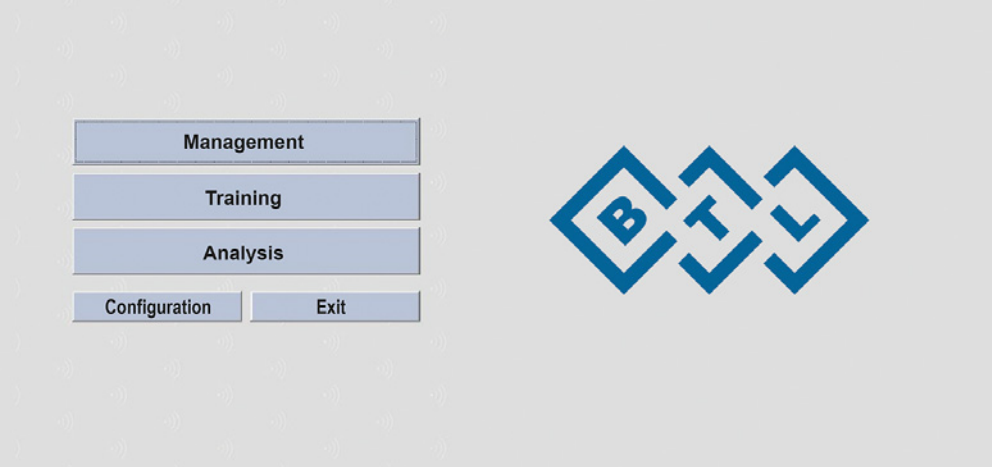
BTL Cardiac Rehab ITP Manual

Operator's Manual

201000781000 • Version 2017-05-05 / Rev 00 • English



Manual

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This manual was written with the utmost care. Should you still find details that do not correspond with the software, please let us know and we will correct the issue as soon as possible.

We reserve the right to modify the design and technical features of the device and are not bound by the information and illustrations provided in this manual.

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This manual is not subject to any change order service. Please contact the manufacturer for the latest document revision.

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1 Introduction

CE Marking Information

The product *ergoline Rehabilitation System (ers2)* bears the CE marking CE-123 (Notified Body TÜV SÜD Produkt Service GmbH, Ridlerstrasse 65, 80339 Munich, Germany), indicating its compliance with the provisions of the Council Directive 93/42/EEC about medical devices, and fulfills the essential requirements of Annex I of this directive.

The product ers2 system is a class IIa device according to Annex IX of the Directive 93/42/EEC.

The product fulfills the requirements of the standard EN 60601-1 "Medical electrical equipment, Part 1: General Requirements for Safety" as well as those of the standard DIN EN 62304 "Medical device software".

Other devices which are part of the system must comply with the requirements of the office equipment standard (DIN EN 60950) and with the medical electrical equipment standard (DIN EN 60601-1).

The electrical installations of the rooms where the system is operated must comply with the applicable local safety requirements.

License Terms

By installing the software, you accept the following terms:

Subject of this agreement is the granting of a license to use the software program and the product documentation.

Ergoline GmbH grants you a personal, non-exclusive and non-transferable right to use the software program and the product documentation. The software program and the accompanying documentation are protected by copyright. The licensee shall comply with the provisions of copyright law.

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The licensee is liable to the licenser for any damage arising from the breach of the copyright or infringement of the conditions of this agreement.

Revision History

Publication Date	Revision	ers2 Software Version	Comment/Note
2017-05-05	00	software version 1.06 and later	initial release

Intended Audience

This manual is geared for clinical professionals. Clinical professionals are expected to have working knowledge of medical procedures, practices, and terminology as required for completing these examinations.

Stylistic Conventions

Buttons and menu items are highlighted as follows: for example, **[Create]** or *Start training*. Numbers or letters in the text (for example, 1 or A) identify details referring to designated items in illustrations or screenshots.

Symbols used on the Data Media

	Manufacturer: Ergoline GmbH, Lindenstraße 5, 72475 Bitz, Germany Distributed by BTL
	Date of manufacture
	CE marking
	Order number
	Note: Consult accompanying documents.

Safety Information

General Information
This manual is an integral part of the device. It should be available to the device operator at all times. Close observance of the information given in the manual is a prerequisite for proper device performance and correct operation and ensures patient and operator safety. Please note that information pertinent to several chapters is given only once. Therefore, read the manual once carefully in its entirety. Also observe all instruction manuals supplied with other equipment, such as the PC, the ergometer, or the ECG telemetry system.

To ensure patient safety and interference-free operation, we recommend using only original accessories that can be obtained from Ergoline GmbH. The user is responsible if accessories from other manufacturers are used.

Ergoline GmbH is responsible for the safety, reliability, and performance of the device, only if

- assembly operations, extensions, readjustments, modifications, or repairs are carried out by Ergoline GmbH or by an organization expressly authorized by Ergoline to carry out these tasks
- the device is used in accordance with the instructions given in this operator manual.

The warranty does not cover damage resulting from the use of unsuitable accessories and/or consumables from other manufacturers.

Always consult with Ergoline GmbH if you intend to connect equipment not recommended in this manual.

Parts and accessories must comply with the applicable safety standards of IEC 60601 and DIN EN 62304 and/or the system configuration must comply with the requirements of the collateral standard IEC 60601-1-1 "Safety Requirements for Medical Electrical Systems".

Safety Information

General Information
The power cords must be certified for use in the respective countries where the equipment is operated.

All publications reflect the device specifications and applicable safety standards valid at the time of printing. All rights are reserved for devices, circuits, techniques, software programs, and names appearing in this manual.

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Definitions
The safety information in this manual is classified as follows:

Forbidden
Strictly forbidden!

Warning
Indicates a hazard. If not avoided, the hazard may result in bodily injury or product/property damage.

Note
Additional information which is important and must always be observed.

Hint
Practical advice which facilitates your work.

Safety Information

System Installation / Assembly

Forbidden
Portable socket outlets delivered with the system may only be used to supply power to devices that are parts of the system. Additional multiple portable socket outlets, cables, and resources that are not part of the system may not be connected to the system. The socket outlets may not be placed on the floor.

Do not open any of the devices. There are no user-replaceable components inside the devices.

Do not insert objects of any kind in any of the devices. They may touch live components and you might suffer an electric shock, cause fire, or damage the device.

Warning
Assembly operations, extensions, readjustments, modifications, or repairs may only be carried out by Ergoline GmbH or by an organization expressly authorized by Ergoline GmbH to carry out these tasks.

The installation includes the configuration of the communication interfaces between the training and the monitoring devices and the ers2 software. Only the service technician is allowed to configure the system. System operators are not able to assign training or monitoring devices themselves.

The system may only be installed in rooms that comply with the applicable local installation regulations.

The PC system must be set up outside the patient environment. The patient environment is the area within a radius of 1.5 meters around the training device.

After the installation and before use, verify that the equipment is in correct working order and operating condition. Check the cables and connectors, in particular, for signs of damage. Damaged cables and connectors must be replaced immediately, before use.

Note
When disconnecting the device from the power line, remove the plug from the wall outlet first before disconnecting the cable from the device.

All devices of a system must be connected to the same electric circuit. Devices that are not connected to the same circuit must be electrically isolated for operation (isolated RS232 interface).

The maximum allowed load in conjunction with a multiple socket outlet is 3200 VA.

Devices may be connected to other devices or to parts of systems only when it has been made certain that there is no danger to the patient, the operator, or the environment as a result:
In those instances where there is any element of doubt concerning the safety of connected equipment, the user must contact the manufacturers concerned or other informed experts as to whether there is any possible danger to the patient, the operator, or the environment as a result of the proposed combination of equipment.

Standards IEC 60601-1-1/EN 60601-1-1 must be complied with in all cases.

All bicycle ergometers and treadmills connected to the system must meet the requirements of the IEC 60601-1 standard.

Ambient Conditions / Operation

Forbidden

The ers2 system is not designed for use in areas of rooms used for medical purposes where an explosion hazard may occur.

The therapist may not touch the patient and the PC system at the same time.

Warning

Liquids must not be allowed to enter the devices. If liquids have entered the devices, the ers2 system must be checked by a service technician before being used again.

RF Interference—Known RF sources, such as cell phones, radio or TV stations, and two-way radios, may cause unexpected or adverse operation of the ers2 system. Check the performance before each use.

Risk of Poisoning—Observe all information provided by the manufacturers of chemical products required for the use and care of the devices. Always keep these chemical products in their original containers to avoid any confusion which may have severe consequences.

The operator must be trained in the use of the device.

Patients may use training devices only on the order of a physician. Users must receive instructions before they are allowed to use the training devices and accessories and they must never be left unattended during the training.

The therapist is responsible for ensuring the safety of the training sessions. The training must never be performed at levels exceeding the patient's exertion limits.

Patients must learn to assess their perceived level of exertion (RPE scale, effort). A patient who does not feel comfortable should stop the training.

All analysis results and the notifications which the system generates on the basis of these results are to be considered only as proposals. The results must be verified and evaluated by a qualified physician to obtain a diagnosis and set up a therapy plan.

The therapist is responsible for monitoring the physical load (watts, speed, etc.) and exertion parameters (heart rate, blood pressure, etc.). The accuracy of the displayed values must be verified through separate, independent measurements.

Before starting the training session, check that the assignment of patients to ergometers is correct. If the assignments are not correct, the load sent to the ergometer from a given training place will not correspond to the patient(s). Load levels configured for a different patient may lead to inappropriate exercise levels, incorrect interpretation, and wrong diagnoses.

Before starting the training session, check that the correct ECG is displayed. If ECG transmitters are mixed up or if the allocation of patients to transmitters is incorrect, the corresponding training place will not show the ECG signal or heart rate of the correct patient. If the displayed heart rate is from a different patient, this may lead to inappropriate exercise levels, incorrect interpretation, and wrong diagnoses.

Note
Do not expose the equipment to direct sunlight to prevent system components from reaching inadmissible high temperatures. The equipment has no additional protection against the ingress of humidity.

Hint
Functional test: Before starting the training session, address the patients with the number of their training place and ask them for their names. If the name assigned in the ers2 system and the name they tell you are not the same, correct the assignment of the training places.

Functional test: Tap on one of the patients' ECG sensor or lift it off the strap to cause an ECG signal disturbance. The disturbance must be visible in the ers2 system in the corresponding training place. If you don't see the disturbance in the window of the ECG transmitter which you are checking, the assignment is wrong and must be corrected.

Safe Use of Treadmills

Warning
Before patients start exercising on a treadmill they must receive detailed instructions and be aware of the intensity of the treadmill movement. They must also bear in mind that the belt does not stop when they stop running.

Inform the patient in advance before you start and stop the treadmill. Otherwise patients may suffer injuries when the treadmill starts and stops unexpectedly. Also inform the patient in advance of a change in speed during the training.

The treadmill parameter settings must be adequate for the patient's level of physical fitness. Patients must always wear the stop tether lanyard when exercising. Patients with reduced physical capabilities must additionally be secured with a safety harness that protects them from falling. The emergency stop function should be activated before the patient steps onto or off the treadmill belt.

Before changing the speed or elevation of the treadmill belt, make sure that the patient does not step onto or off the treadmill belt at the same time.

Inform patients that they are not allowed to change any settings at the control terminal of the treadmill.

Information About Pacemaker Detection

Note
The ers2 system is not capable of automatically detecting pacemaker pulses. Be aware that ECG signal interference may erroneously be interpreted as pacemaker pulses.

System and Data Security

Warning

Make sure that viruses, malware, etc. do not infect your PC (check USB sticks for viruses before connecting them).

Do not set up the PC or the ergometers in the direct vicinity of a window. Rain, humidity, and sunlight may damage the equipment.

Set up the PC in a location that provides sufficient ventilation. The ventilation openings must not be obstructed. The ambient conditions stated in the user manual must be ensured at all times.

The PC should not be used adjacent to, or stacked with, other equipment. If adjacent or stacked use is necessary, the equipment or system should be tested to verify normal operation in the configuration in which it is being used.

Note

Consult with Ergoline GmbH if you intend to install third-party software (anti-virus program) on the PC. The responsibility for connection of the PC system to a network or to the Internet lies with the system operator.

As system owner you are responsible for regular backups of the data and the system software. Back up the program directory and the database directory (as determined during installation) every day to avoid loss of data.

Only your authorized Ergoline service partner is allowed to install the ers2 software or updates or to configure the system.

Ergoline GmbH does not assume responsibility for changes to the data after they were exported from the ers2 system to your office management software or hospital information system. Data generated by the ers2 system should only be edited in the ers2 system.

System Requirements

Operating system	Windows 10 professional (32 or 64 bit)
Processor	Intel i3 minimum or compatible
RAM	4 gigabyte
Hard drive	500 gigabyte (GB) of free memory
Graphics card	full HD capable graphics card with one to three monitor outputs (depending on number of connected ergometers)
Monitor(s)	TFT monitor 22-inch full-HD (1920 x 1080 pixels), one monitor for up to 8 ergometers, 2 monitors for 9 to 16 ergometers, 3 monitors for 17 and more ergometers
PCI slots	one to three free PCI express slots for serial multiple interface boards (depending on number of connected ergometers)
USB ports	one to eight free USB ports (depending on configuration)

Equipment Symbols

The symbols that you will find on the PC and on the ergometer are explained in the corresponding user manuals. On-screen explanations pop up for symbols displayed on the screen.

A double-click on the icon will start the program.

Description of the ers2 System

Intended Use
The ers2 system controls patient-specific training programs on training devices for medical purposes. Each phase of the training protocol is documented, providing the therapist/physician with up to date information about the performance data and training progress of the rehabilitation patient at any time.

The ergometers used must be medical ergometers that meet the requirements of the standard IEC 60601-1-1. Both, ergometers and treadmills, can be used.

The ers2 software is capable of running up to 24 training devices at the same time.

For mere fitness purposes, the use of non-medical training devices is allowed.

The ers2 system is intended for use in rehabilitation centers, cardiology offices, and fitness centers with cardiac rehabilitation programs.

The values displayed and stored in the ergoline rehabilitation system (ers2) are for information only.

The ers2 system is intended only for use by trained individuals under direct supervision of a licensed health care practitioner on adult and pediatric patients.

Parts and accessories must comply with the applicable IEC 60601 safety standards and/or the system configuration must comply with the requirements of the standard IEC 60601-1-1 for medical electrical equipment.

Contraindications

Warning
Patients with the following conditions are excluded from training with the ers2 system:

- dizziness, nausea, or pain
- under influence of substances that may impair the individual's vigilance (alcohol, drugs, medication).

Introduction

The role of exercise therapy as a part of the rehabilitation of cardiac patients in the follow-up treatment phase II is viewed positively to a large extent today, based on decades of favorable experience.

In recent years, various studies have been able to show the positive impact of exercise therapy on coronary patients (*Kellermann* et al., 1967; *Hellerstein*, 1973; *König* et al., 1977; *Hollmann* et al., 1983; *Rost* et al., 1991 among others).

Through constant advancement of new diagnostic and therapeutic methods, there has additionally been a fundamental transformation of the rehabilitation process of cardiology patients in the past few years. Along with the phases of early mobilization and exercise therapy, sports therapy has also taken on greater importance today. "Early mobilization" refers to passive and active mobilization as soon as the patient's clinical condition allows.

"Exercise therapy" is medically indicated and prescribed movement which is planned and regulated by the specialist therapist, monitored together with the physician, and performed with the patient alone or in a group. "Sports therapy" is an exercise therapy measure which uses appropriate sports means to compensate for and regenerate disrupted physical, mental and social functions, prevent secondary injuries, and promote health-oriented behavior. It is based on laws of biology and includes, in particular, educational, psychological and sociotherapeutic methods and aims to achieve lasting health literacy.

Ergometer training is used in this case, particularly in the areas of early mobilization and exercise therapy within the scope of inpatient and increasingly also in outpatient rehabilitation in order to increase the performance capacity of cardiovascular patients.

As studies have been able to show, the performance capacity and thus also the quality of life can be significantly improved even in patients with heart failure by selecting an appropriate form of training (interval training).

The increased requirements with regard to efficient work but also quality assurance and complete documentation ("efficiency monitoring") of the training performed with all registered data can, however, only be met by an appropriately designed ergometer training system.

In the development of the new ergoline rehabilitation system ers2, we were able to draw on the experience gained from an installed base of over 250 ergoline rehabilitation units. Through intensive collaboration with many users, therapists, sports scientists, and physicians, a new, modular system for controlled ergometer training was developed, which meets all of the requirements listed. The PC software takes control of the patients' predefined training protocol, simultaneously documents all relevant data (e.g., ECG, heart rate, training data) and thus frees the therapist from routine tasks—greater attention can be paid to the patients. But even the training equipment itself, the ergoselect Reha ergometer, places the patient in the focus. Options for modular expansion and upgrades allow the equipment to be adapted to increasing demands (e.g. options for adjusting the saddle, etc.).

System Configuration

The central component of the ers2 system is a PC with an MS Windows operating system and special software which runs the training programs. The training ergometers are connected to the PC system via control lines or a WiFi interface. All data are shown on one to three 22-inch TFT monitors; up to eight patients can be displayed and supervised on each monitor. The ergometers are equipped for ECG monitoring with single-channel ECG amplifiers, whose signals are transmitted to the PC via the serial interfaces. Wireless ECG monitoring is also possible as an alternative. The signal will be transmitted to the system via a Bluetooth interface.

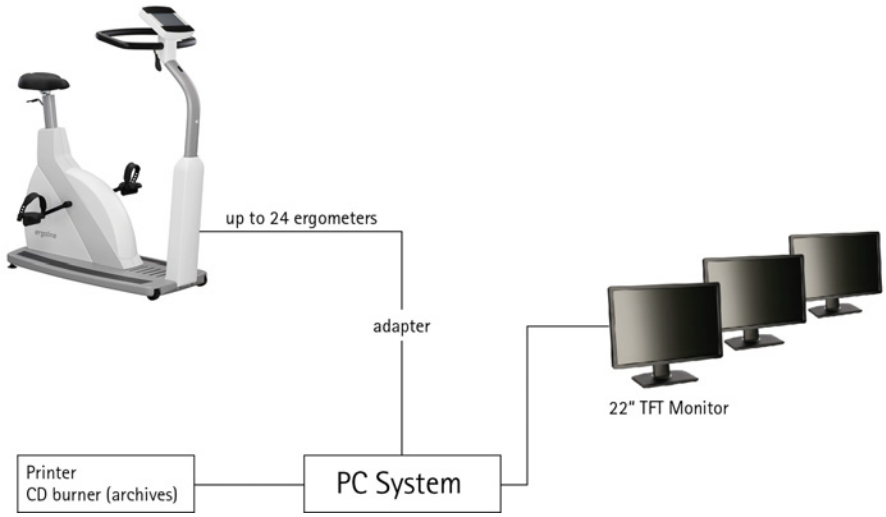


Figure 1 – 1: ers2 system configuration

An overview of the most important software features:

- Training with ECG monitoring for up to 24 patients
- Control of up to 24 training devices
  - Load, speed, elevation
  - Adjustable height of saddle and handlebar (ergoselect bicycle ergometers)
- Comprehensive individual training protocols for each patient
  - Constant load
  - Constant pulse
    (The software controls the ergometer load such that the patient's heart rate is constantly kept at a defined level.)
  - Interval training
  - Interval training with pulse monitoring
    (The software controls the ergometer load by reducing it in the subsequent exercise interval by a predefined value (in watts or %) as soon as the patient's heart rate exceeds a preset limit.)
  - Definition of global warmup and recovery phases
  - Warmup and recovery load levels that adapt automatically based on the average load during the exercise phase of the previous training session
- Training parameters that the therapist may directly change at any time
- Group training (all patients start at the same time)
- Single training (patients come when convenient and train as long as desired)
- Notification if preset limits are violated
- Immediate printout of a patient's current ECG is possible at any time
- Quality assurance:
  - Full documentation of the complete training session
  - Storage of all data recorded during the training session
  - Full-disclosure ECG data
    (The ECGs of all patients and all training sessions are stored.)

Start-up and Preparation

Installation considerations

Warning
Install the system outside the patient environment. Danger from electrically conductive connections between patient and PC.

The patient environment is the area within a radius of 1.5 meters around the training device.

Scope of Delivery

The manufacturer takes care of installing the ers2 software on the PC system. The configuration of the ers2 software includes an initial configuration of the training devices and a 24-hour test run of the entire system.

Note
The configuration does not include the adjustment of limit values or training ranges. This part of the configuration is the responsibility of the therapist. Limit values and training ranges are defined individually for each patient.

The standard PC system includes:
PC, MS-Windows operating system, keyboard, mouse, monitor, USB dongle for license management, ers2 software.

Installation

Only the manufacturer, the authorized dealer, or the service partner is allowed to install the product.

Warning
Risk of equipment damage due to unauthorized installation.

Risk of malfunction if operated in conjunction with other devices.

The most recent firmware version must be installed in the ergometer.

The following devices are approved for control via the ers2 software:

- Ergoline ergoselect series
- Ergoline ergosprint treadmill

Please contact the manufacturer or authorized dealer to find out about other approved devices.

Licensing System

The supplied license dongle must always be connected to the ers2 system when in use. The purchased license dongle remains valid after a software update.

Network Operation

The ers2 system uses floating licenses, which allows reviewing the data retrospectively on another PC running the ers2 Client Viewer software. The installation of the Client Viewer must be referred to a certified service partner.

Warning
Before using the system for the first time:
Patients may use training devices only on the order of a physician. Users must receive instructions before they are allowed to use the training devices and accessories and they must never be left unattended during the training.

2 Patient ITP

The Individual Treatment Plan (ITP) is an additional function of the ers2 software program for documentation of health parameters as well as of the contents and goals of cardiac and pulmonary rehabilitation measures. At specific intervals, all of these parameters, contents and goals are checked, assessed, and analyzed.

The ITP covers the documentation of the multi-disciplinary and individual therapy program in successive assessments.

Each assessment consists of the following core components:

- **Evaluation**
  Under Evaluation, the individual patient parameters are acquired.

- **Intervention**
  Under Intervention, the individual interventions are defined and planned, based on the evaluated core components.

- **Education**
  Under Education, the patient-specific educational measures accompanying the functional therapy are defined.

- **Goal**
  Under Goal, the patient's individual and general goals are defined.

Within the documentation structure of the ITP, the assessments reflect the core components that are subdivided into the following main areas:

- Exercise
- Nutrition
- Patient
- Psychosocial

The main areas are further divided into menus where data can be entered:

- **Exercise**
  - Blood Pressure
  - Exercise Test (Evaluation only)
  - Exercise Training

- **Nutrition**
  - Diabetes
  - Lipids
  - Weight Management

- **Patient**
  - Knowledge
  - Safety
  - Smoking Cessation

- **Psychosocial**
  - Psychosocial

The content of these menus varies with the selected core component and the menu items allow the user to document the assessment.

The rehabilitation progress is verified on the basis of the ITP and the current status is documented in the successive assessments. After the initial assessment, these assessments must be performed and closed on a regular basis:

The patient normally passes through the following phases:

- Initial assessment
- 30-day reassessment
- 60-day reassessment
- Discharge

With respect to the defined goals, the interventions and educational measures can now be evaluated as *Met/Attended, In progress*, or *Not Met/Not Attended*. Furthermore, if the patient's condition changes, it may become necessary to adapt the goals or interventions and educational measures.

For the *Discharge*, the defined interventions are finally reviewed and the defined goals are compared/evaluated according to the expected/defined outcomes.

2.1 Definitions

Term	Explanation
ITP	Individual Treatment Plan
IA	Initial Assessment
RA	Reassessment
DC	Discharge
AS	Assessment
Active ITP	An ITP in progress (neither completed nor canceled).
Selection mode	The ITP can be commented, completed, canceled, or deleted.
Edit mode	The ITP can be edited. The AS can be edited.
AS core component	Root structure of the AS.
AS main area	Subdivision within the core components of the AS.
AS input menu	Subdivision of the main areas in the AS.
AS item	Input fields within the AS input menus.

2.2 User Rights

User	Permissions	
ITP Admin	ITP	View, create, edit, comment, complete, cancel, delete.
	AS	View, create, edit, comment, complete, delete.
ITP User	ITP	View, create, edit, comment an active ITP.
	AS	View, create, edit, comment an AS in the active ITP.

2.3 ITP Standard Workflow

The standard workflow encompasses the basic operating functions for managing and performing a patient ITP. With the ers2 program, you have considerable leeway in creating workflows that meet the most diverse requirements of medical facilities. The following diagram illustrates a standard workflow.

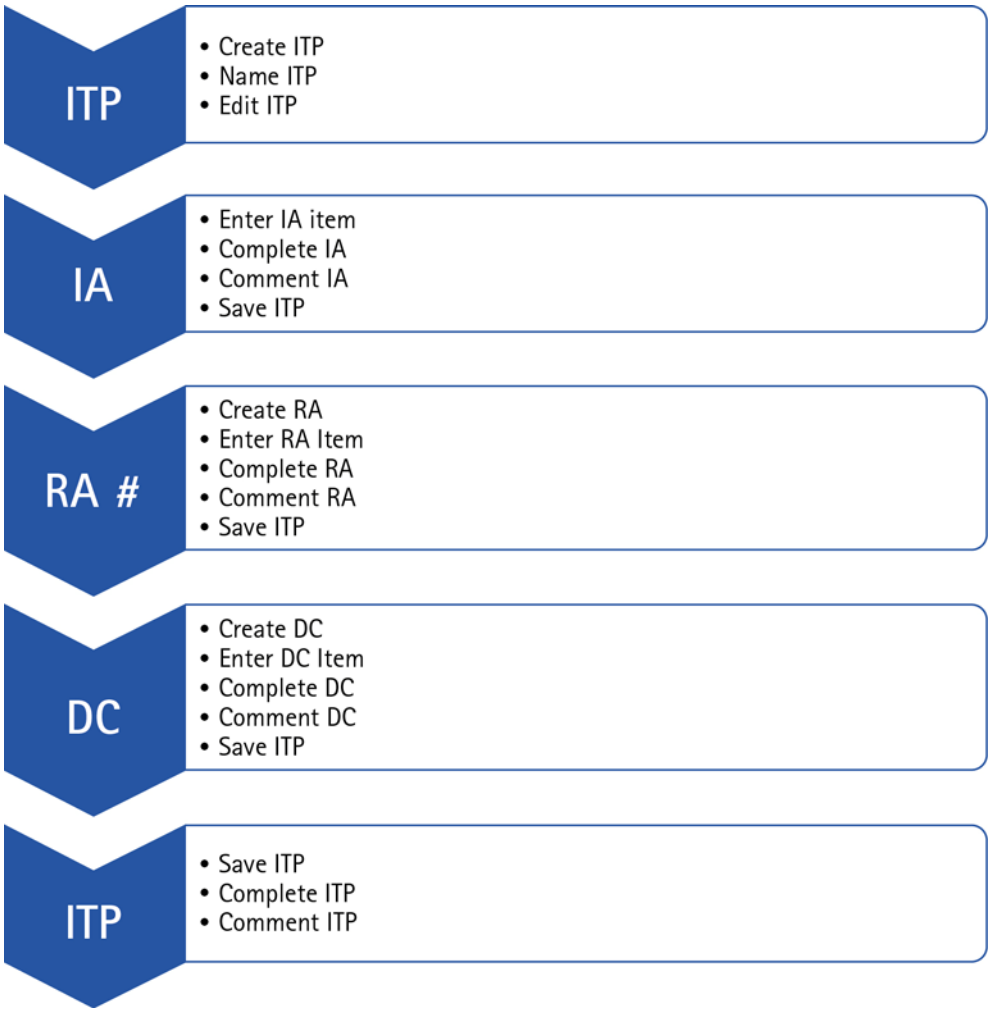


Figure 2 – 1: ITP standard workflow

3 ITP Structure

The functions of the ers2 ITP module will be described for an ITP administrator.

3.1 ers2 ITP Management

On the ITP tab of the management function, you will find an overview of all patient ITPs.

- The patient name is displayed.
- The patient ID is displayed.
- The ITP name is displayed.
- The ITP status is displayed.
- The first assessment is displayed.
- The last assessment is displayed.

If the last assessment of an active ITP is older than a given number of days, the corresponding ITP is highlighted yellow. The number of days is configurable.

The ITP list can be filtered by patient names, patient IDs, and groups.

To sort the list, click the appropriate column header.

A selected ITP can be opened by double-clicking or by clicking **[Edit]**.

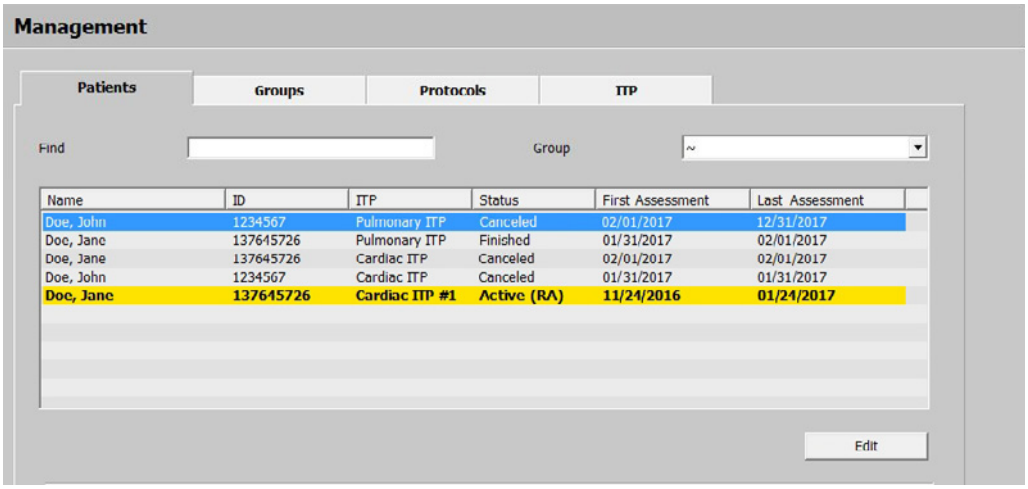


Figure 3–1: ITP – general management

3.2 ers2 ITP Patient Data

In the patient data, click the ITP tab. The ITP input window will open.

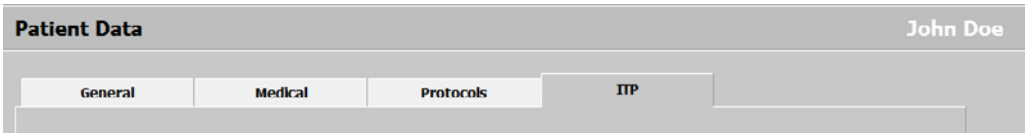


Figure 3–2: Tabs of the Patient Data window

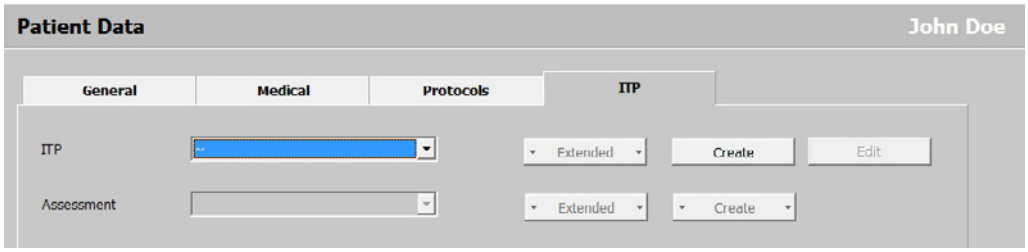


Figure 3–3: ITP tab of the Patient Data window

The following sections describe the functions of the ITP menu:

- Creating an ITP
- Selecting an ITP
- Editing an ITP
- Renaming an ITP
- Applying an ITP
- Discarding an ITP
- Commenting an ITP
- Canceling an ITP
- Completing an ITP
- Deleting an ITP

3.2.1 Creating an ITP

If an active ITP has not been defined for the patient, you can create a new ITP.

To do so, click the **[Create]** button. You can choose from the ITP templates created in the ers2 system. Select one of the templates. After selection, the template will be opened in the ITP edit mode. The created ITP is the active ITP.

Note
Only one active ITP can be defined for each patient.

Requirement:

- No active ITP

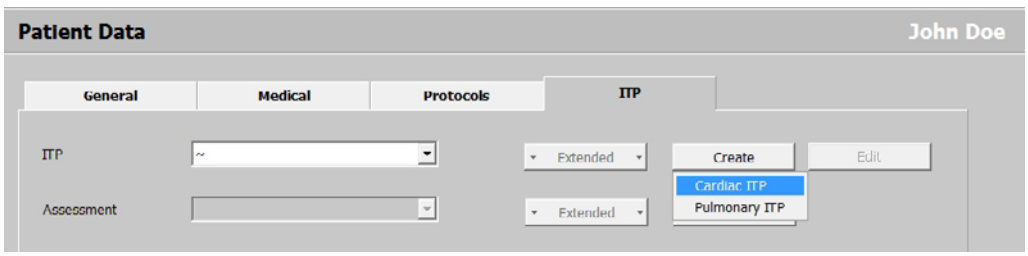


Figure 3–4: Creating an ITP

3.2.2 Selecting an ITP

If ITPs have already been created for the patient, they can be selected from the ITP menu. All the patient's ITPs are displayed. If available, the patient's active ITP is labeled *(Active)*.

The following ITP statuses exist in the patient management:

- Active
- Canceled
- Completed

Select an ITP by clicking.

Requirement:

- At least one ITP has been created.

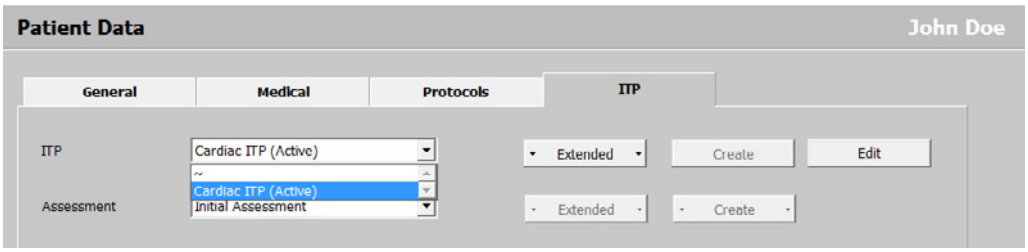


Figure 3–5: Selecting an ITP

3.2.3 Editing an ITP

To enable the edit mode for the selected ITP, click the **[Edit]** button.

Note
A new created ITP is automatically in edit mode. The *Initial Assessment* is already highlighted.

Requirement:

- An ITP has been selected.
- The ITP is in selection mode.

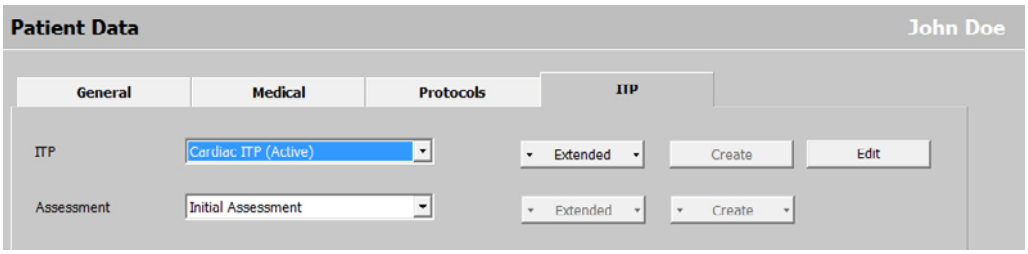


Figure 3–6: ITP selection mode

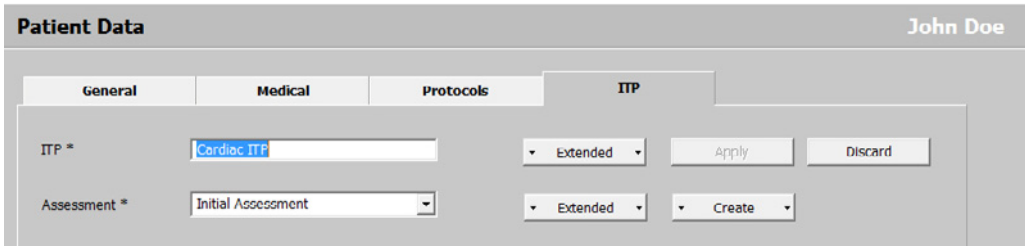


Figure 3–7: ITP edit mode

3.2.4 Renaming an ITP

In the edit mode, an ITP can be renamed. After changing the name, the new name can immediately be saved with the **[Apply]** button.

Note
The name of an ITP must be unique.

Requirement:

- An ITP has been selected.
- The ITP is in edit mode.

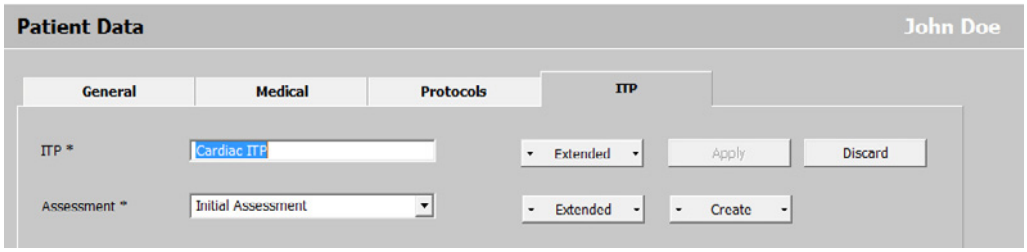


Figure 3–8: ITP edit mode – entering an ITP name

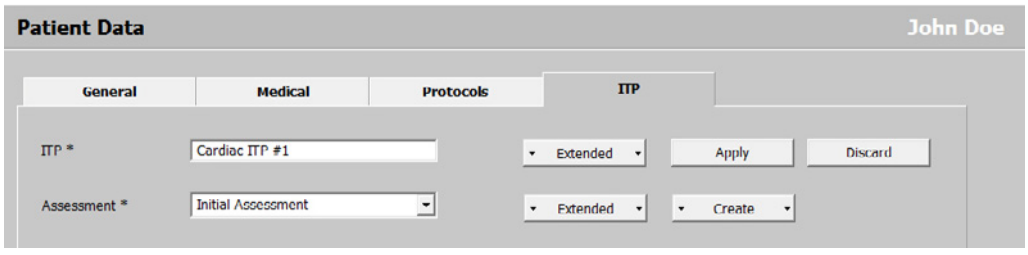


Figure 3–9: ITP edit mode – ITP renamed

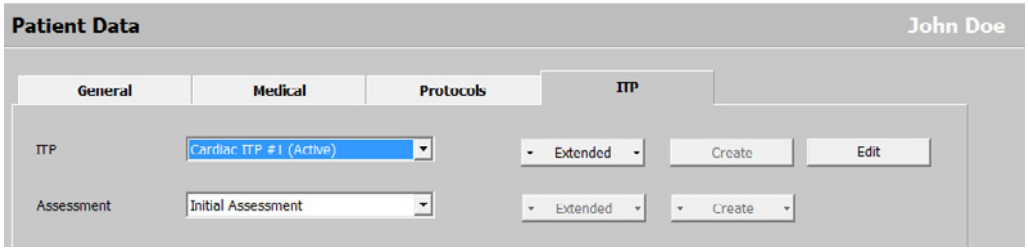


Figure 3–10: ITP saved, new name applied, ITP available for selection

3.2.5 Applying an ITP

After editing the ITP in the edit mode, the change can immediately be saved. Once saved, the changes to the ITP will automatically be applied to the assessments of the ITP if appropriate.

Requirement:

- Change in edit mode

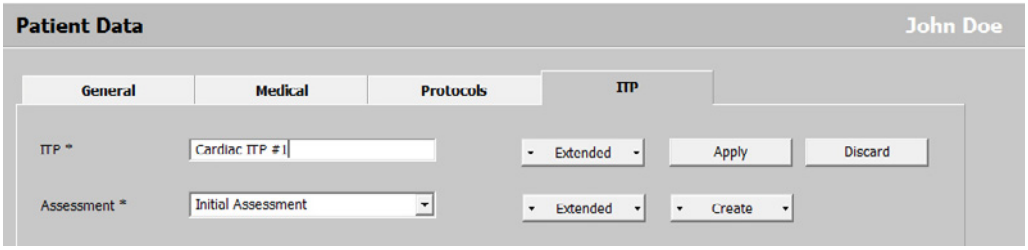


Figure 3 – 11: ITP edit mode – ITP renamed

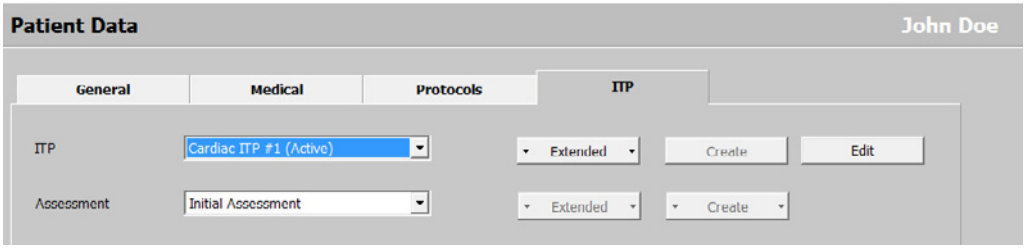


Figure 3 – 12: ITP saved, new name applied, ITP available for selection

3.2.6 Commenting an ITP

A comment can be entered for an ITP in edit mode at any time. All comments are saved in the comment field. Click the **[Extended]** button and select **[Edit Comment]**. A window opens for input of the comment.

Requirement:

- An ITP has been selected.
- The ITP is in edit mode.

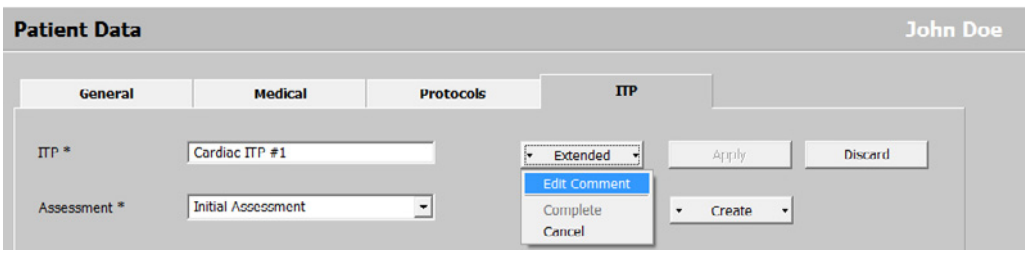


Figure 3 – 13: ITP selection mode – editing a comment

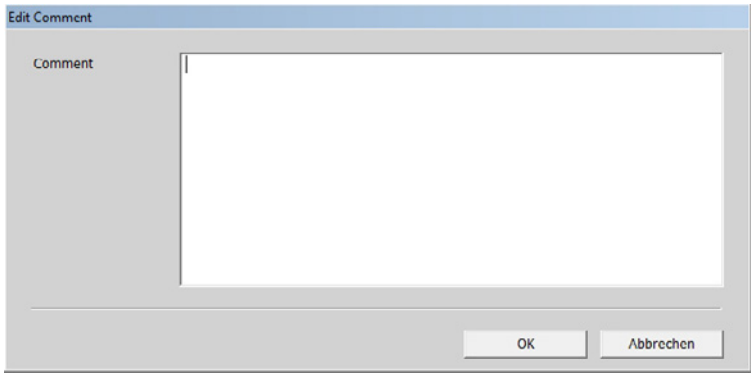


Figure 3 – 14: ITP comment window

3.2.7 Completing an ITP

An active ITP can be completed as soon as the configured number of assessments (one initial assessment, at least one reassessment, and one discharge assessment) is reached. If this requirement is not fulfilled, the ITP can only be canceled.

Select the ITP you want to complete. Click the **[Extended]** button and select the menu item **[Complete]**.

Confirm that you want to complete the ITP. Subsequently, you can enter a comment.

Requirement:

- An ITP has been selected.
- The ITP is in selection mode.
- IA completed
- Minimum number of RAs (configuration)
- DC completed

Note
The option *Complete* is only available if the ITP fulfills the completion criteria.

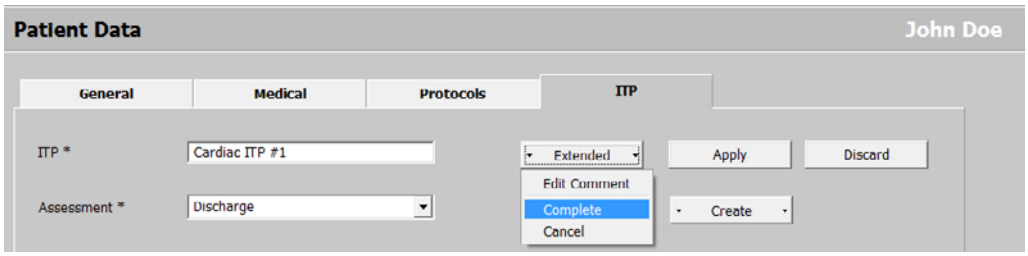


Figure 3 – 15: ITP selection mode – completing an ITP

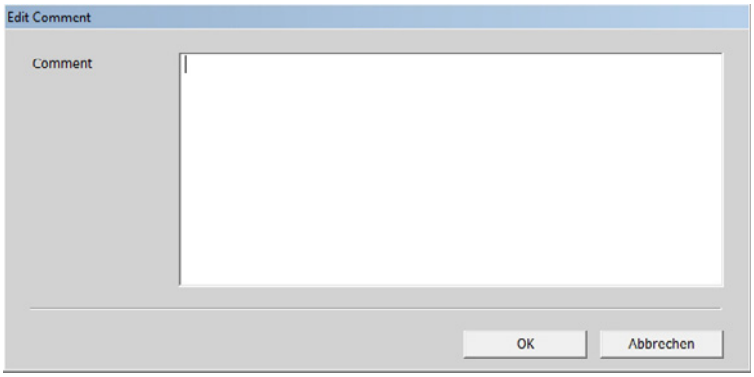


Figure 3 – 16: ITP comment window

Note
A completed ITP cannot become active again.

3.2.8 Canceling an ITP

In the selection mode, an ITP can be canceled at any time. Select the ITP you want to cancel. Click the **[Extended]** button and select the menu item **[Cancel]**.

Confirm that you want to cancel the ITP. Subsequently, you can enter a comment and the reason for canceling the ITP.

Hint
Reasons for cancellation can be created during configuration and on the user interface and they can be edited during configuration.

Note
A canceled ITP cannot become active again.

Requirement:

- An ITP has been selected.
- The ITP is in edit mode.

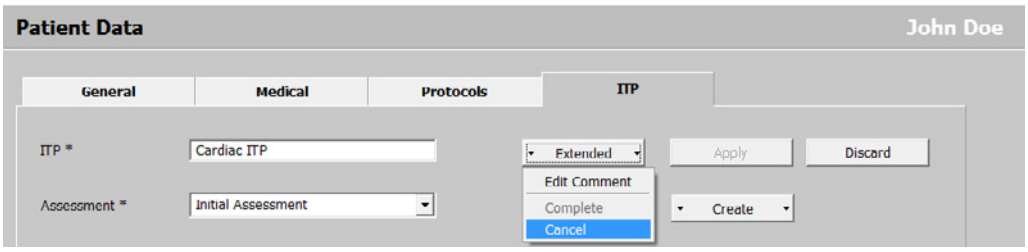


Figure 3 – 17: ITP edit mode – canceling an ITP

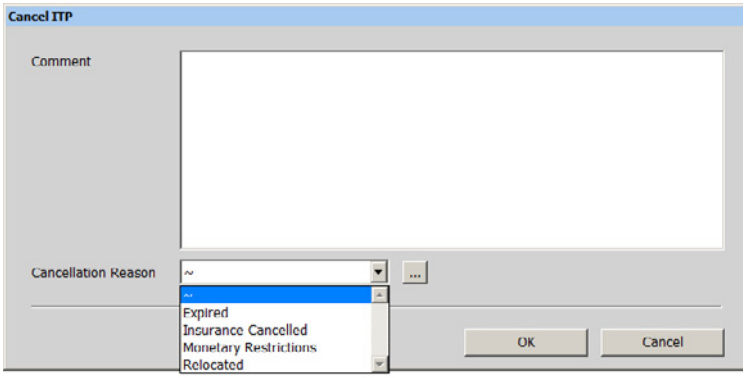


Figure 3 – 18: ITP comment window with reason for cancellation

3.2.9 Deleting an ITP

In the ITP menu, click the **[Extended]** button and select **[Delete]**. Confirm the deletion command.

Note
An ITP must be completed or canceled before it can be deleted.

Requirement:

- An ITP has been selected.
- The ITP is in selection mode.
- The ITP was completed or canceled.

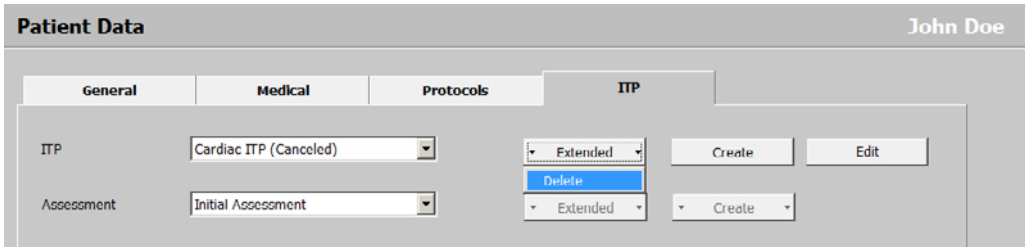


Figure 3 – 19: ITP selection mode – deleting an ITP

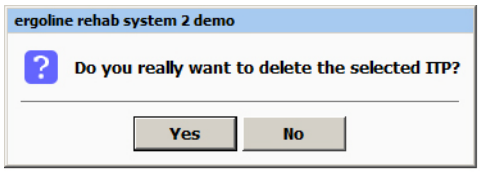


Figure 3 – 20: Deleting an ITP – confirmation

3.3 Assessment Categories

An ITP includes several assessments. Each ITP begins with an initial assessment (IA) that is created automatically and is followed by a configurable number of reassessments (RA). The ITP ends with a final assessment (DC) with which the patient is discharged.

Note
General rules:

- An RA can only be created for a completed IA or RA.
- A DC can only be created for a completed RA. The minimum number of RAs defined during configuration must be completed.

3.3.1 Initial Assessment

Requirement:

- ITP edit mode

An IA is automatically created for each new ITP. After creation of an ITP, the IA can be edited in the edit mode.

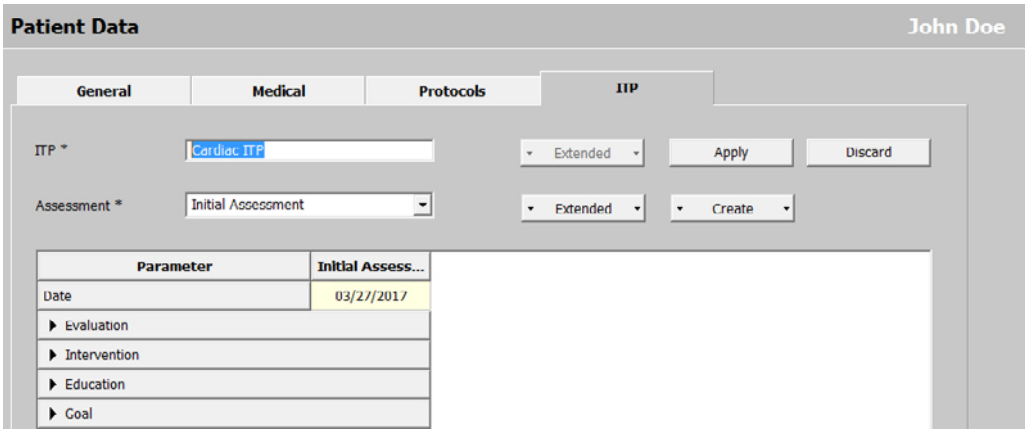


Figure 3–21: ITP edit mode – IA created automatically

3.3.2 Reassessment

Requirement:

- Active ITP
- ITP edit mode
- Preceding assessment (IA, RA) completed.

An RA can only follow a completed IA or RA. Therefore, the items in the *Create* menu for the assessments are active only when the requirement is fulfilled.

Click the **[Create]** button and select the menu item *Reassessment*. With this operation, you create a new reassessment. The assessment automatically changes to the edit mode.

Hint
Number the reassessments in chronological order.

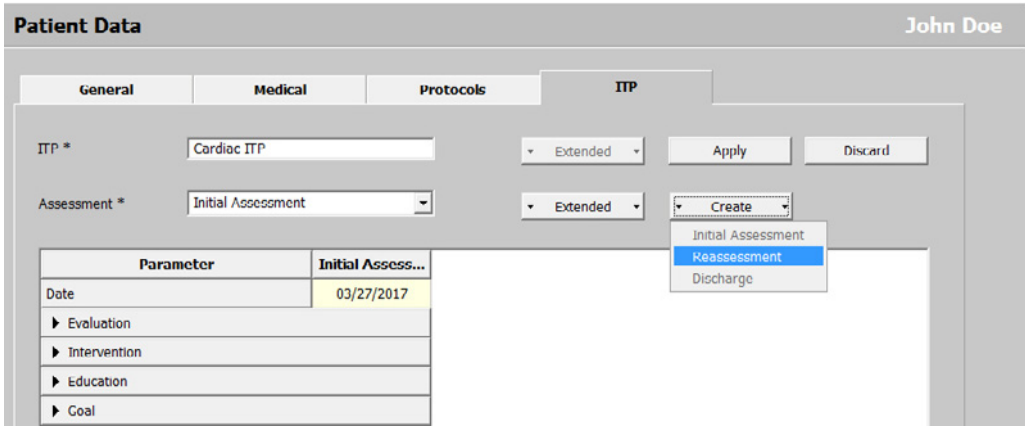


Figure 3–22: ITP edit mode – creating an RA

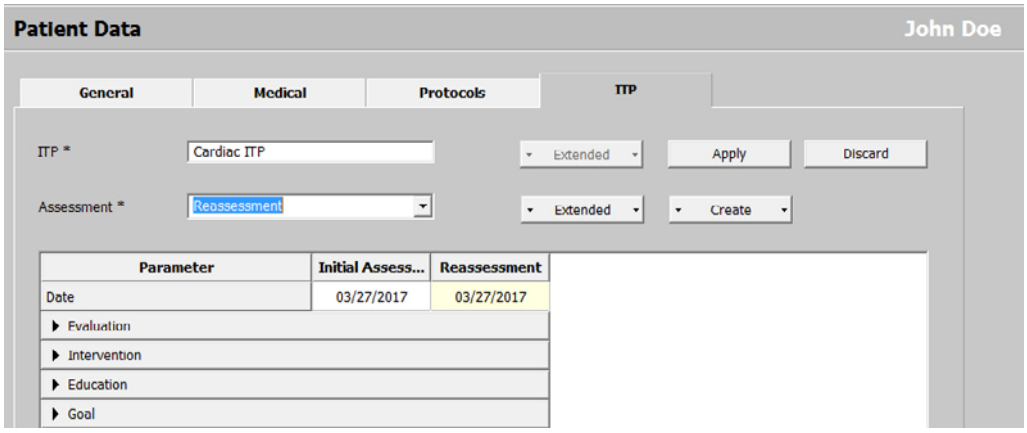


Figure 3–23: ITP edit mode – RA created

3.3.3 Discharge

Requirement:

- Active ITP
- ITP edit mode
- IA completed
- Minimum number of completed RAs

Note
A DC can only be created if the defined minimum number of RAs has been completed. Therefore, the menu item *Discharge* of the *Create* menu for assessments is active only when the configured minimum requirement is fulfilled.

Click the **[Create]** button and select the menu item *Discharge*. With this operation, you create a new discharge, which is automatically in the edit mode.

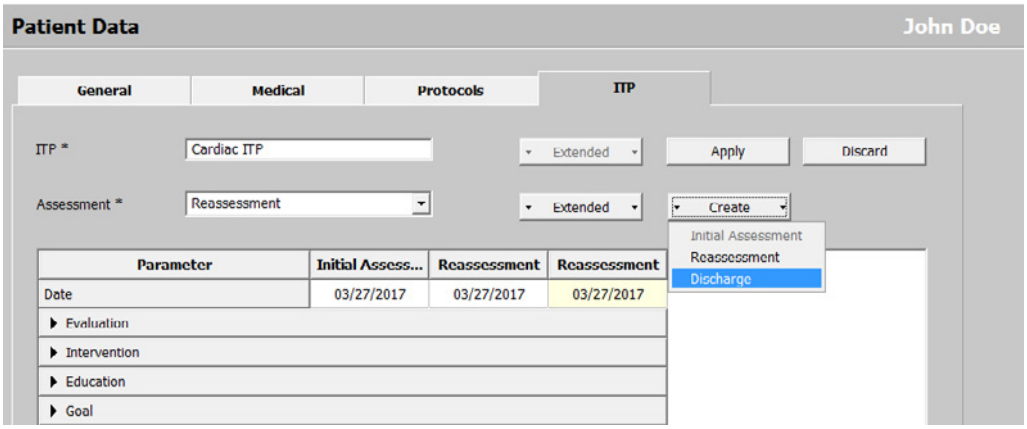


Figure 3–24: ITP edit mode – creating a DC

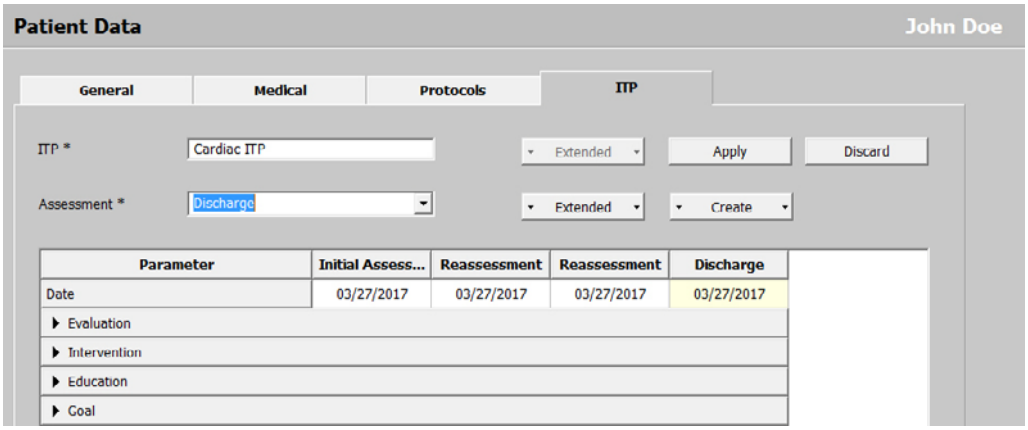


Figure 3–25: ITP edit mode – DC created

3.4 Assessment Functions

The following functions are available:

- Create an assessment (see Assessment Categories)
- Select an assessment
- Edit an assessment
- Rename an assessment
- Apply an assessment
- Discard an assessment
- Comment an assessment
- Complete an assessment
- Delete an assessment

3.4.1 Selecting an Assessment

Requirement:

- Selected ITP in edit mode

The assessments created in the selected ITP can be edited. Select the assessment you want to edit.

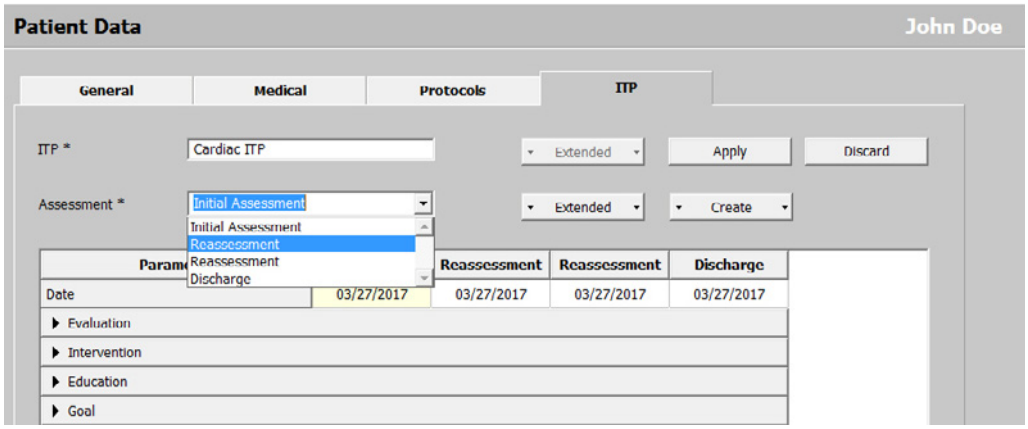


Figure 3–26: ITP edit mode – selecting an assessment

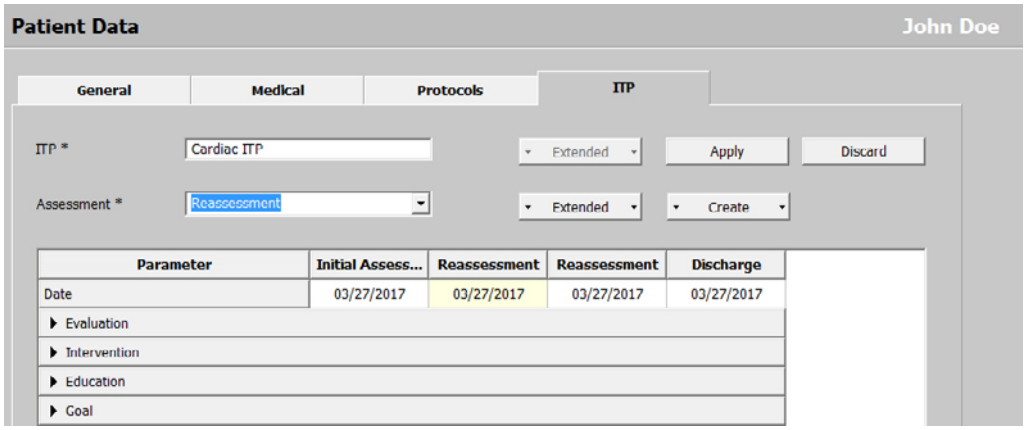


Figure 3–27: Assessment selected

3.4.2 Editing an Assessment

The acquired patient data can now be entered in the assessment parameter areas *Evaluation*, *Intervention*, *Education*, and *Goal* for the active or selected assessment (ITP edit mode).

After input of the patient data, they can be saved to the ITP. Click the **[Apply]** button (see section 3.2.5 "Applying an ITP"), the data input session will be terminated.

Hint
Use the keyboard to control the data input on the assessment screen.

3.4.3 Renaming an Assessment

Requirement:

- ITP in edit mode

In the edit mode, an AS can be renamed. After changing the name, the new name can immediately be saved with the **[Apply]** button.

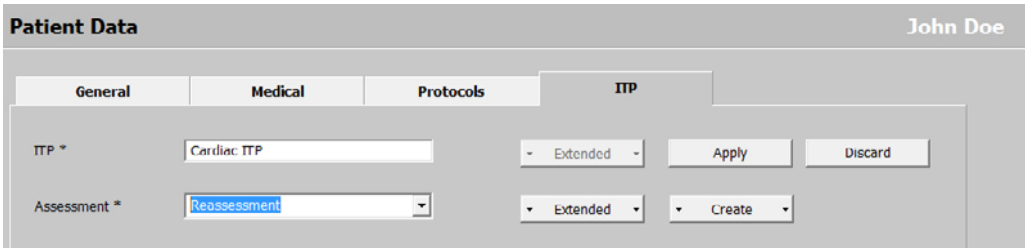


Figure 3 – 28: Editing an assessment

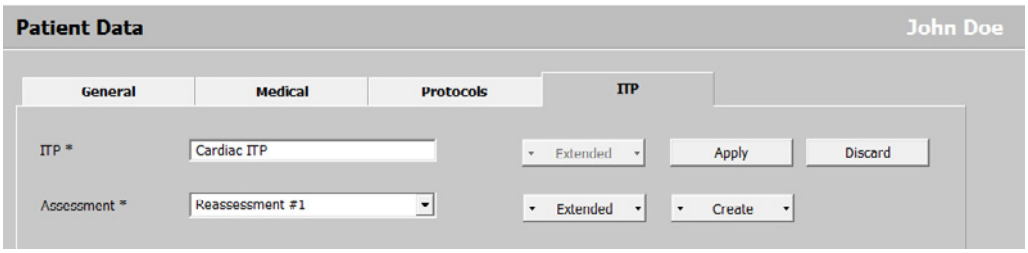


Figure 3 – 29: Renaming an assessment

3.4.4 Applying an Assessment

Requirement:

- ITP in edit mode

After editing an assessment, the change can immediately be saved with the **[Apply]** button. The modification will be saved to the ITP.

3.4.5 Commenting an Assessment

Requirement:

- ITP in edit mode

In the selection mode, a comment can be entered for a selected assessment or existing comments can be edited / corrected.

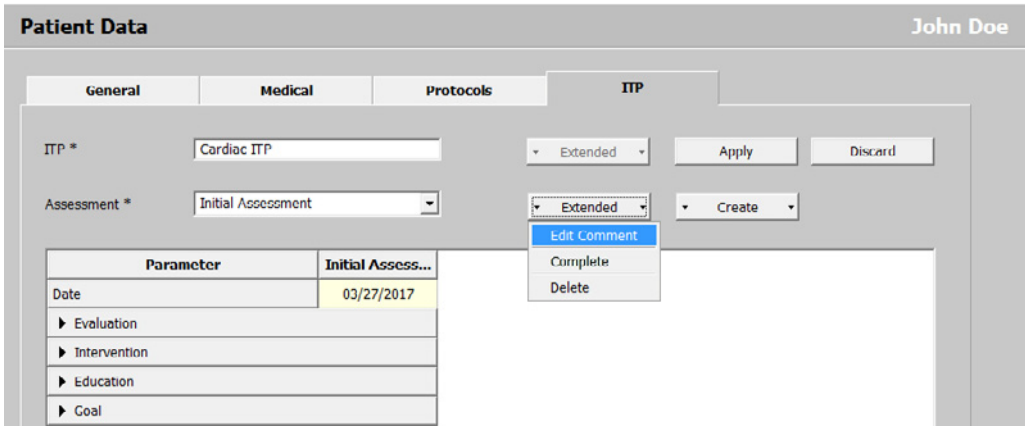


Figure 3–30: Editing an assessment comment

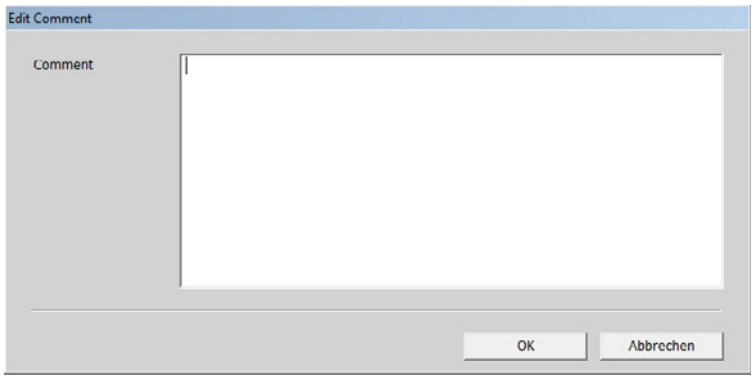


Figure 3–31: Editing a comment

3.4.6 Completing an Assessment

An assessment must be completed before you can add a new assessment to the ITP.

Select the assessment you want to complete (according to the process definition, this is always the assessment added last).

Click the **[Extended]** button and select the menu item *Complete*.

Requirements:

- ITP in edit mode

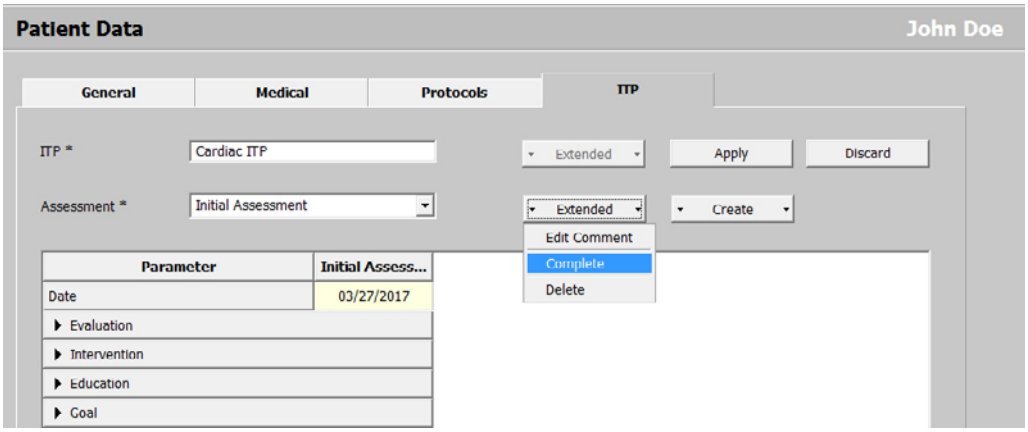


Figure 3–32: Complete an assessment

You can add a comment for the completed assessment if you want to.

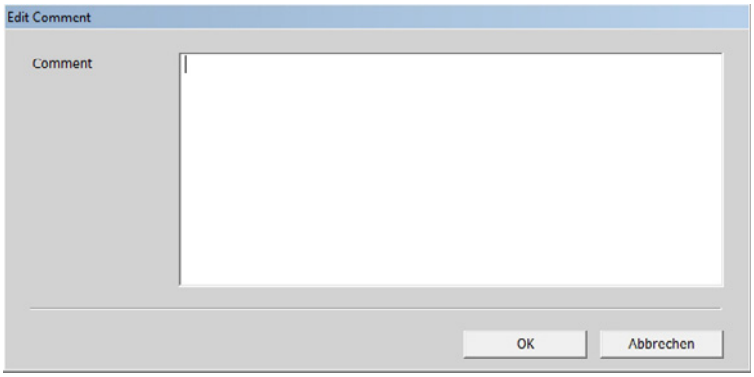


Figure 3–33: Editing a comment

After confirmation with **[OK]** the selected assessment is completed. You can now use the **[Apply]** button to update the ITP with the completed assessment.

3.4.7 Deleting an Assessment

You can delete the assessment created last.

Select the assessment created last, click the **[Extended]** button and select *Delete*. Confirm the deletion command.

Requirement:

- ITP in edit mode
- The assessment created last is selected.

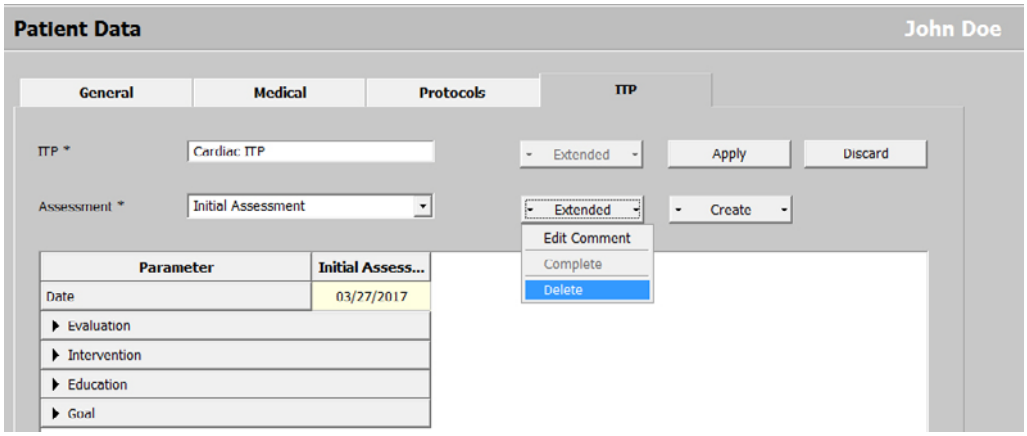


Figure 3–34: AS in selection mode

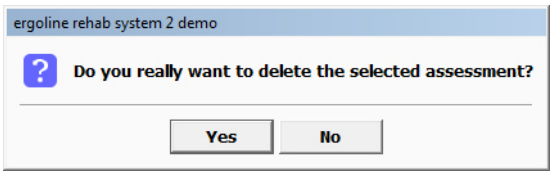


Figure 3–35: AS in selection mode – Deleting the AS

4 ITP Functions

The ers2 software offers two ITP templates.

- Cardiac ITP
- Pulmonary ITP

The selected ITP can be populated with patient data in the created and selected assessments for individualized therapy planning and documentation. Each new created assessment always refers to the preceding assessment. One of the purposes of ITP is the documentation of the rehabilitation progress over a selected period of time.

4.1 Core Components of an Assessment

The ITP structure differentiates between the following core components for each assessment:

- **Evaluation**
  The Evaluation comprises the initial acquisition of the patient's personal diagnostic parameters (IA) and the documentation of their change in the subsequent assessments (RA, DC).

- **Intervention**
  Based on the Evaluation, the Intervention covers the definition of individual therapeutic interventions (IA) and their documentation in the subsequent assessments (RA, DC).

- **Education**
  Under Education, the measures to be implemented and that accompany the therapy as well as the learning content specifically intended for the patient (IA) and the subsequent assessments (RA, DC) are documented.

- **Goal**
  Under Goal, the specific and general patient goals and/or therapy goals are defined (IA) and the degree of achievement is documented in the assessments (RA, DC).

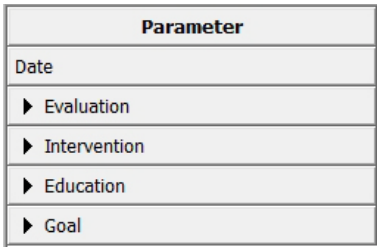


Figure 4 – 1: AS core components

4.2 Assessment Main Areas

The core components are divided into the main areas:

- Patient
- Exercise
- Nutrition
- Psychosocial

This is where the data for the core components are entered. By clicking a core component, you open the corresponding main area. Using the *Patient* main area of the *Evalulation* core component as an example, we will explain the possible entries for *Knowledge*.

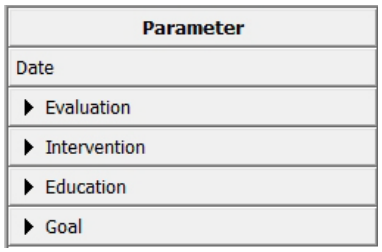
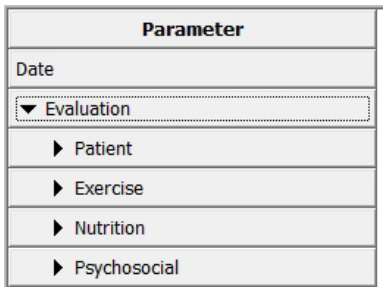
Core Components	Main Areas
	

Figure 4–2: AS core components and main areas

By clicking a main area, you display the defined data input options.

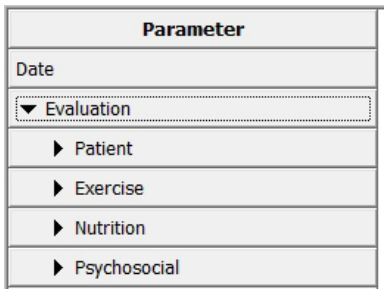
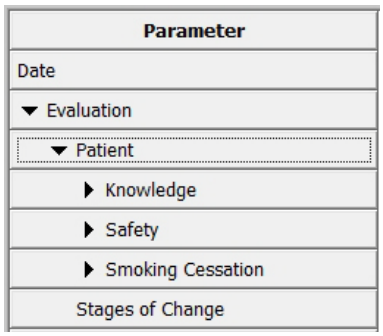
Main Areas	Data Input Options
	

Figure 4–3: AS main areas and data input options

By clicking a data input option, you open the corresponding list of items to which data can be assigned in a selected assessment.

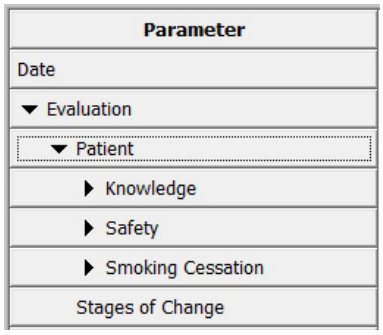
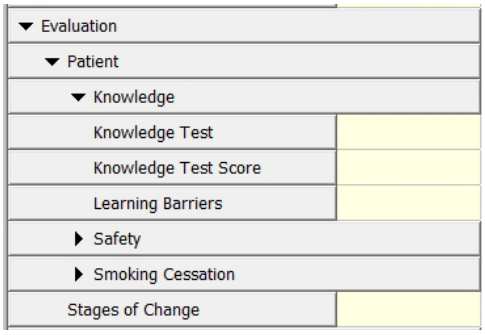
Data Input Option	Item
	

Figure 4–4: AS data input options and items

Symbols

Menu closed	Menu open
▶	▼

Hint
By right-clicking an area you open a context menu where you can expand the area or expand/collapse all parameters.

4.3 Assessment Item

To be able to enter data in a selected assessment of an ITP, the assessment needs to be in edit mode.

Note
Selected assessments are identified by a yellow background.

4.3.1 Assessment Input Menus

The program offers a number of different input menus. The following section describes each menu type.

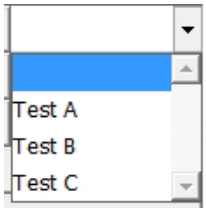
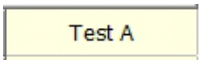
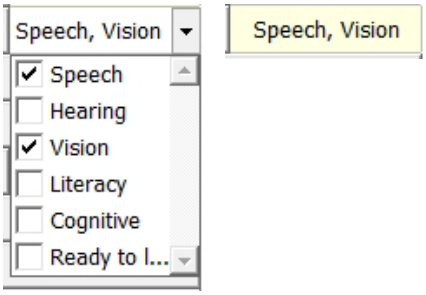
Before selection	Selection	Description
		Parameter input: the input fields are formatted for the respective item types. If the input is incorrect (wrong format, e.g., if you enter text and the program expects a number), the field turns red and the input is rejected.
		Check box
		Selection of a single item
		Selection of multiple items: if the number of selected items exceeds the available space, the entries are displayed in a pull-down menu (mouse pointer on item).

Figure 4–5: AS item input menus

Note
If an input for any of the items is incorrect, it will not be possible to save the AS or ITP. A warning will be displayed.

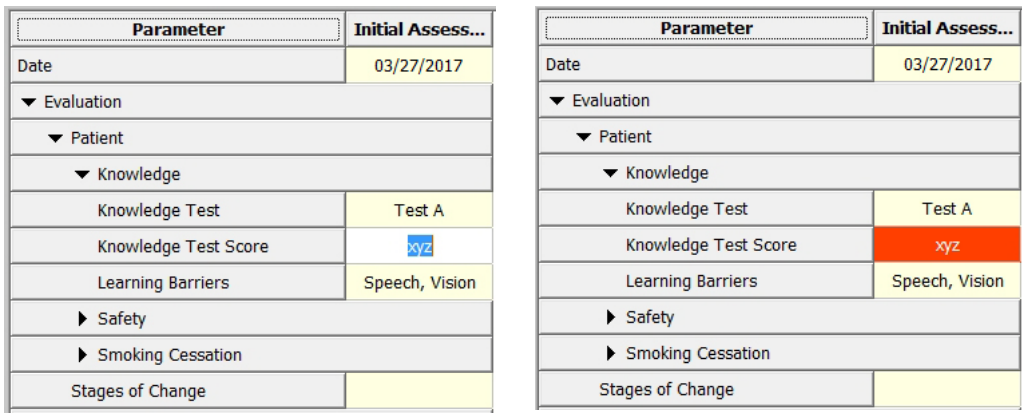


Figure 4–6: AS item input menus – warnings

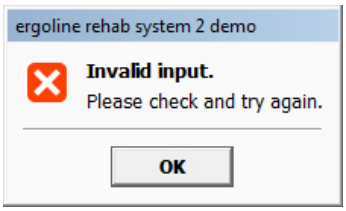


Figure 4–7: AS item – warning

Warning
The values entered in the ITP must correspond to the units specified in the items. The therapist is responsible for verifying that this condition is met.

4.4 Printing an ITP

The ITP can be documented and printed at any time in the form of a defined report.

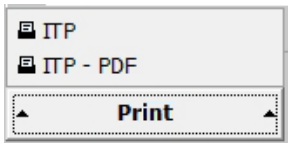


Figure 4–8: Printing an ITP

Note
The generated ITP report only provides a summary of the data entered in the ITP. Please contact your ergoline service partner if you want to configure reports.

Warning
The values included in the ITP report must correspond to the units specified in the items. The therapist is responsible for verifying that this condition is met.

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