Instructions for use

RAUMED DataView

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1 Introduction

1.1 Intended use of the software

The software **RAUMED DataView is not a medical device** in the sense of the German Medical Devices Act (MPG). The Software is compatible with a MPR1/2 firmware version from **2.00.0063**.

The software RAUMED DataView serves to display measuring data online/offline on computers, without any monitoring and alarm function. The software is not part of the basic equipment of RAUMEDIC AG's medical devices. The RAUMED DataView software is not absolutely necessary for the function of the devices.

Therapy decisions may be made only on the basis of the data measured with the medical equipment and displayed on said medical equipment.

RAUMEDIC AG devices can be connected to a computer via USB interface.

The software serves for the

- online display of the measured values
- expanded storage of the measured values on the computer hard drive
- offline display of the stored values
- administration of patient data
- data export of measured values to other data evaluation programs (e.g. Excel)
- printout of measured charts

1.2 Program structure

The software is divided into three main areas (see Figure 1):

- **Main menu** to access the main functions of the software **(W1)**
- **Program contents** for the display of the data **(W2)**
- **Status bar** with information on the software and hardware **(W3)**

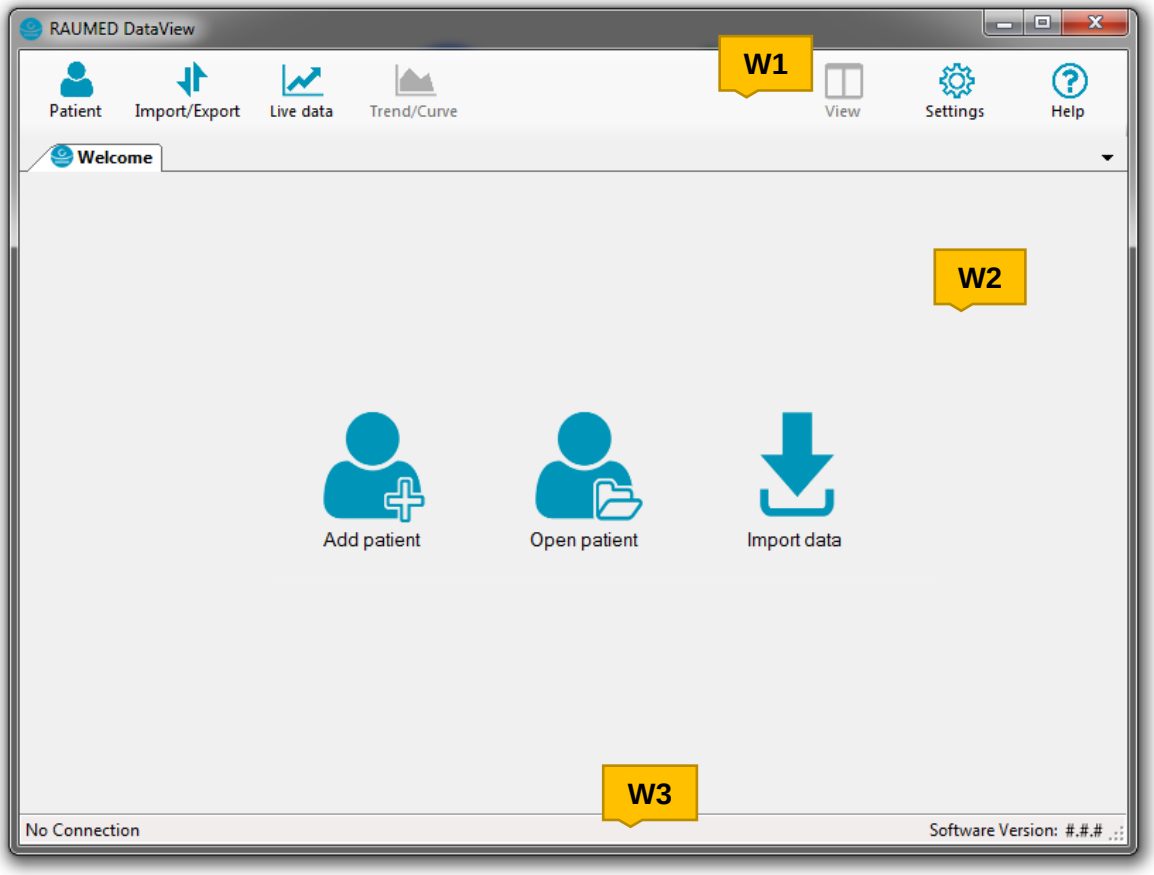

Figure 1 Program structure

1.2.1 Main menu

The Main menu contains the following menu items:

- Patient
- Import/Export
- Live data
- Trend/Curve
- View
- Settings
- Help

1.2.2 Program contents

On program start, the Welcome screen appears (see Figure 1). This provides access to frequently used functions:

- Add patient
- Open patient
- Import data

1.2.3 Status bar

The status bar (see Figure 2) provides important information on the software and connected hardware. Amongst these are:

- Type of connected device
- Serial number of the RAUMEDIC DATALOGGER (SN)
- Firmware version
- Software version

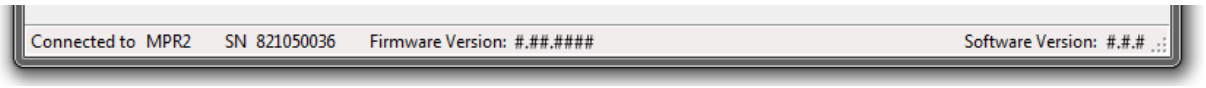

Figure 2 Information of the status bar

1.2.4 Arrangement of window contents

Individual tabs or contents can be arranged side by side or vertically within the RAUMED DataView program window, in order to display the content more clearly and, if required, to make it visible at the same time for comparison purposes. The following steps can be used to arrange the window contents (see also Figure 3):

1. Click and hold the tab of the window in the tab bar with the mouse
2. Move the window
3. Drag the mouse pointer to the required position **(A1)**
4. Release the mouse

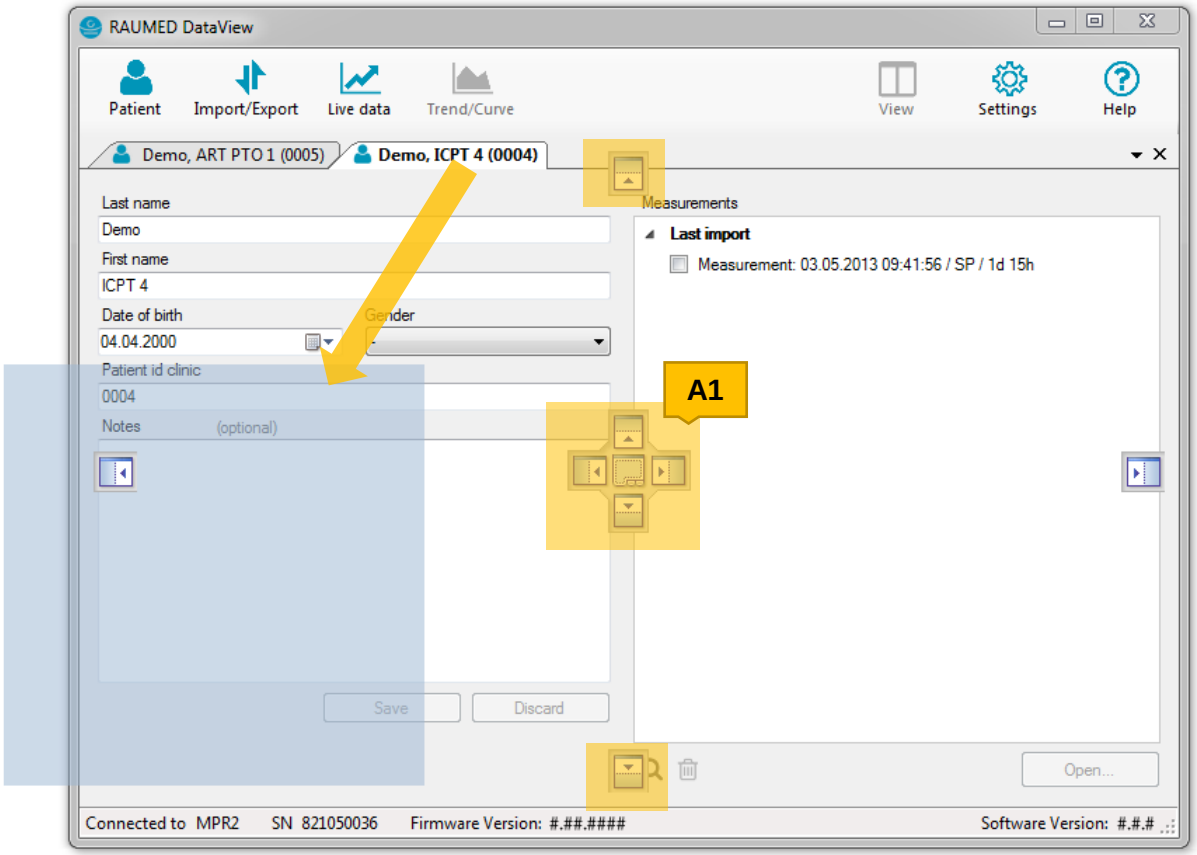

Figure 3 Arrangement of window contents

Note If a window is moved to a position (A1), you can already see from the highlighting which position the window will be in after the mouse has been released.

Note If one of the windows is no longer positioned within the program window, it can be moved back into the program window by double-clicking on the window title.

2 Patient management

RAUMED DataView sorts the data at the top level by patients. The patient data, which can be created, edited, and deleted, are therefore the first contact point for data management.

2.1 Adding a patient

A patient can be added directly from the Welcome screen using "Add patient", or from the Main menu item "Patient > Add patient". The following dialog opens.

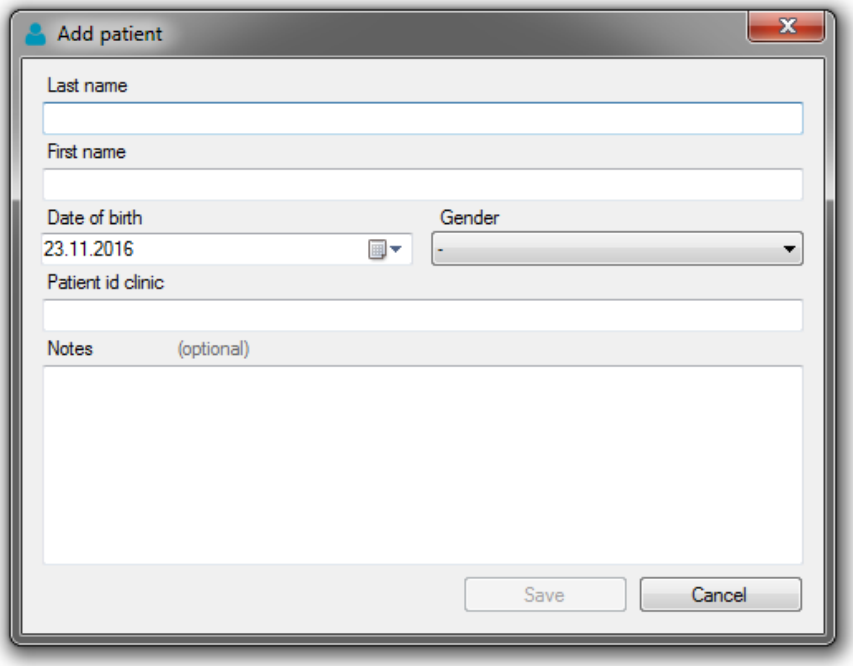

Figure 4 Patient management: Add patient

A patient can only be saved when all the information required has been entered.

This includes:

- Last name and first name
- Date of birth
- Gender
- Patient ID clinic

Optional information includes:

- Comments

2.2 Opening a patient and additional actions

Patient information can be loaded directly from the Welcome screen using "Open patient", or from the Main menu item "Patient > Open patient". The following dialog opens.

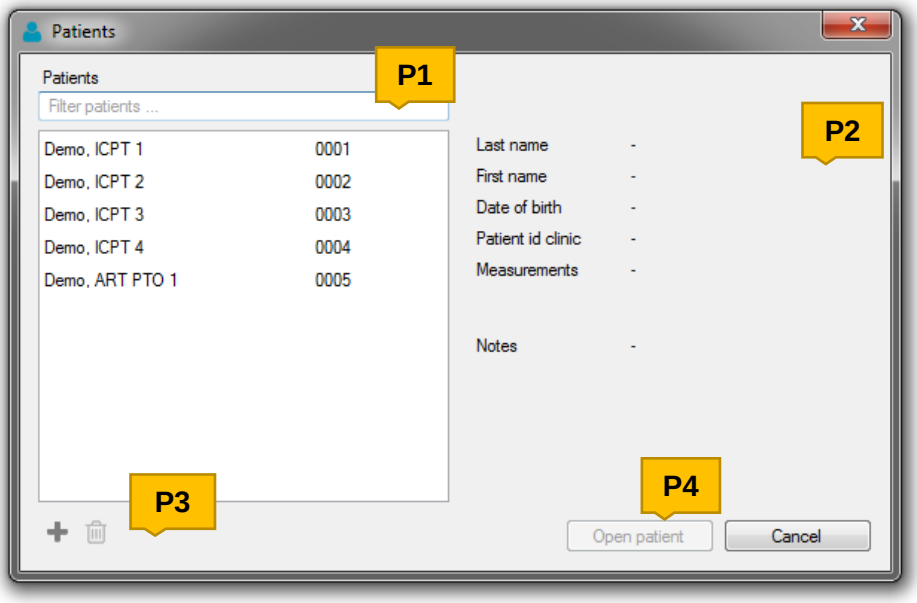

Figure 5 Patient management: Opening patient information

The dialog contains the following information:

- Patient list with filter function **(P1)**
- Detailed information on the patient selected **(P2)**
- Actions which can be applied to the selected patient **(P3)**
- Open patient or close dialog **(P4)**

The filter function from **(P1)** can be used to limit the number of patients that are displayed. All data from **(P2)** are searched when search terms are entered. Several search terms can be entered one after the other. Multiple search terms are combined with the logical operator **AND**. The order of the terms entered is irrelevant.

The patient information of a patient selected from the patient list can be opened by double-clicking on it or by using the "Open patient" button **(P4)**.

The actions from **(P3)** can be used to:

- Create a new patient with ✚ (see section 2.1)
- Delete the selected patient using 🗑 (see section 2.3)

2.3 Deleting a patient

A patient is deleted using the list actions in the "Open patient" dialog (see Figure 5, **(P3)**).

To do so, select a patient and then click on the 🗑 button.

Note	A deleted entry (patient) is **permanently** removed from the database! Before deleting a patient, a dialog asks for confirmation that this action should really be carried out.

2.4 Editing a patient information

Patient information can be edited in the detail view of a patient. Please click on “Open patient” first as described in section 2.2. The following view is displayed:

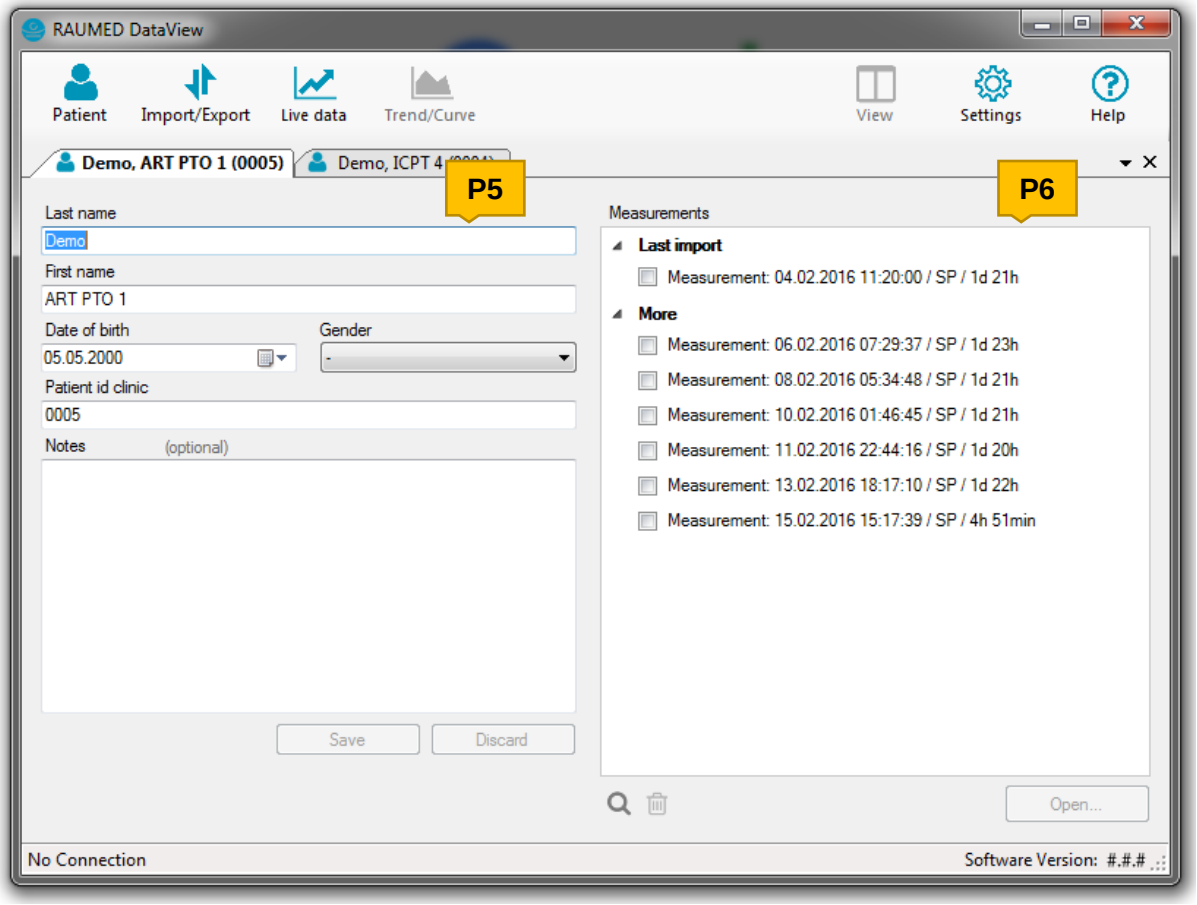

Figure 6 Patient information

This view is divided into 2 areas:

1. Patient information (left) **(P5)**
2. Measurements of a patient (right) **(P6)**

Patient information can be saved and edited in this view simply by typing into the text boxes. However, the button “save” is only enabled when all the information required has been entered correctly. The "Cancel" button can be used to reset the entries of the information that was saved last.

3 Measurements

3.1 Managing measurements

The measurements of a patient can be managed via the measurements of a patient window **(P6)**. Please click on “Open patient” first as described in section 2.2.

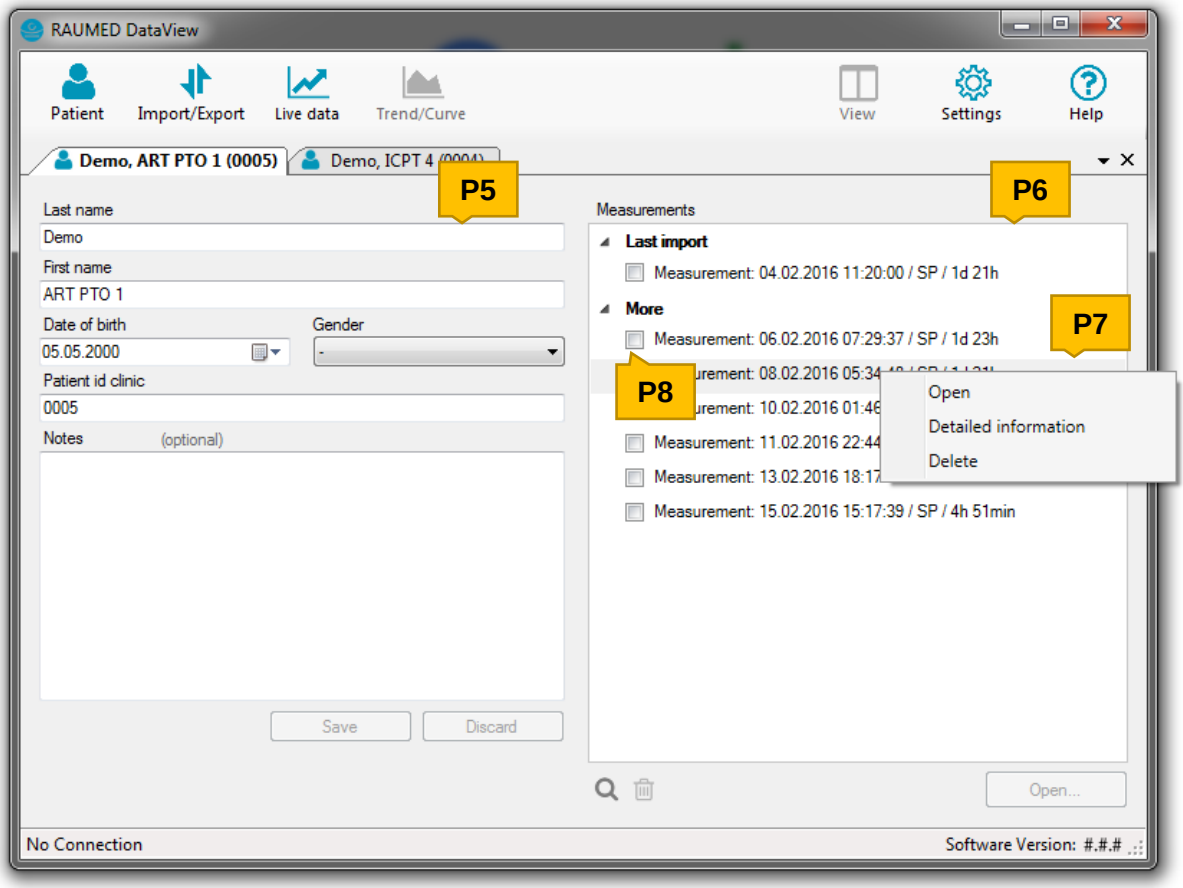

Figure 7 Patient information

All measurements of a patient are listed here. This list is sorted by the **date of import**. In addition, the last imported measurements are grouped at the top of the list.

3.1.1 Opening measurements

A measurement can be opened from this view in several ways:

a) Double-clicking on a measurement
b) Right-clicking on a measurement > Open **(P7)**
c) Select the measurement and tick the checkbox **(P8)** > Select the "Open" button from the list actions
(makes it possible to open several measurements at the same time)

3.2 Importing measurements

Measurements can be imported into RAUMED DataView in several ways:

a) Via the Welcome screen by using the button "Import data"
b) Via the Main menu using the button "Import/Export > Import data ..." (see Figure 8, **(I1)**).

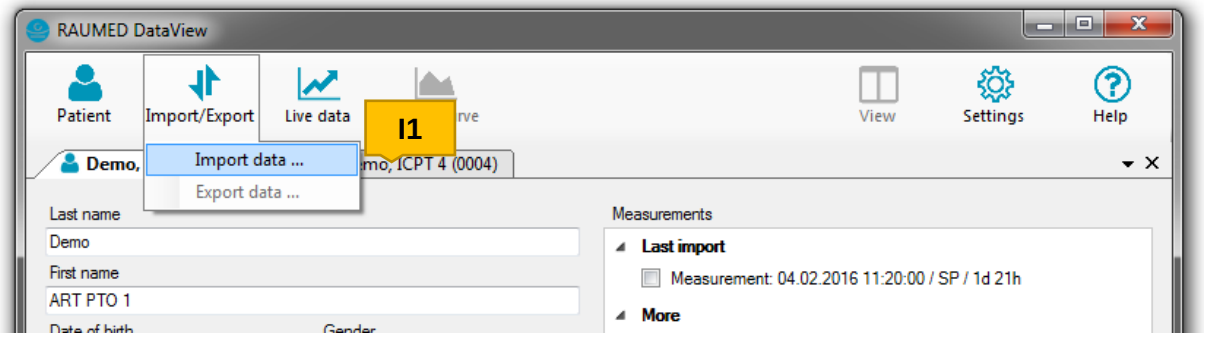

Figure 8 Main menu: Import/Export

The import dialog opens (see Figure 9). This can be used to import data from

1. A connected device
2. A DataView data file (***.dvdata**)
3. A data file of the Software Datalog (***.mdb**)

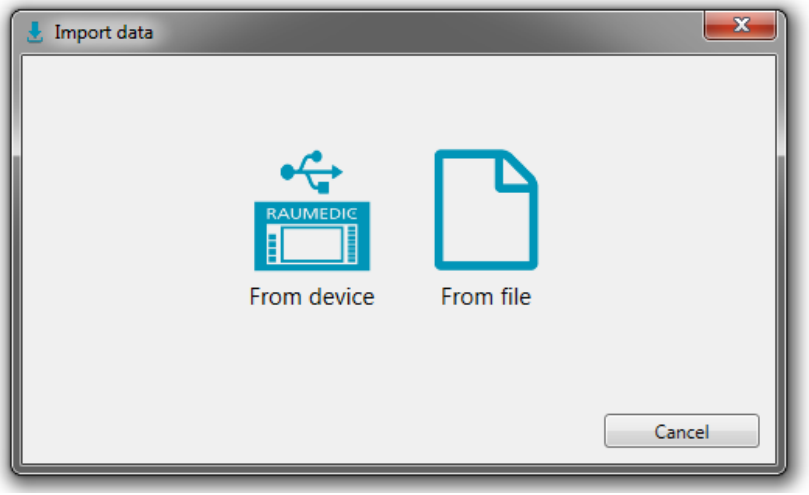

Figure 9 Import dialog

Depending on the selection of the data to be imported, additional settings are required. These are in particular described in the help pages of the software.

1. Import from devices
2. Import from data files

3.3 Exporting measurements

Measurements can be exported from RAUMED DataView in several ways:

a) Via the Main menu using "Import/Export > Export data ..." (see Figure 8, **(I1)**)
b) Via the list of measurements from the patient details by right-clicking on a measurement > Export (see Figure 7, **(P7)**)
c) Via the action menu of a plot (see Figure 11, **(C3)**)

The export dialog opens (see Figure 10). Select the data format to be exported.

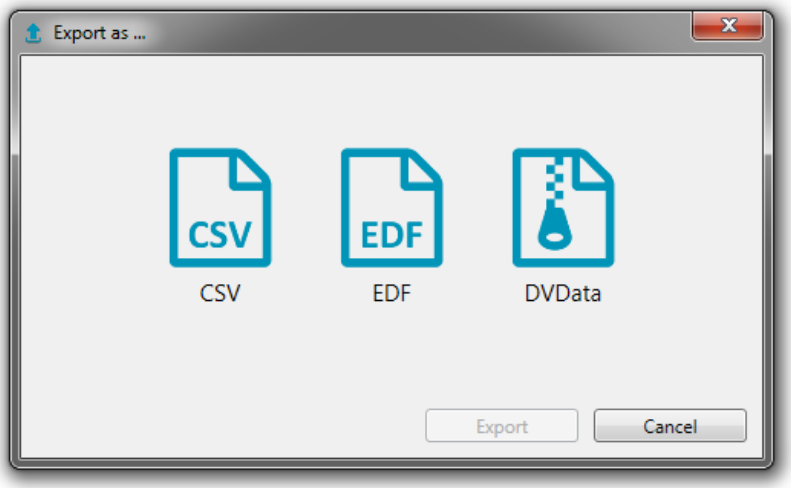

Figure 10 Export dialog

4 Curve and trend data

Curve and trend data are displayed together in the plot view (see Figure 11).

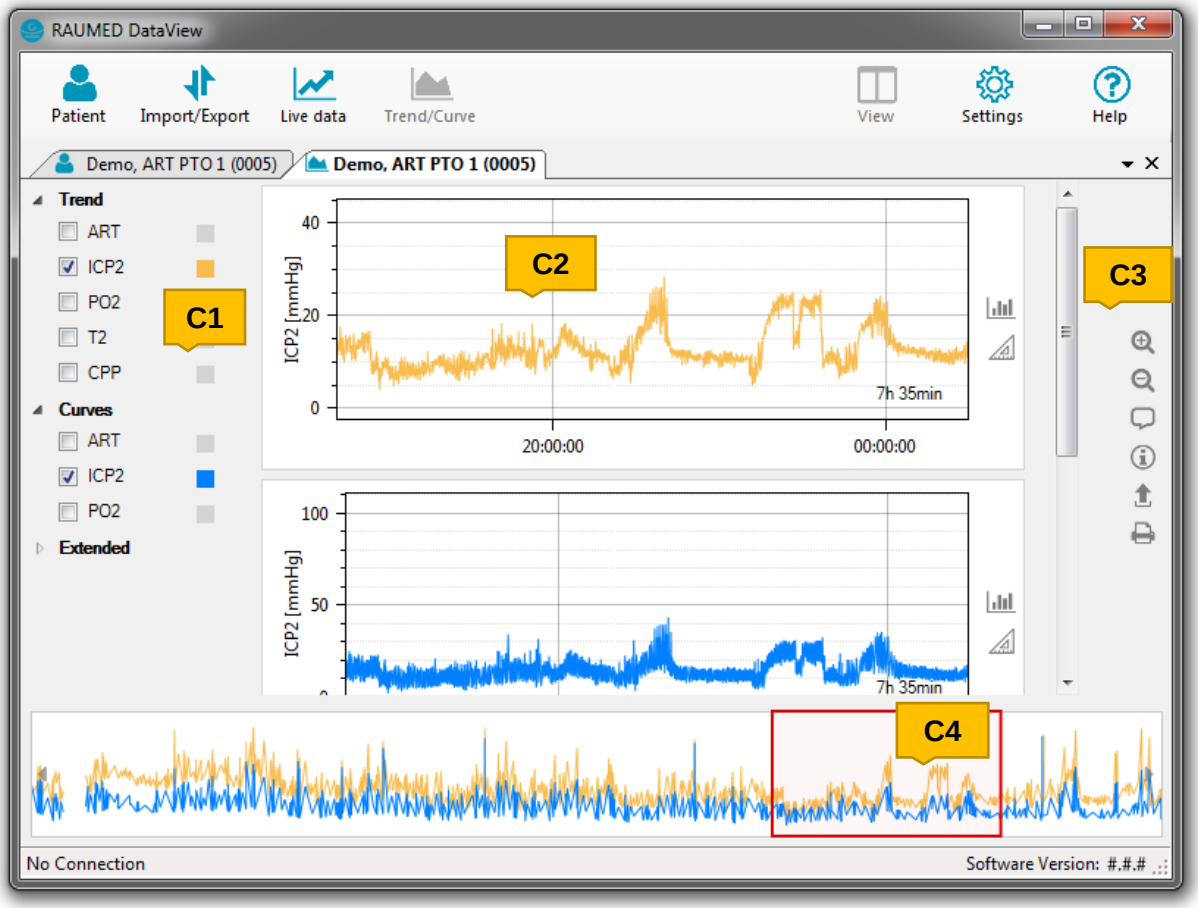

Figure 11 Curve and trend data

The plot view is divided into 4 main areas:

1. Data selection (left) **(C1)**
2. Diagram view (centre) **(C2)**
3. Actions (right) **(C3)**
4. Timeline, navigation **(C4)**

4.1 Selection of channels and data

In the data selection **(C1)** all measuring channels and data, which are available for this measurement and which can be graphically displayed as a diagram, are listed. The data are grouped according to:

a) Trend data (frequency 1 Hz)
b) Curve data (frequency depending on the catheter)
c) Extended data (ORx, PRx, integral curves, comments)

Data are enabled or disabled via the checkbox of the respective row (see Figure 12). Depending on the data type, a corresponding graph is loaded into the diagram display.

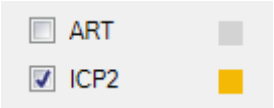

Figure 12 Plot view: Data selection

Color selection
Each channel of the data selection can be associated with a color. A click on the color box opens the color dialog. The selected color is then associated with all representations with this designation and is therefore also used in the measurements of other patients, statistics, print views, etc.

4.2 Navigation in plot data

4.2.1 Timeline

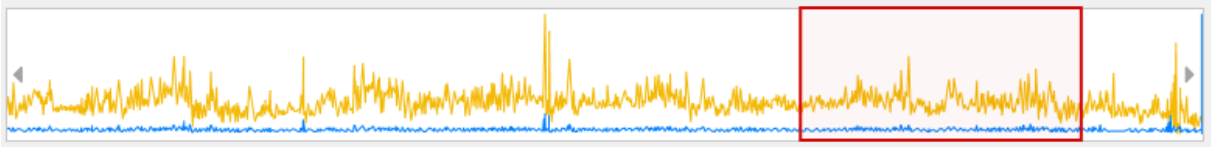

Figure 13 Plot view: Navigation in timeline

The timeline is used for rapid chronological navigation in diagram data. In this view, all active diagrams are displayed one above the other. The area framed in red always indicates the area which is displayed in the actual diagram display (see Figure 11, **(C2)**).

The scaling of the diagrams is automatically adjusted to the red selection. The closer one zooms in on the diagram data, the more details are displayed in the diagrams. This allows smooth scrolling between minimum and maximum resolution.

1. Minimum resolution: Diagram width = time of the entire measurement
2. Maximum resolution: Diagram width = 2 seconds

4.2.2 Zooming and moving

The resolution of the display can be adjusted either by using the actual diagrams or the timeline.

Zooming is carried out with the mouse wheel. Moving is carried out by holding and moving the mouse.

If a mouse wheel is not available, the zoom level of the timeline can be adjusted using the and (see Figure 11) action buttons additionally.

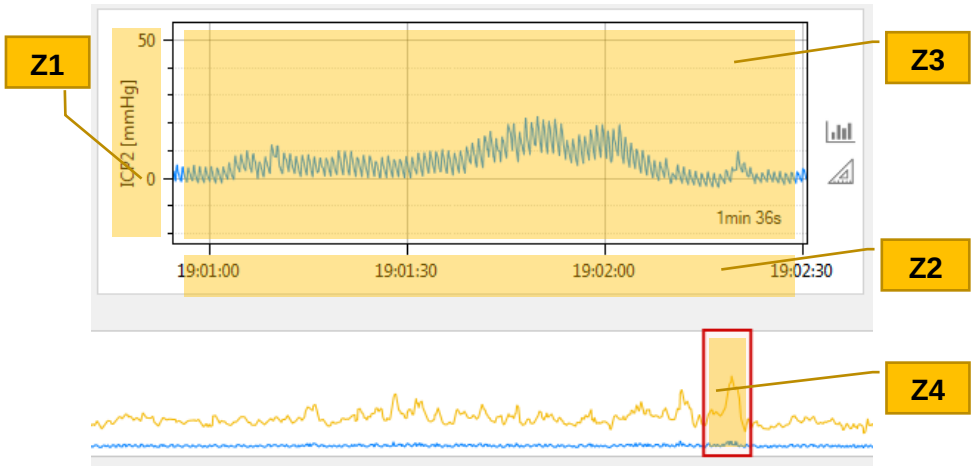

Figure 14 Plot view: Zooming and moving

The individual areas of a diagram react differently to zooming or moving:

Area	**Zooming** (moving the mouse wheel)	**Moving** (holding and moving the mouse)
Z1 **y-axis** of the diagram	Adjusts the resolution of the **y-axis**	Moves the diagram display in the direction of the **y-axis**
Z2 **t-axis** of the diagram	Adjusts the resolution of the **t-axis** (time)	Moves the diagram display in the direction of the **t-axis** (time)
Z3 Plotting area of the diagram	Adjusts the resolution of the **t-axis and y-axis** at the same time	Moves the diagram display in the direction of the **t-axis and y-axis** at the same time
Z4 Selection of the timeline	Adjusts the resolution of the **t-axis** (time)	Moves the diagram display in the direction of the **t-axis** (time)

4.2.3 Predefined intervals and automatic scaling

Right-clicking on a diagram (see Figure 14, **(Z3)**) makes it possible to select the display options. The following three settings are available:

Predefined intervals
Depending on the entry selected from the context menu (see Figure 15), the diagram displays are automatically adapted to the selected interval. The intervals can be defined in the settings themselves (see section 7.1).

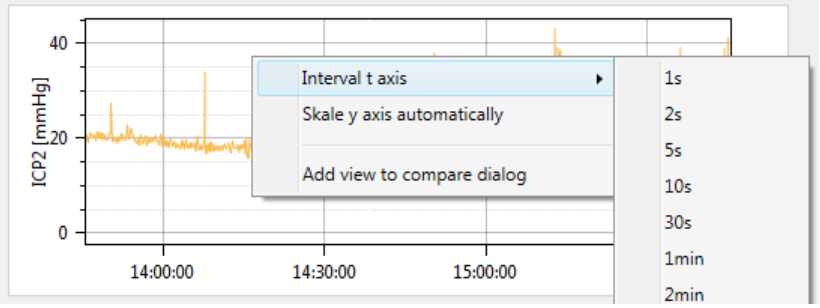

Figure 15 Predefined axis intervals and automatic scaling

Automatic scaling of the y-axis

The values of the y-axis can be scaled automatically. The size of the section depends on the minimum and maximum values of the overall measurement.

4.3 Comments

RAUMED DataView offers the possibility to add comments in diagram data. This allows the user to store additional information for the specific times of the individual measurements.

Figure 16 Diagrams: Comments

Showing/hiding comments

Comments can be shown or hidden in the data selection under "Extended" group **(K1)**. The checkbox next to the entry "Comments" shows the display status.

Creating a comment

A new comment can be added using the action button **(K2)**. A comment dialog opens **(K3)**, where the contents of the comment can be added.

The new comment is always inserted in the middle of the current diagram display. The position of a comment is indicated directly in the diagram with a red position marker **(K4)**.

After the comment has been entered, the data must be stored using the "Save" button.

Editing a comment

The position of a comment can be changed using the position marker: Take hold of the position marker with the mouse, move it to the new position and release it.

The comment text can be edited using the comment dialog. This dialog is opened by double-clicking on the position marker of a comment. After the comment has been adjusted, the data must be stored using the "Save" button.

Deleting a comment

A comment can be deleted using the comment dialog. This dialog is opened by double-clicking on the position marker of a comment. The comment is deleted using the **(K5)** action button.

4.4 Distances in diagram data

Figure 17 Diagram data: Distances

Indicating distance values

The distances of the chart data can be carried out for each diagram using the action **(M1)**. Clicking on this button opens the dialog **(M2)** and the cursors **(M3)** are displayed in the diagram.

Depending on requirements, the cursors for t (time axis) and y (data axis) can be activated separately.

The distances between the associated cursors are displayed in the dialog. The value of the distance of the t cursors (t1 and t2) is displayed as a time. The distance value of the y cursors (y1 and y2) is based on the unit of the y-axis of the diagram display.

The cursors can be easily positioned or moved with the mouse: Take hold of the cursors with the mouse, move them to the new position and release them.

During the process the diagram display can be moved or scaled as usual, in order to carry out more accurate distances. The cursors remain in their position while this is being done. If the cursors disappear from the visible area, they can be brought back by using the "Bring cursor into view" **(M4)** button.

The distance view is terminated as soon as the distance dialog is closed.

4.5 Statistics

Statistical data can be called up for every diagram. A click on the (see Figure 16) action button next to the diagram opens the statistics dialog (see Figure 18).

This dialog consists of

1. Selection of the measurement data **(S1)**
2. Available statistics **(S2)**
3. Statistics diagram **(S3)**
4. Statistics actions **(S4)**

Selection of the measurement data
By default, the selection of the measurement data is based on the current view **(S1)** of the associated diagram. Additional options are:

1. Statistics from of complete measurement data
2. Statistics for a specified time range (from / to)

Statistics
The values for minimum, maximum, average and median value are displayed in the statistic dialog **(S2)**. The values here depend on the selected measurement data.

Statistics diagram
The frequency distribution of the values which occurs in the measurement data is displayed as a bar diagram. The limit values and interval width can be set in the program settings. Details of the settings are described in more detail in section 7.3.

The settings can be accessed directly using the **(S4)** action button.

This diagram view can also be printed directly from this dialog by using the action button **(S4)**.

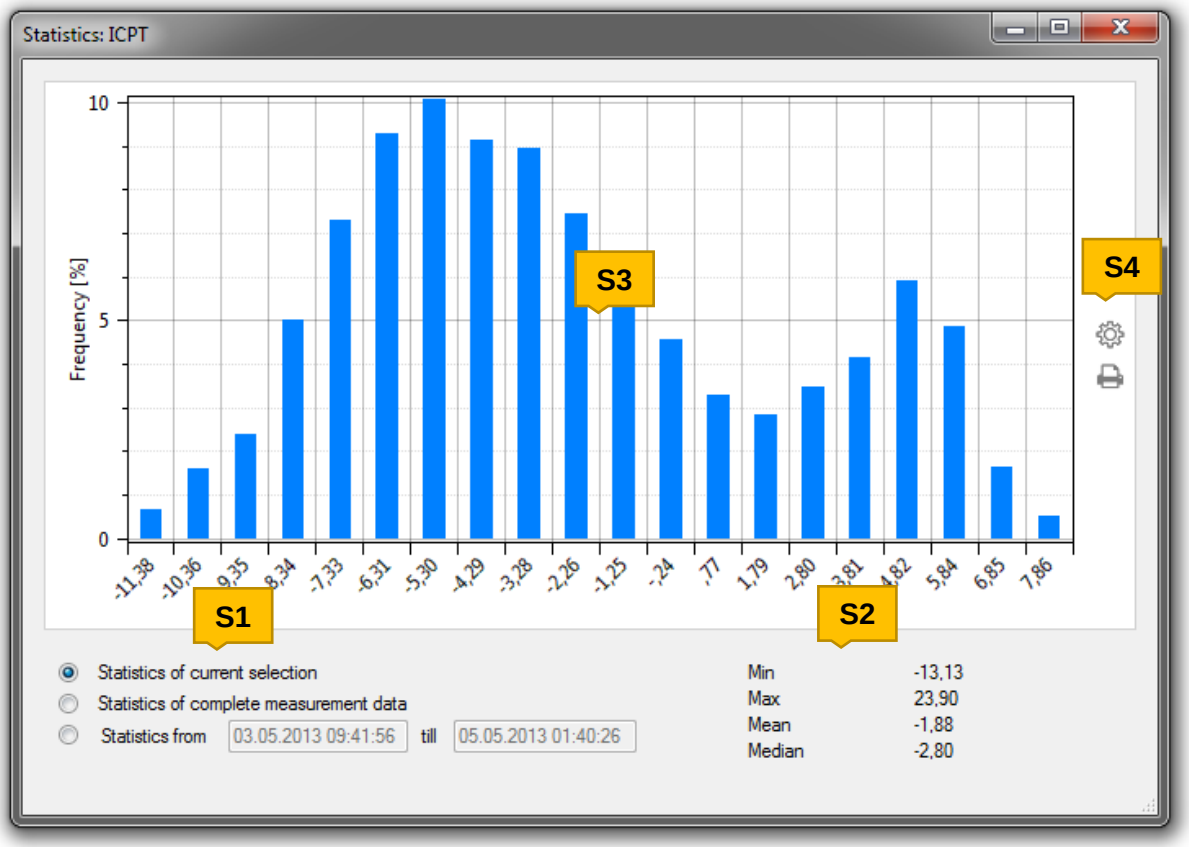

Figure 18 Diagram data: Statistics

4.6 Comparison of statistics

The statistics described in the previous section can also be compared with each other.

Right-clicking on a diagram displays the "Add view to comparison dialog" menu item. If this entry is selected, statistics for the measurement data of the current selection are added to the statistical comparison dialog.

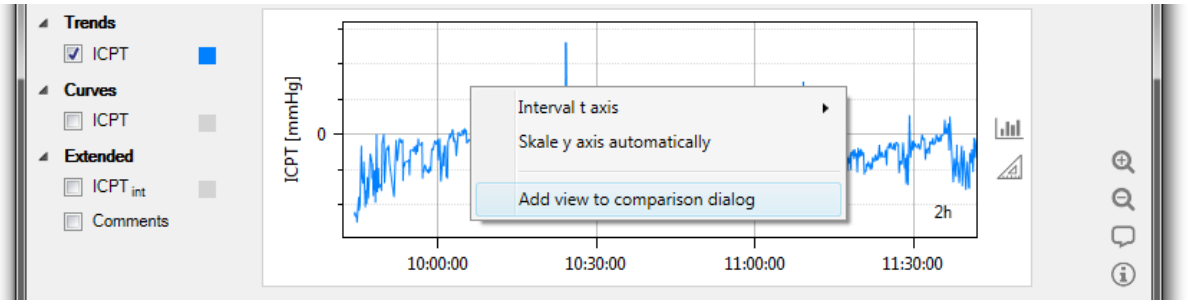

Figure 19 Diagram data: Statistic comparison

The statistic comparison dialog opens and the data of the current selection appear in the list of statistical data (see Figure 20).

The values are grouped by patients and measurement value. Individual rows can be removed again using the − action button.

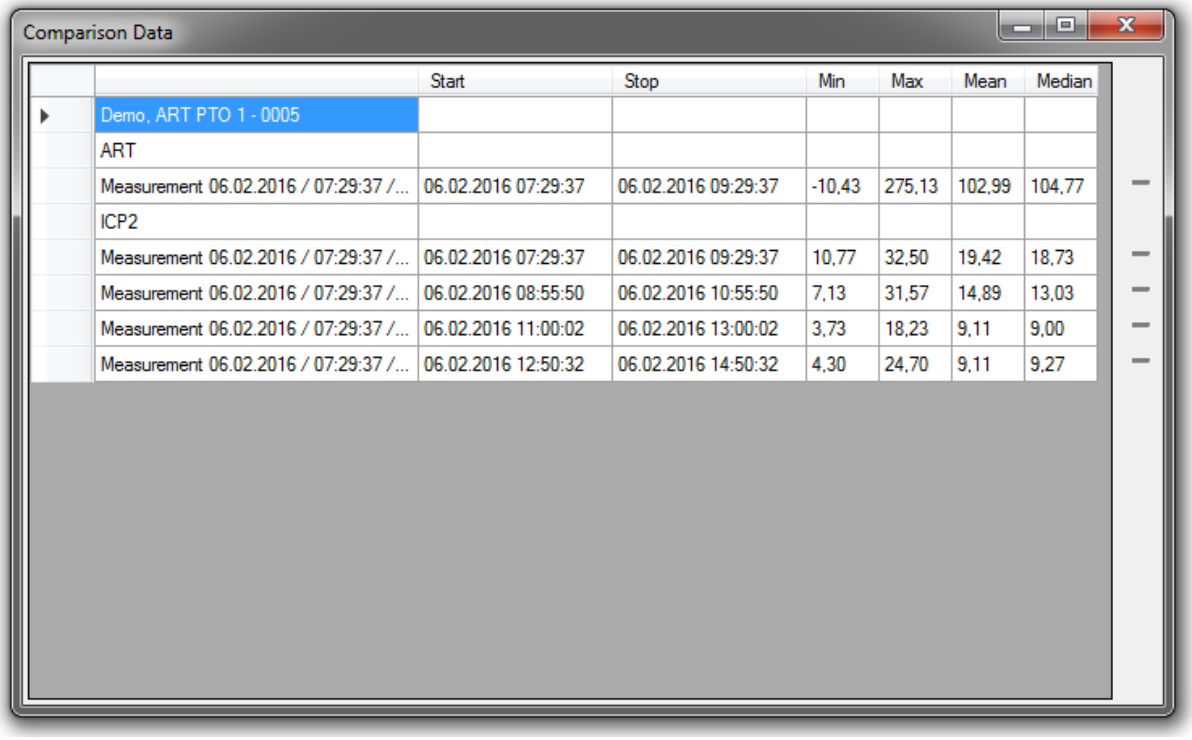

Figure 20 Statistic comparison

4.7 Printing

Each diagram view can be printed by using the print dialog. The (see Figure 19) action button next to the diagram data can be used for this purpose.

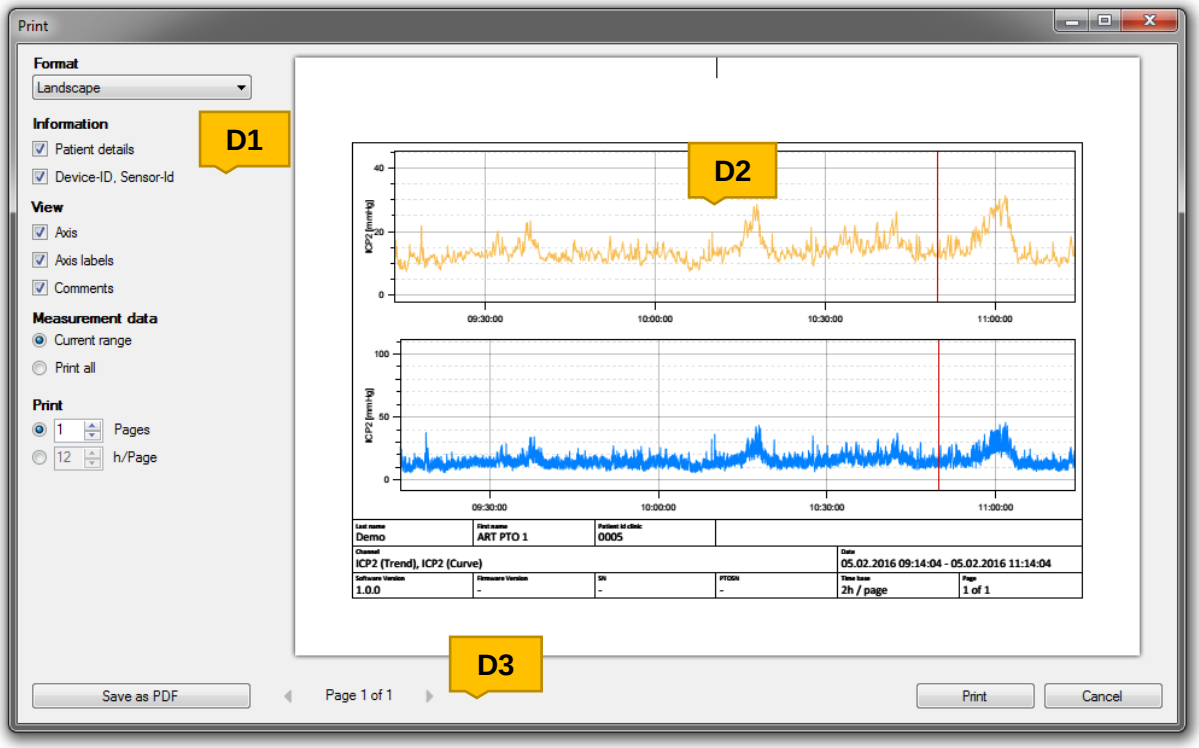

Figure 21 Printing

The following settings are available in the print dialog **(D1)**:

Format
The format can be set between portrait and landscape. The default format for the print view is landscape.

Information
The page format has a title block, which provides additional information on the measurement. The checkboxes can be used to specify the information to be displayed in the title block:

1. Patient information (name, date of birth, ...)
2. Device ID, sensor ID (hardware information)

View
These options are used to specify the way the diagrams are displayed on the printout and the information represented on it:

1. Axes
2. Axes labels
3. Comments

Measurement data
The current selection of the diagram display or all data of a measurement can be used as the measurement data.

Print
This setting determines the time distribution of the diagram data across a number of pages. The following settings are possible:

1. The distribution of the measurement data across a specified number of pages.
2. The distribution of the measurement data across a fixed time period per page. The number of pages then depends on the measuring time of the data selected.

5 Live mode

5.1 Starting live mode

Live mode is started using the "Live data" menu option from the Main menu (see Figure 22).

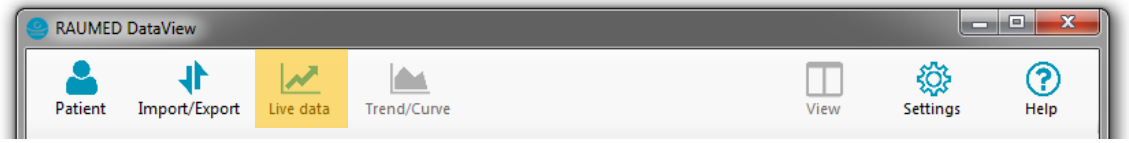

Figure 22 Starting live mode

Live data must be assigned with a patient. Before live mode can be used, a patient must therefore be selected first. This is done when using the following dialog:

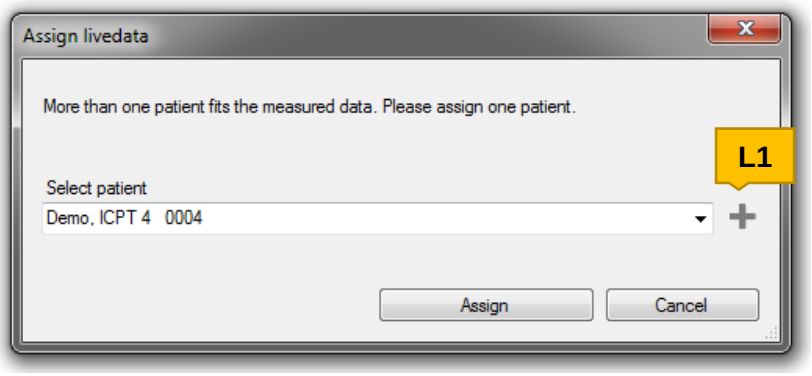

Figure 23 Live mode: Selecting a patient

Select an existing patient from the list or add a new patient with the (+) action button **(L1)**.

Then click on "Assign" to use the selected patient.

5.2 Using live mode

5.2.1 Display of chart data

The live mode display is structured in the same way as the view for curve and trend data (see section 4).

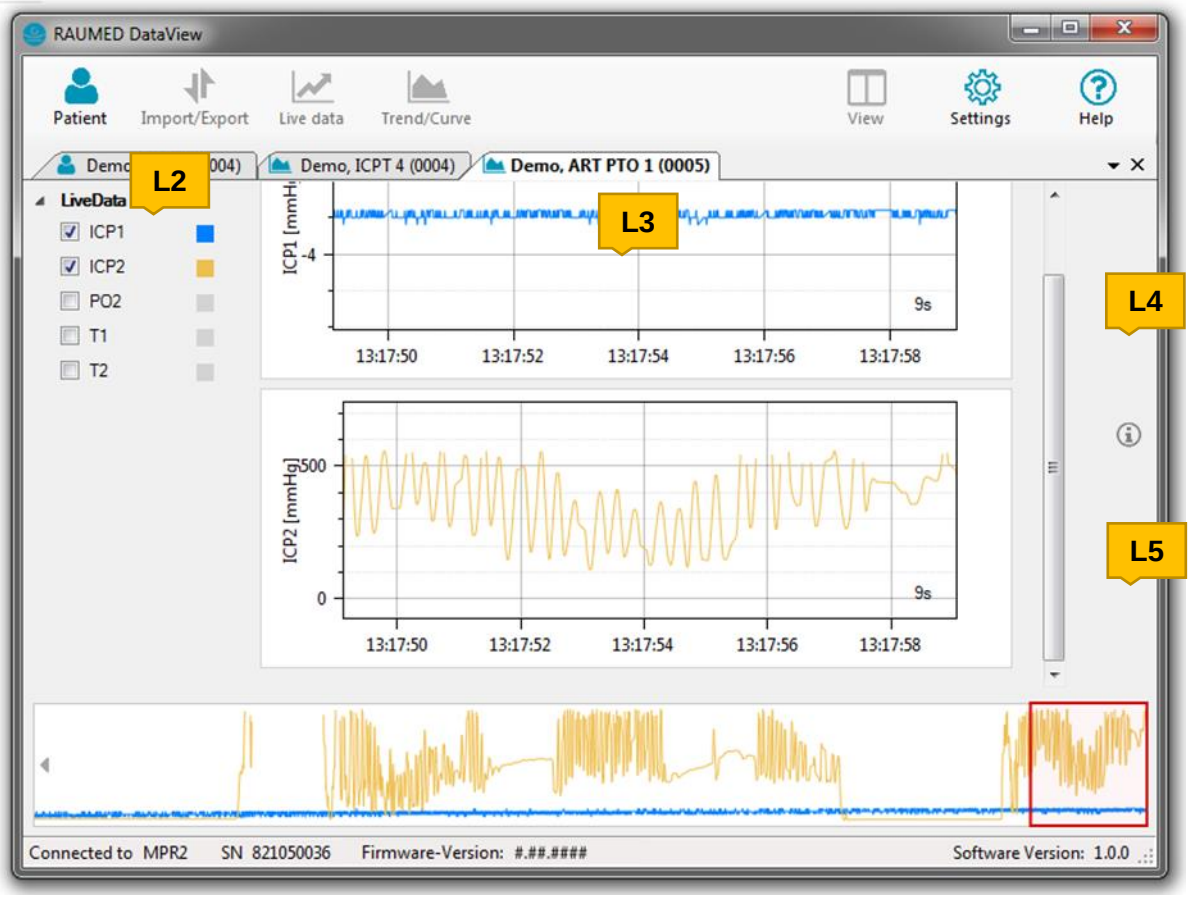

Figure 24 Live mode

The live mode plot view is divided into 4 main areas:

1. Data selection (left) **(L2)**
2. Diagram view (center) **(L3)**
3. Actions (right) **(L4)**
4. Timeline, navigation **(L5)**

The data selection displays all the channels of the catheters which are currently connected to the device.

The timeline shows the time sequence of the measurement values. It is possible to navigate the measurement data in the same way as already familiar from the curves and trend data.

6 Extended functions

6.1 ORx and PRx

Curve data (100 Hz) are used for the display of ORx and PRx. The correlation parameters ORx and PRx are based on the principle of Karl Pearson. The plot of PRx is based on the publication of Czosnyka et al. [1]. The plot of ORx is based on the publications of Jaeger et al. [2] and Götzinger et al. [3].

[1] M. Czosnyka, J. D. Pickard: “Monitoring and interpretation of intracranial pressure”. J Neurol Neurosurg Psychiatry, 2004, vol. 75, pp 813-821, DOI: 10.1136/jnnp.2003.033126.

[2] M. Jaeger, M. - U. Schuhmann, M. Soehle, C. Nagel, J. Meixensberger: “Continuous Monitoring of Cerebrovascular Autoregulation After Subarachnoid Hemorrhage by Brain Tissue Oxygen Pressure Reactivity and Its Relation to Delayed Cerebral Infarction”. Stroke, 2007, vol. 38, pp 981-986, DOI: 10.1161/01.STR.0000257964.65743.99.

[3] G. Götzinger, M. Schenk, M. H. Morgalla, C. Thiel, K. Thiel, M. U. Schuhmann: „The Value of Cerebrovascular Pressure Reactivity and Brain Tissue Oxygen Pressure Reactivity in Experimental Anhepatic Liver Failure”. Neurocrit Care, 2012, DOI: 10.1007/s12028-012-9714-0.

6.2 Integrals

Integral curves are available for the curve data (100 Hz). These are listed under "Extended" in the data selection.

7 Settings

The settings dialog has several tabs, under which different settings are grouped together. All settings are applied directly, it is not necessary to save the settings.

7.1 Views

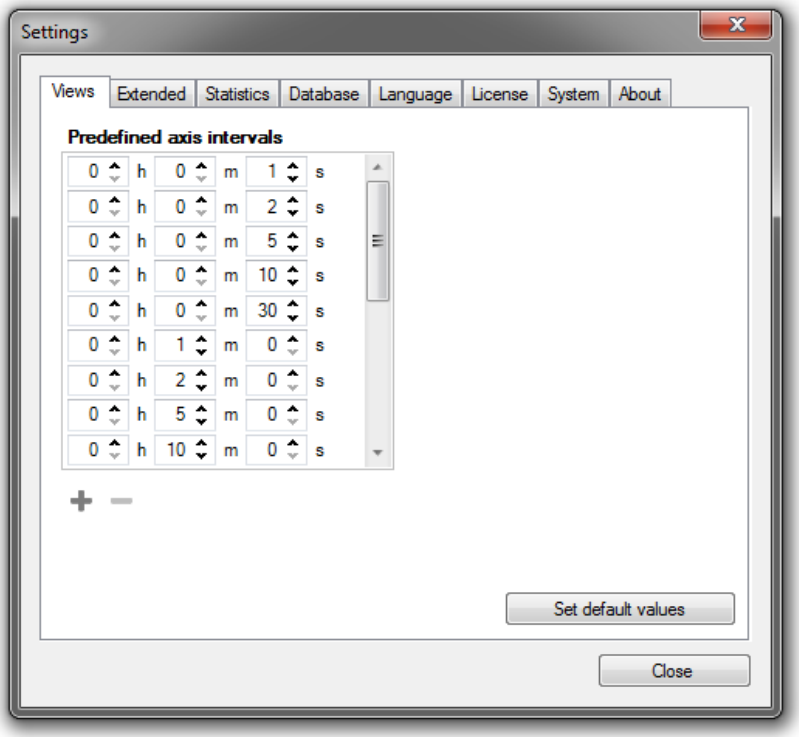

Figure 25 Setting: Views

The following settings are possible under "Views":

Predefined time axis intervals
Predefined time axis intervals allow the scaling of chronological data profiles (plots) according to set time intervals. These can be called up and applied from a plot (see section 4.2.3).

Each row corresponds to an interval. This is divided in hours (h), minutes (m) and seconds (s).

A new interval can be added through the + action. If a row is selected, then this interval can be removed again using the − action.

Set default values
Resets the axis intervals to a list of default intervals.

7.2 Extended

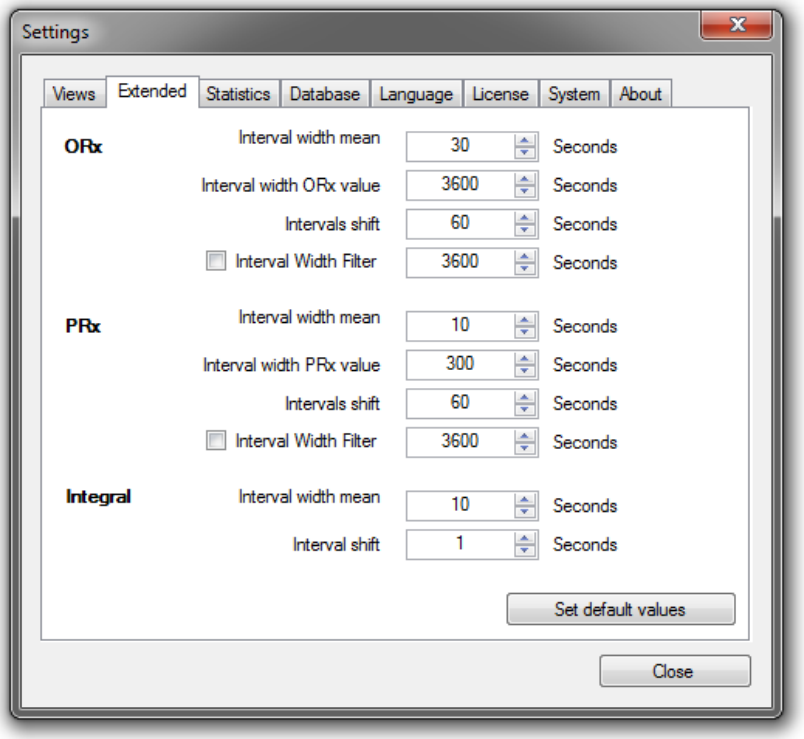

Figure 26 Setting: Extended

The following settings are possible under "Extended"

ORx
Specification of settings which are required for ORx values (see section 6.1).

PRx
Specification of settings which are required for PRx values (see section 6.1).

Integral values
Specification of settings which are required for integral mean values (see section 6.2). With “Interval width mean value”, a time period will be defined from the curve data (100 Hz) for the mean value. With “Interval shift” a shift for the next mean value will be defined.

Set default values
Resets all settings to predefined values.

7.3 Statistics

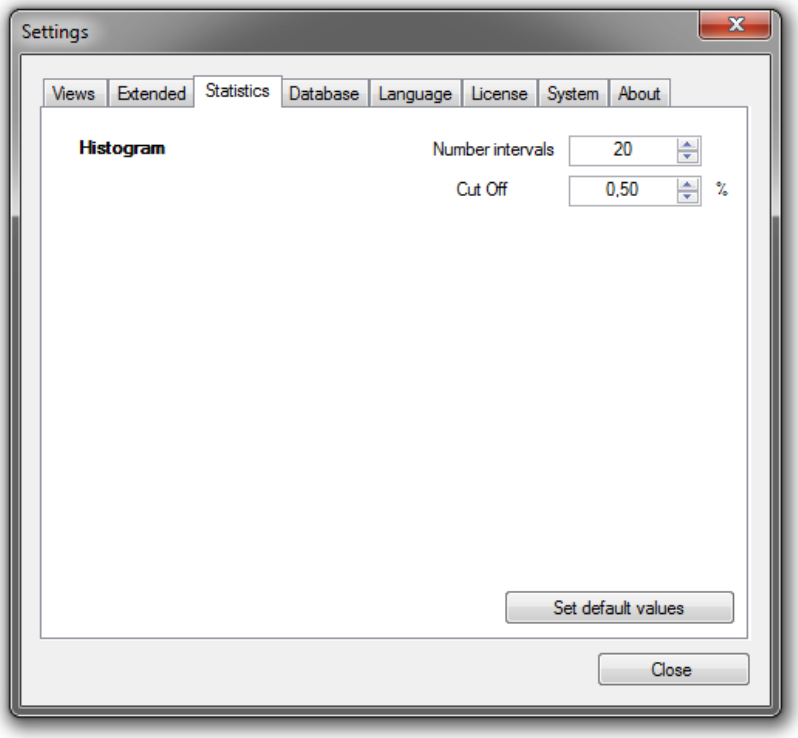

Figure 27 Setting: Statistics

The following settings are possible under "Statistics":

Histogram: Number of intervals
Value determines how many intervals are visualized in the histogram of the statistics. This corresponds to the number of bars displayed.

Histogram: Cut-off
Value determines the frequency up to which an interval is no longer displayed. Each interval with a frequency less than this percentage is "cut off" in the histogram display, that is to say it is hidden on the left and/or right.

Set default values
Resets all settings to predefined values.

7.4 Database

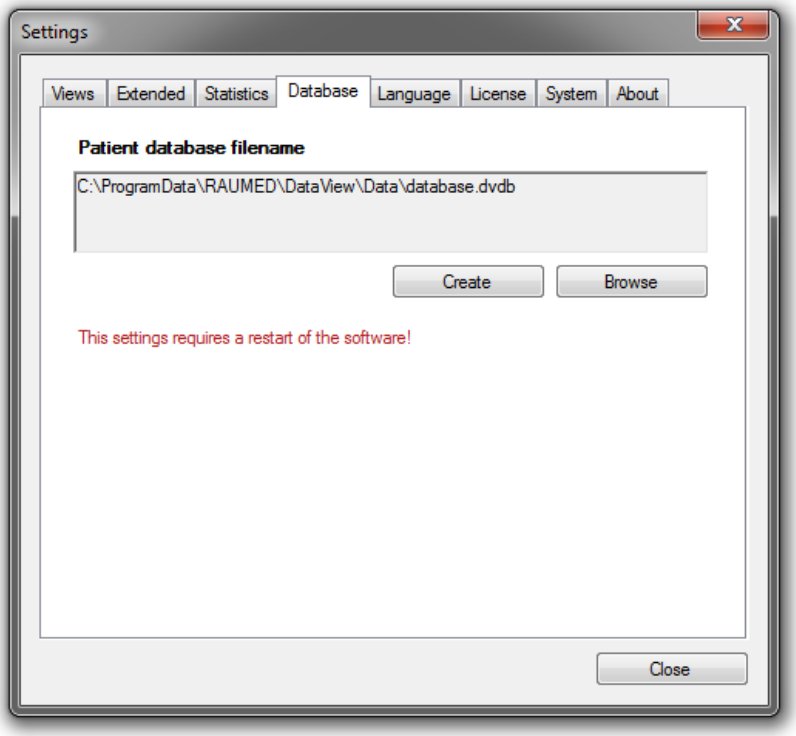

Figure 28 Setting: Database

The following settings are possible under "Database":

Patient database file
This setting determines where the currently used database file is stored.

Create
This button opens a "Save as" dialog which is used to select a path and a type file name for a new database file. A new, empty database file is created in the selected location.

Browse
This button opens an "Open" dialog which is used to select a path for an existing database file. The database in the selected location is used as of now.

Note After a new database has been created or selected, the software must be restarted! If data of a previous database are still open, incorrect data assignments or even data loss may be caused.

7.5 Language

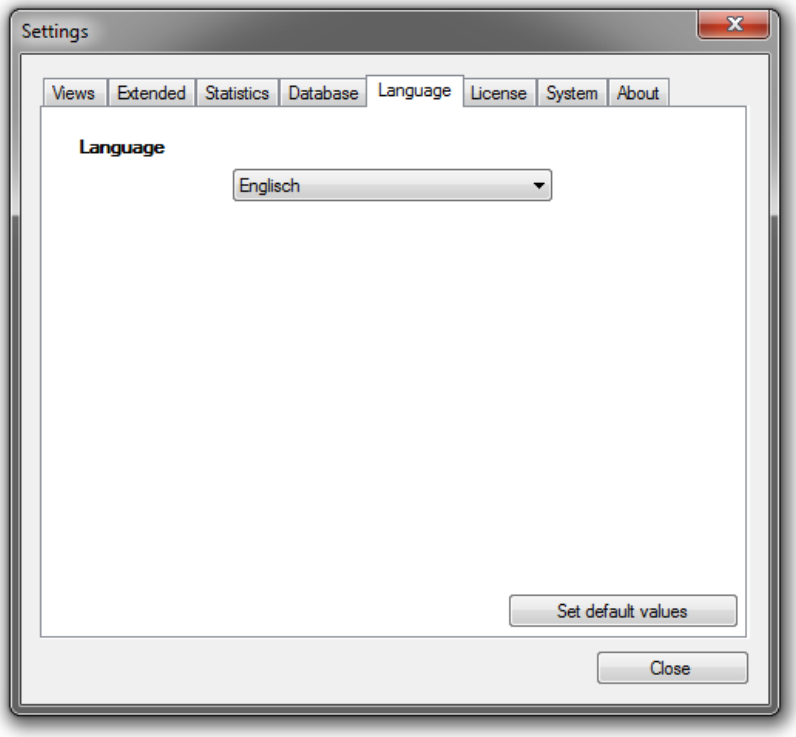

Figure 29 Setting: System language

The following settings are possible under "Language":

Language

The "**System language**" setting is used by default, i.e. the same language as that of the overall Windows system is used for the software. If this language is not available, the default language is **English**.

In addition to this setting, a language can also be defined permanently. If "**German**" or "**English**" or another available language is used, then this language is retained regardless of the Windows settings.

Set default values
Resets the setting to the "System language" values.

7.6 License

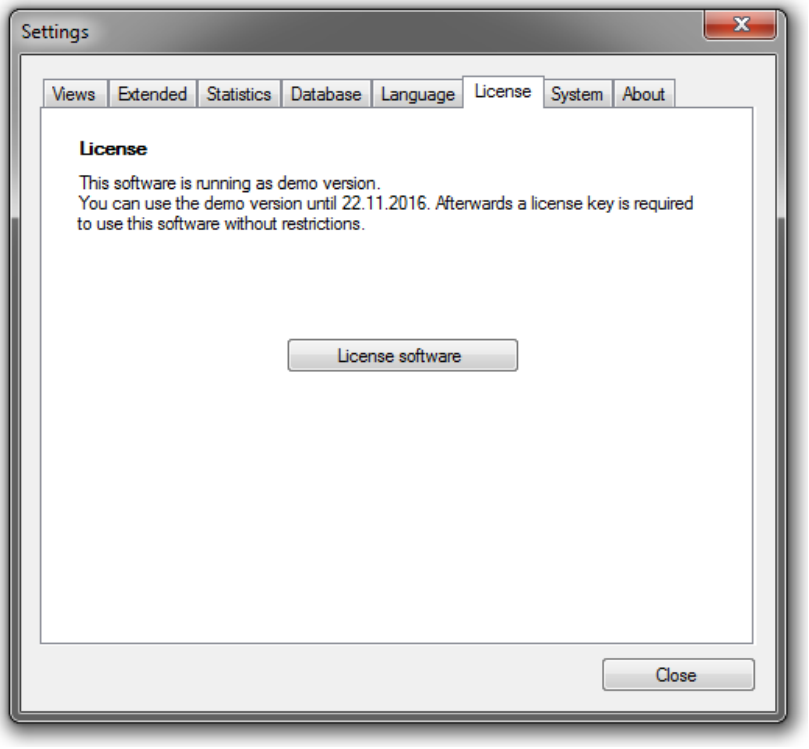

Figure 30 Setting: License

The following settings are possible under "License":

License
By default, the RAUMED DataView software runs as a 7-day demo version without any functional restrictions. The status of the currently used license is displayed under "License".

License software
As long as the software runs in demo mode, a license code can be entered via this button, which removes the time limitation of the demo version.

Licensing takes place through the license dialog (see Figure 31). Using the software ID displayed, a licence key can be requested from RAUMEDIC.

There is only one valid license key for each software ID.

License keys are limited to one main version n.#.#.

License keys are not time-limited.

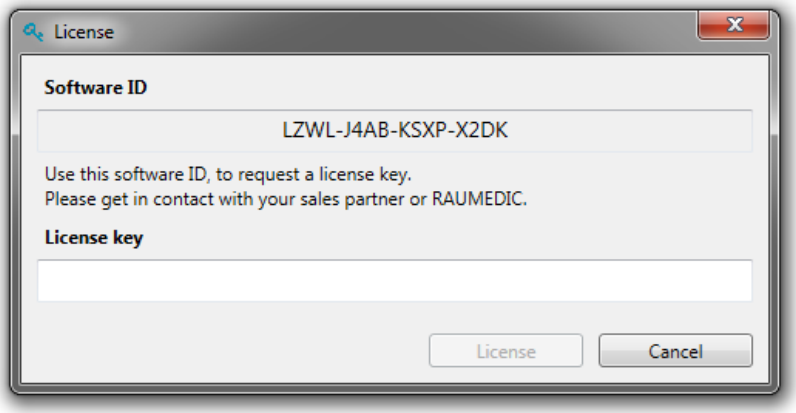

Figure 31 setting: Entry of license code

8 Help und documentation

RAUMED DataView provides an internal help function which can also be used without an internet connection. This can be opened under the "Help" menu item of the Main menu.

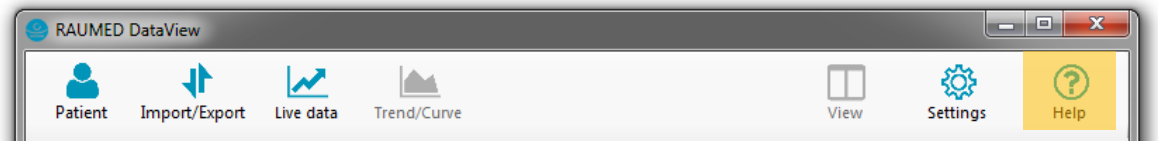

Figure 32 Opening help

The help browser opens, which provides a collection of help topics on the software functions. The view of the help browser is shown in Figure 33.

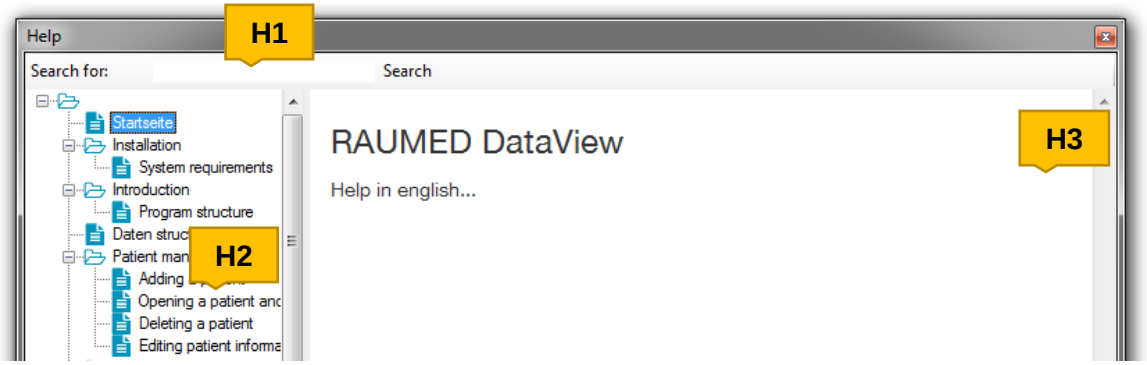

Figure 33 Help browser

This view is divided into 2 areas:

1. Topic index (left) **(H2)**
2. Topic contents (right) **(H3)**

The search function **(H1)** can also be used for a targeted search for content: Enter the search term and then click "Search".

The topic index then only lists contents containing the search term specified.

Help topics can be accessed from different views of the software using the **F1** key.