prismaTSlab

PC Software for Display and Remote Configuration of Löwenstein Medical Technology Therapy Devices

Version 5.17

LÖWENSTEIN
medical

Contents

1 Introduction

This user manual/online help contains information on the operation of prismaTSlab.

The following information can be found in the separate installation instructions:

- Intended use and function

- Safety information

- System requirements

- Network settings

- Installation and update

- Function check

- Troubleshooting

- Remote maintenance

- Technical data

$\mathbf{i}$ The software version of the screenshots in this document may vary from the installed software version.

2 Description and preparation

2.1 Setting up a 1:1 connection

You can set up a fixed connection to the patient room with the module which is connected to the network (prismaCONNECT or prisma HUB). The fixed connection is only to this communication module, irrespective of which therapy device is connected to the module.

1. Right-click on the prismaTSlab shortcut on your desktop.

2. Now select **Properties** in the context menu.
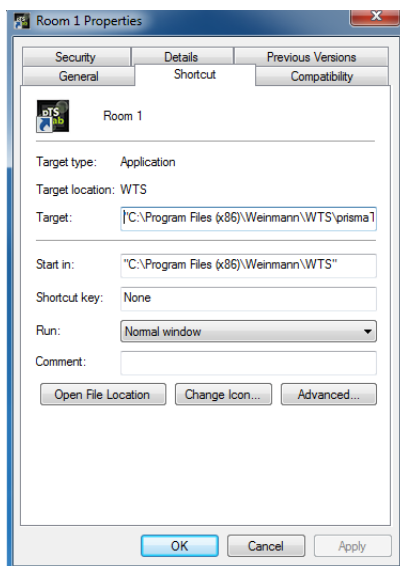
3. Select the **Shortcut** tab.

4. There is a target path in the **target** field, e.g., "C:\Program Files (x86)\Loewenstein Medical Technology\prismaTS\prismaTSlab.exe".

5. Enter the serial number of the module used after the target path. The serial number can be found on the module's type plate. You can enter a name for the patient room. Entering a name is optional.

• Please use the following format:

[Blank space] lansn=[serial number of the module**] [Blank space] title="[**preferred name of patient room**]"**

Entering "title" is optional.

Please pay attention to the correct syntax: Blank spaces before and after the arguments. **No** blank spaces before and after **=**. Example:

```
VTS\prismaTSlab.exe" lansn=4714 title="Room1"
```

6. To save your input, click on **Apply**.

   or

   To save your input and close the window, click **OK**.

   or

   To discard your input and close the window, click **Cancel**.

7. Start the prismaTSlab application via the shortcut set up on the desktop.

8. Check whether the therapy device connected to the module is selected automatically.

9. To provide additional therapy devices with a fixed connection to a patient room, copy the prismaTSlab shortcut and then enter the corresponding serial number of the module and, if required, the name of the patient room.
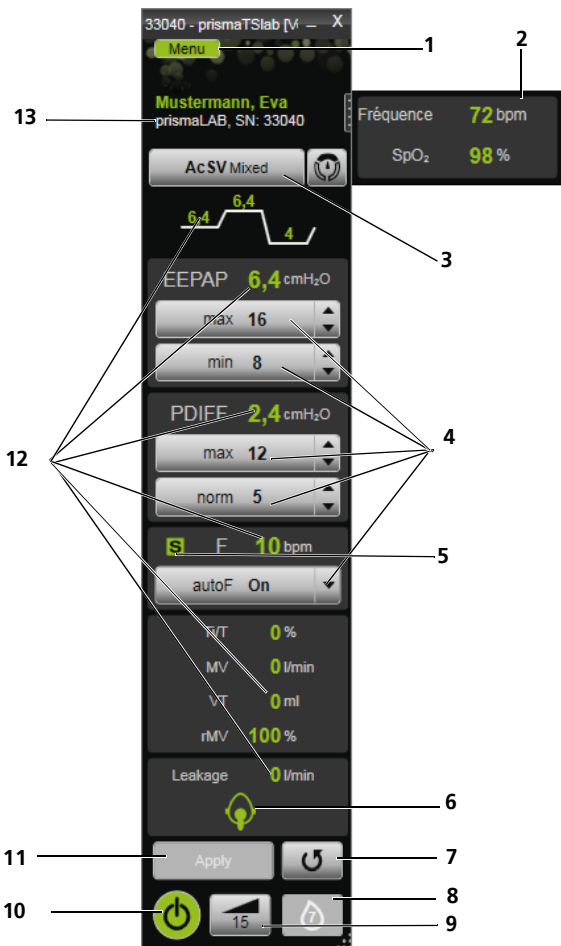
It is no longer possible to select the devices manually (see "Selecting therapy device manually"). The menu item **Menu** > **Select device** is no longer available.

2.2 User interface

> **i**
>
> Please note that the user interfaces may differ slightly in appearance depending on the selected therapy device and ventilation mode.

2-1   User interface in main window (AcSV Mixed mode)

No.	Designation	Description
1	Menu button	Provides access to the menu.
2	SpO$_2$ window	The window with SpO$_2$ and the pulse rate opens automatically when the SpO$_2$ module is connected. You can close and reopen the window again if necessary by clicking on it.
3	Ventilation mode list	Here you can select the ventilation mode. Please note that you can only select one of the ventilation modes offered by the connected therapy device.
4	Parameter	Here you can set the most important parameters.
5	Respiration status	Displays the respiration status.
6	Mask status symbol	Displays how well the respiratory mask is positioned and if it displays any leaks.
7	Update/Reset button	Resets the changed and not yet applied ventilation modes, SCOPE, and therapy settings by loading the current device configuration from the device.
8	Respiratory air humidifier button	Shows whether the respiratory air humidifier is connected and switched on as well as the set humidifier level.
9	softSTART button	This button allows you to switch softSTART on or off during the therapy. If it is switched on, the remaining duration of the softSTART is shown in minutes. Additional information on softSTART can be found in the instructions for use of the therapy device.
10	Therapy analysis button	Enables printing of the therapy analysis. The therapy analysis is displayed for all modes and for the respective last therapy night. The tabular overview illustrates in detail the relevant respiratory parameters and respiratory disorders as well as unintentional leak flow depending on the respective pressure/pressure range over the course of the last therapy night. Once therapy starts, the **Therapy analysis** button changes to the **softSTART** button. When the therapy is over, the button changes back again.
10	On/off button	This button is used to start and end the therapy.
9	Therapy protocol button	Enables printing of the therapy protocol (see "Printing therapy protocol"). Once therapy starts, the **Therapy protocol** button changes to the **Respiratory air humidifier** button. When the therapy is over, the button changes back again.
11	Apply button	This button is used to transfer the parameters set in prismaTSlab to the therapy device.

No.	Designation	Description
12	Current values	Displays the current values (different values and modes are possible depending on device version). The values currently on the therapy device are sent to prismaTSlab approximately once a second. The therapy pressures shown (depending on mode P, IPAP, EPAP, EEPAP, PDIFF) are setpoint pressures. The frequency shown (F) is the patient's respiratory rate averaged based on several breaths.
13	Information bar	Displays the selected therapy device and, if applicable, the assigned patient.
4	Button 1/2/3 (WM110TD/ WM120TD only)	You can change the ventilation program here.

Once therapy starts, the **Therapy analysis** and **Therapy protocol** buttons change to the **softSTART** and **Respiratory air humidifier** buttons. When the therapy is over, the buttons change back again.

2.2.1 Symbols on the user interface

| Symbol	Designation	Description
S	Respiration status symbol	S=Spontaneous
T		T=timed (assisted breathing)
/		/=no respiration
(mask symbol)	Mask status symbol	Mask position is good, no leaks
(mask symbol)		Mask is not well positioned, considerable leaks, the efficacy of the therapy is not guaranteed

3   Operation

3.1   Starting prismaTSlab

Requirement:

• The therapy device is connected to the PC via LAN (see prismaTS instructions for use). (When using the prisma HUB module, see prisma HUBconfig instructions for use).

1. Double-click on the program icon.
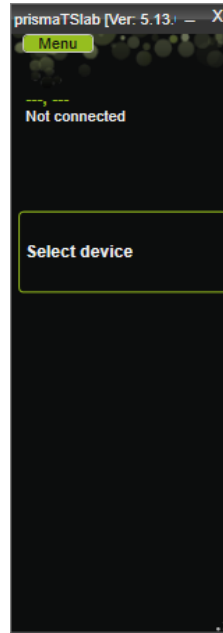
Settings can either be performed on the therapy device **or** in the software. As soon as you set parameters on the therapy device, the prismaTSlab user interface is disabled.

2. To control another device remotely at the same time, you will need to open another prismaTSlab application .

3.1.1 Calling up the online help/user manual

1. Press F1 to call up the online help.

   or

   Click **Menu** > **Help**.

You can find the user manual in PDF format in the **Manuals** folder on the installation medium and on the hard disk under the installation path in the **Manuals** folder. It is identical to the online help.

3.1.2 Selecting the language of the user interface

The user interface is available in a number of different languages.

1. Click on **Menu** > **Change language**.

2. Select your preferred language.

3.1.3 Selecting the unit of pressure

There are a number of different units of pressure available for the pressure values displayed in prismaTSlab.

1. Click **Menu** > **Options** > **Configuration** > **DISPLAY**.

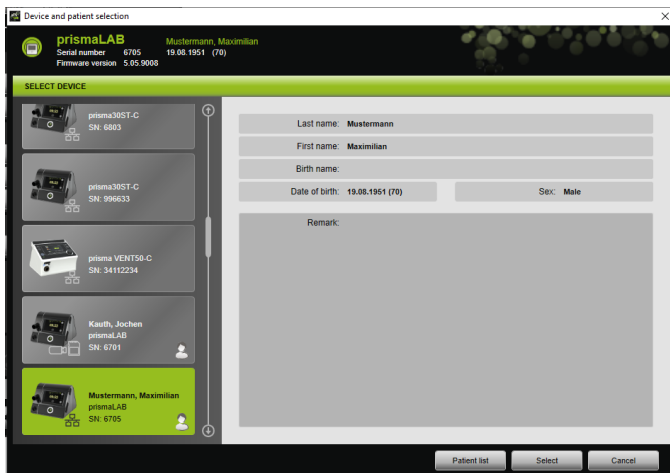2. Select your preferred pressure unit.

   The selected pressure unit is also adopted automatically for prismaTS.

3.2 Selecting therapy device manually

1. To select a therapy device, click on **Select device**.

   or

   Click on **Menu** > **Select device**.

All the Löwenstein Medical therapy devices connected are automatically displayed in the **SELECT DEVICE** window.

2. Click on the corresponding device in the list for further information on the required therapy device and, if applicable, a patient assigned to the device.

   The serial number and version of the firmware are shown in the information bar.
   If the selected therapy device is already assigned to a patient, the patient's data are shown.

3. To accept the device for setting, click on **Select**.

   or

   Double-click on the device in the list.

3.3 Selecting patient

3.3.1 Assigning therapy device to a patient

To set the selected device for a patient, you can assign it to a patient.

Requirement:

A therapy device is selected (see "Selecting therapy device manually").

1. Click **Patient list** in the **SELECT DEVICE** window.

   or

   Click **Menu** > **Patient list**.
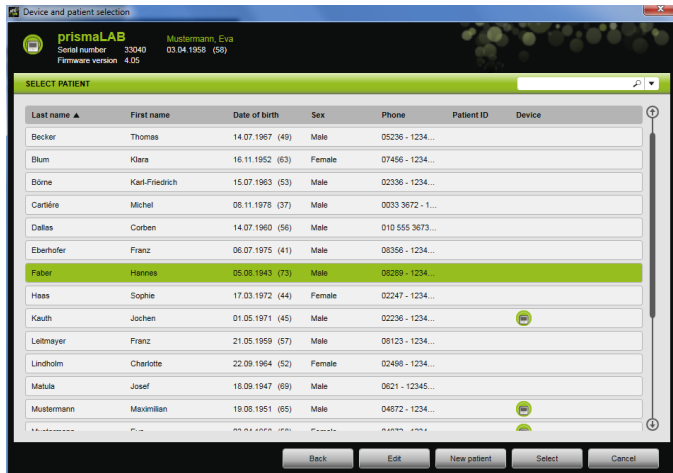
2. To assign an already existing patient to the selected device, double-click on the respective name.

   or

   Click on the corresponding name. Click on **Select**.

3. If the patient is not already saved in the system, create the patient (see "Creating a new patient").

3.3.2 Creating a new patient

Requirement:

A therapy device is selected (see "Selecting therapy device manually").

1. Click **Patient list** in the **SELECT DEVICE** window.

2. Click on **New patient**.

3. Enter the patient's data.

The fields marked with * (**First name**, **Last name**, and **Date of birth**) are mandatory fields, which must be filled in.
The age of the patient is calculated automatically based on the date of birth.

To use the telephone number provided by a patient in the prismaTS information bar and the titration and short reports, you can store a telephone number as the *preferred* telephone number.

4. After entering the telephone number, right-click the telephone number field.

5. Now select **Specify as standard**.

   A green check designates the preferred contact number.

This telephone number appears in the prismaTS information bar and in the titration and short reports.

6. Click on **Save**.

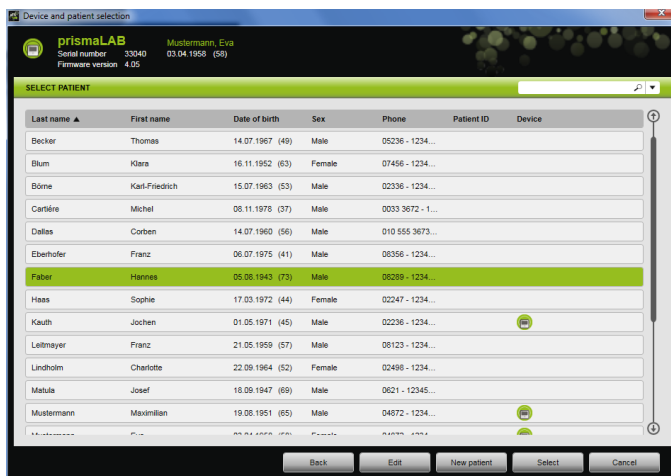### 3.3.3 Edit patient data

Requirement:

A therapy device is selected (see "Selecting therapy device manually").

1. Click **Patient list** in the **SELECT DEVICE** window.

   or

   Click **Menu** > **Patient list**.

2. To select an existing patient, click on the respective name.

3. To edit the patient's data, click on **Edit**.

4. Edit the patient's data.

5. Click on **Save**.

3.4 Configuring therapy settings

- For information on which therapy parameters can be set for the individual ventilation modes, please refer to the instructions for use for the therapy device.

- You can set the most important therapy settings in the **main window** of the user interface.
  You can set all the therapy settings in the **Therapy settings** window.

- You can also set the therapy settings in Standby mode or when therapy is running and transfer them to the therapy device.
  When therapy is running, the therapy pressures are adapted to the new values in increments over the course of several breaths.

3.4.1 Selecting a ventilation mode

You can select one of the ventilation modes offered by the connected therapy device.
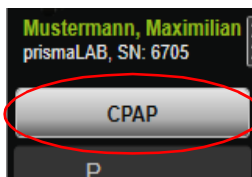
1. Select the required ventilation mode from the ventilation mode list.

   If you change the ventilation mode, the preset therapy parameters are changed automatically.

   Exclamation marks **!** to the left of the **ventilation mode** list and the **parameters** fields show that the **ventilation mode** and **parameters** have been changed.

2. To apply the changed ventilation mode to the therapy device, click **Apply**.

   or

   To discard the set parameters and reset the therapy device to the current device configuration, click the **Update/Reset** button **↺**.

3.4.2 Configure ventilation program

You can preconfigure up to three ventilation programs. If, for example, the patient needs different ventilation settings during the day and at night, you can quickly change the program in the main window.

1. Activate the required program under the menu **Therapy settings** > **Programs**.

2. Select the required program in the **main window**.

3. Make settings as required (mode, parameters, alarms).

3.4.3 Setting therapy parameters

The most important therapy parameters of the selected ventilation mode are shown on the interface.

1. Select the required value by clicking on the arrow keys next to the value.

   or

   Change the values by clicking in the field and entering the value using the keyboard.
   You need to leave the input field again after making your changes so that the **Apply** button can be activated and the value can be applied to the therapy device.

2. To apply the set parameters to the therapy device, click **Apply**.

   or

   To reset the set parameters to the current values on the device, click **Update/Reset** ↻ .

3. To set additional therapy parameters for the selected mode, click **Menu** > **Therapy settings**.
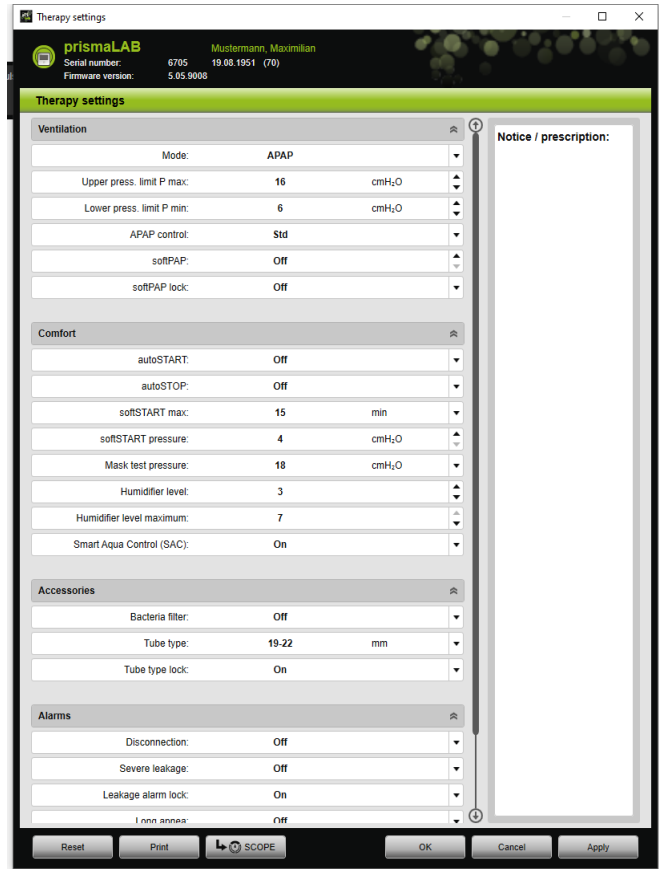
4. Select the required values with the arrow keys.

   or

   Click in the required field.

   Enter the values using the keyboard.

5. To apply the set parameters to the therapy device, click **Apply**.

   or

   To apply the set parameters to the therapy device and close the window, click **OK**.

6. To discard the set parameters, click **Cancel**.
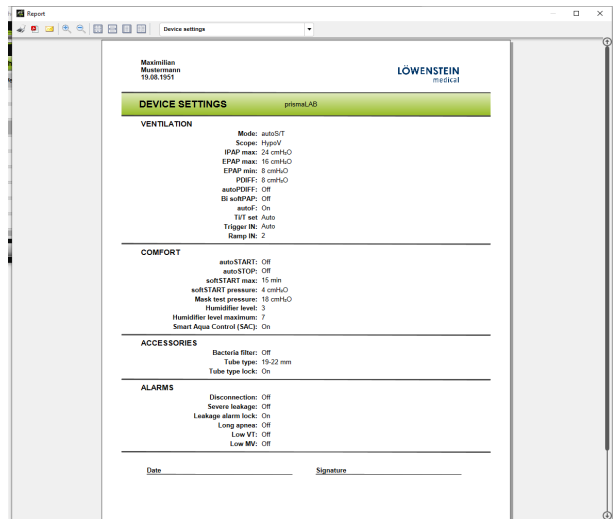
   or

   Click on **Reset**.

3.4.4 Printing a report

You can read out therapy settings in a report in order to save them all together and in a clear manner, print them, or send them via e-mail.

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Any notice or prescription text which has been entered is not saved in prismaTS/prismaTSlab but rather only read out in the report.

1. Click **Menu** > **Therapy settings**.

2. Click **Print**.

3. To print the report from the print preview, click on the **Print** symbol.

4. To save the report from the print preview as a PDF, click on the **Save as PDF** symbol.

5. To send the report as a PDF by email, click on the **Send as email** symbol.

3.4.5 Printing therapy protocol

The therapy protocol contains all the events of a titration night in the form of a table. You can filter by type if you only wish to list certain types of events.

1. Click **Therapy protocol** 📋 **.**

   or

2. Select **Menu** > **Protocol of the current therapy night**.

3. Click **Filter** if you only want selected types of events to appear in the therapy protocol.

4. Select the required types of events.

5. Click **Therapy protocol**.

6. To print the therapy protocol, click **Print**.

3.5 Starting and ending therapy

Requirement A therapy device is selected (see "Selecting therapy device manually").

1. To start the therapy, click on the **on/off** button on the user interface ⏻ .

   The button is green when the therapy is running ⏻.

2. To end the therapy, click on the **on/off** button on the user interface ⏻ .

   In **Standby** mode, the button is gray ⏻.

ℹ

Once therapy starts, the **Therapy analysis** and **Therapy protocol** buttons change to the **softSTART** and **Respiratory air humidifier** buttons. When the therapy is over, the buttons change back again.

3.6 Switching the respiratory air humidifier on and off

Type WM110TD/WM120TD

1. Click **Menu** > **Therapy settings**.

2. Within the **Comfort** section, select **On** or **Off** for the **Humidifier** parameter.

3. Select a **humidifier level**.

3.7 Delete therapy data in the device

You can delete the therapy data recorded in the therapy device with prismaTSlab in the therapy device.

Before deleting them, import the data from the therapy device to the software prismaTS **pTS** (see online help/user manual prismaTS).
The data will otherwise be permanently deleted.

1. Click on **Menu** > **Delete therapy data in the device**.

2. Confirm that you want to delete by clicking **Yes**.
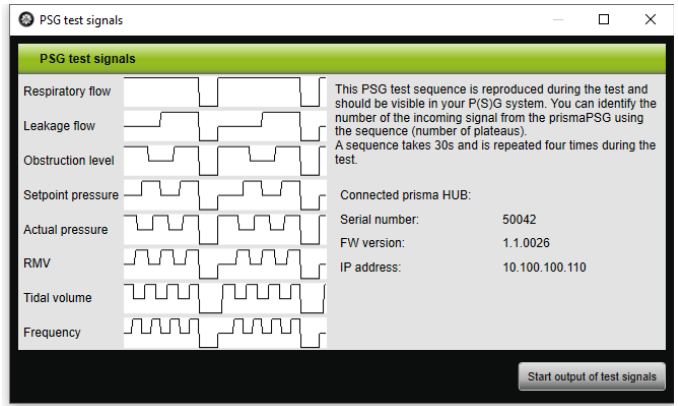
3.8 Performing a PSG test

You can perform a PSG test in order to test whether the prismaPSG module is connected properly.

Requirement:

The therapy device is connected to a prisma HUB module.

1. Click on **Menu** > **Outputting PSG test signals...**.

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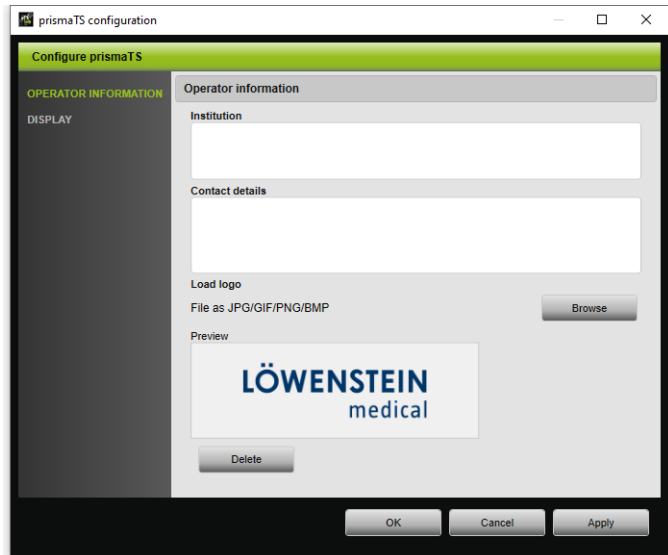2. Click on **Start output of test signals**.

   The PSG test is performed.

3.9 Creating reports

3.9.1 Customizing the header of the reports

You can customize the header of the reports. This setting applies to all reports.

1. Click **Menu** > **Options** > **Configuration**.

2. Select the **OPERATOR INFORMATION** section.

3. Enter the operator's data in the **Institution** and **Contact details** fields.
   The data are visible in the report header.

4. To load your logo, click on **Browse** and select the logo.
   The logo is visible in the report header. The size is adapted automatically.

5. To save your inputs, click on **Apply**.

6. To save your inputs and close the **prismaTS Configuration** window, click **OK**.

7. To discard your inputs and not save them, click on **Cancel**.

4 Appendix

4.1 Technical Data

Specification	prismaTS
Product class to directive 93/42/EEC	IIa
Software risk class according to IEC 62304	B

4.2 Labels and symbols

Label	Description
	Follow the user manual
UDI	Unique device identifier (uniform product code for medical devices)
MD	Indicates the product is a medical device
$C\!\!\in$ **0197**	CE symbol (confirms that the product conforms to the applicable European directives/regulations)

4.3 Declaration of conformity

Löwenstein Medical Technology GmbH + Co. KG, Kronsaalsweg 40, 22525 Hamburg, Germany, the manufacturer, hereby declares that the product complies with the relevant regulations of the Medical Device Directive 93/42/EEC.
The complete text of the Declaration of Conformity is available on the manufacturer's website.

In the EU: As a user and/or patient, you must reportary serious incidents occurring in conjunction with the product to the manufacturer and to the responsible authority.

CE 0197

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