelessly via Bluetooth®
Data transfer between the recording PC and the review PC	Ethernet network via TCP/IP protocol
Parameter Bluetooth - Dongle	
Version	2.0
Power class	1
Max. power	100 mW
Max. open-air range (line of sight)	approx. 100 m
Max. range in buildings	depending on the environment and shielding measures
Connection to the PC interface	USB
PC - Minimum requirements	
Operating system	Windows® 7 Professional 64 Bit
Processor	Intel Core i5 3.1GHz
Hard disc space	500 GB
RAM	4 GB
Graphics card	DirectX10 support, 1920 x 1080 pixels
Monitor	1920 x 1080 pixels (up to 3 monitors as needed)
Input devices	Keyboard and mouse
Interfaces	• USB interface to connect the dongle • USB interface for Bluetooth connection • USB interface to connect a printer • RS-232 interfaces, depending on the number of pieces of exercise equipment (in case of serial data transfer) • USB interfaces, depending on the number of pieces of exercise equipment (in case of USB data transfer)

Display screens and functions	
Display language	English, German or country-specific adaptation
Recording of physiological parameters via data transfer	• ECG • Heart rate • Blood pressure • Lactate • SpO2
XRCISE CARE - Software approval data	
CE marking	CE 0297
	The product meets the requirements of the Medical Device Directive 93/42/EEC and its national implementation in the form of the German Medical Devices Act (MPG).
Standards	DIN EN 60601-1 IEC 62304
PC system approval data	
CE marking	CE
Standard	EN 60950

9.1 Allowable combination with other devices

Exercise equipment	The XRCISE CARE© software supports the following exercise equipment: • **XRCISE CYCLE** • **XRCISE RUNNER** Others upon request.
Sensors (medical products to record physiological data, which are not part of the exercise equipment)	**XRCISE ECG**

10 Warranty

The following waives the warranty:

- Improper use or handling
- Improper operation causing device damage
- Failure to follow the user manual
- Altering the device (modifications, changes, extensions etc.) without written permission,
- Opening of the housing by persons not authorised to do so,
- Use of other than original accessories and/or spare parts,
- Force majeure (e. g. lightning strike),
- Transport damage due to improper packaging for return shipment.

In case of unjustified complaints, we are entitled to demand commensurate compensation for the inspection and shipment of the device.

In case of warranty claims or repairs, please return the entire device in the original packaging only.

If a device is not shipped in its original packaging, special packaging to return the device will be charged separately.

Thank you for your understanding!

cardiowise GmbH
Blocksbergstraße 165
66955 Pirmasens

Phone: +49 (6331) 2461-87
Fax: +49 (6331) 2461-55
Email: contact@cardiowise.com
Web: www.cardiowise.com