BERTHOLD

detect and identify

LB 9526

Sirius 2 Single Tube Luminometer

Operating Manual
84018BA2

Rev. Nr.: 04, 05/2024

detect and identify

Please contact our Service Center at service@berthold.com if you have any
operational issues.

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detect and identify

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1   Prefatory Comments

1.1   Contact Information

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1.2   Typographical Conventions

⚠ **CAUTION**

Refers to a potentially dangerous situation, which can result in medium or minor physical injuries or damages to property, if it is not avoided.

NOTICE

If this information is not observed, deterioration in the operation and/or property damage may occur.

IMPORTANT

Sections marked with this symbol point out important information on the product or on handling the product.

Symbols	Description
●	Enumerations
1)	Actions
< >	Buttons
[ ]	Menu titles, items, dialog boxes and select lists

1.3   Safety Manual and Operating Manual

Sirius 2 is supplied with two manuals in the currently valid version.

- The **Safety Manual**, ID No. 84018BA27, contains the safety relevant information to be observed by the user.
- The **Operating Manual,** ID No. 84018BA2, contains additional informationon on operating software, and other important information of the manufacturer.

NOTICE

Validity of Safety Manual and Operating Manual

This revision of the Operating Manual is only valid with the corresponding Safety Manual, also supplied with the unit.

Always read the Safety Manual completely prior to the Operating Manual and both before first use of the instrument.

1.3.1   The Operating Manual

The operating manual is valid from the delivery of the Berthold product to the user until its disposal. Version and release date of this operating manual can be found in the bottom of each page.

Read all instructions thoroughly and completely before working with the product. Keep the operating manual for future reference.

The operating manual contains copyright-protected information. None of the chapters may be copied or reproduced in any other form without prior authorisation from the manufacturer.

The information in this guide is subject to change without notice.

However, should questions arise which are not answered in this manual please contact bio@berthold.com.

Revision history of the Operating Manual 84018BA2

Revision, Date	Changes
Rev 04, 05/2024	Reformulation by changing the intended use in the safety manual
Rev 03, 04/2020	Update and transfer of safety-relevant information into a separate Safety Manual, ID 84018BA27. This revision of the Operating Manual is only valid with the corresponding Safety Manual, also supplied with the unit.
	Addition of information on models without control unit.
	Update of information on return shipment.
Rev 02, 07/2019	Change of manufacturer and revision of the respective information.
	Transfer of the document Sirius II-e-2016-11 into Berthold Technologies Design. Adaptation of document name and revision designation.
Sirius II-e-2016-11	Manual of Berthold Detection Systems for Sirius II Tube Luminometer

NOTICE

The current revision of this Operating Manual in combination with the Safety Manual replaces all previous versions.

2 Models with Control Unit

NOTICE

Installation and setup of the luminometer

Install and set up the device according to the description in the safety manual and refer to the recommendations on proper handling and priming the tubing before start of any operation.

Sirius 2 models with control unit (ID No. 84018-01/-02/-03) are operated via onboard software on a control unit with touchscreen. It is switched on together with the luminometer.

2.1 Onboard Software Structure

The software consists of 4 main menus.

Protocols:
This menu and its submenus are used to create, edit or delete a protocol and to start a measurement.

Results:
The Results menu contains all measurement files and the options for measurement file management.

System:
The System menu contains the systems settings to be defined by the user, e.g. language or separators for decimals and thousands.
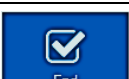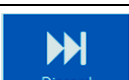
About:
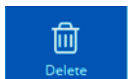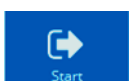The About dialog contains information about the software and Berthold Detection Systems.

One of the main menus is always enabled (highlighted icon on a dark blue button), the others are grayed out. Tap on a button to enable the respective menu and its submenus.

2.2 Working with the Onboard Software

The software is operated using the following actions:

- Buttons on the different menus simplify program handling

Button	Meaning
Edit	Edit the parameters of the selected protocol.
New	Tap on the <New> button to setup a new protocol and select a protocol type in the drop down menu.
Delete	Delete the selected protocol or measurement file. Protocol types and default protocols cannot be deleted.
Start	Starts the selected protocol or action. The measurement window will appear.
End	Finish an experiment. All measurement values will be stored automatically.
Cancel	Cancel an experiment.
Discard	Discard a measurement and re-measure the replicate again
Stop	Stops a current measurement and re-measure the replicate again
Table	Result view of a measurement file
Export	Export measurement file to CVS (Excel), HTML, PDF
Print	Print measurement file to PDF or connected network printer (see Technical data)
Graph	Graph view of a measurement file

- Besides using the buttons it is possible to wipe an enabled **<protocol name>** to the right to enter the **<Edit>** menu and to the left to **<Start>** a measurement. In the **<Results>** menu wiping can be used to switch between **<results file name>**, table **<view>** and **<graph.>**
- Tap on and insert information in a dialog box, using the alphanumerical display or select a pull-down menu.
- Scroll up and down

Depending on the context, action buttons may be enabled (highlighted) or disabled (grayed out). Some submenus are hidden and will be shown after enabling a switch or button only.

2.3 Protocols

The Protocols menu contains the available protocol types:

- **Prime&Wash** with the default protocol "Wash"
- **Quick Measurement** with the "Default" protocol
- **Single Ass**ay
- **Dual Assay**

Tap on a protocol type button and/or a protocol name to select a protocol.

2.3.1 Total Reaction Volume

Sirius 2 enables the user to inject into different sample formats. Before preparing a measurement protocol, please check that the total reaction volume is within the volume range of the selected tube.

> ⚠️ **CAUTION**
>
> **Total reaction volume**
>
> Especially when microfuge tubes are used, the sample and injection volume have to be reduced to avoid overflow and splashes outside the tubes.
>
> If liquid gets inside the instrument, pull the power cord immediately. Do not operate the instrument if internal components have been exposed to fluids, since they create a potential for electric shock and burning.

Recommended maximum total reaction volume:

75x12mm tubes : ≤3000µl
55x12mm tubes: ≤2000µl
Microfuge tubes 2ml: ≤1000µl
Microfuge tubes 1,5ml: ≤750µl

2.3.2   Prime&Wash Protocol

The Prime&Wash protocol is used to prime and/or wash injectors prior and after use. Injector tubing has to be washed with 5ml of distilled water prior to first use. Wash also before starting a measurement and when changing reagents. Proceed as described below.

- For measurement injections, the tubing has to be primed first to ensure that the full volume is injected with the first shot.

- To wash or prime the tubing, insert an empty sample tube into the sample holder!

The dead volume of the tubing is lower than 700µl.

⚠ **CAUTION**

Priming volume

Depending on the sample holder and the sample tubes selected, the total volume for priming is limited.

Prime the injectors consecutively and check the total priming volume to be lower than the capacity of your sample tubes to avoid overflow. Prime every injector separately into a new and empty tube.

If liquid gets inside the instrument, pull the power cord immediately. Do not operate the instrument if internal components have been exposed to fluids, since they create a potential for electric shock and burning

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Proceed as follows to wash and prime the tubing:

1. Place the reagent bottles into the reagent holders.

2. Connect the reagent bottles to the white tubing of the respective injector pump. The numbers of the injectors used in the software are in accordance with the numbers on the pumps.

3. Check afterwards that reagent bottles have been connected to the appropriate pump and have not been mixed up.

4. Select **<Prime&Wash>** in the protocol menu and edit the default wash protocol or set up a new one. See Fig. 7-1 on the next page.

5. Enable the respective injector.

6. Set the injection direction. Select between **[To Tube], [To Bottle], [Pick up], [Dispense to Tube], [Dispense to bottle]**. It is recommended to select **[To Tube].**

7. Set the **[number]** of Strokes and the **[Volume]** of a single stroke.

8. The **[Total volume]** is calculated automatically:

   [Volume] x [Strokes] = [Total volume]

9. To avoid leavings of air, reagents or water in the injector system, the **[Total Volume]** should not be lower than 750µl. It is recommended to operate a second priming cycle with a new empty tube for every injector, to make sure that residua have been eliminated.

   Recommended maximum total volume (µl) for priming of a single injector:

   75x12mm tubes : ≤3000µl
   55x12mm tubes: ≤2000µl
   Microfuge tubes 2ml: ≤1000µl
   Microfuge tubes 1,5ml: ≤750µl

Fig 7-1: Edit Prime&Wash dialog box

10. Click on **<Start>** and follow the instructions on the screen. The selected injectors are initialized and the lines are washed/primed. The injectors are now ready for use.

For all protocol types:

Please set the parameter **[volume]** of the injectors in your protocol in accordance to this recommendation. If necessary adapt your assay accordingly.

2.3.3 Assay Protocols

The user may select between 3 protocol types for assay operation.

Quick Measurement:

This protocol type measures the raw data of consecutively numbered samples.

Single Assay:

This protocol type allows you to run background measurements and to measure replicates of samples. An average and %CV of the replicate measurements will be calculated.

Dual Assay:

In the Dual Assay two sample series A and B are measured. For each sample A or B the average and %CV are calculated. The sample series can either be measured in the order ABAB or AABB. Each series may start with an injection. A mathematical ratio may be calculated between both measurement series.

<u>**Measurement order***:* ABAB</u>

Typical applications: **Dual Luciferase Reporter Gene Assay**

IMPORTANT

Dual Assay

If the Dual Assay is selected, the measurement sequence is automatically divided into two cycles; an injection may be performed in each cycle.

The delay times for measurements and injections are calculated starting with the cycle 1.
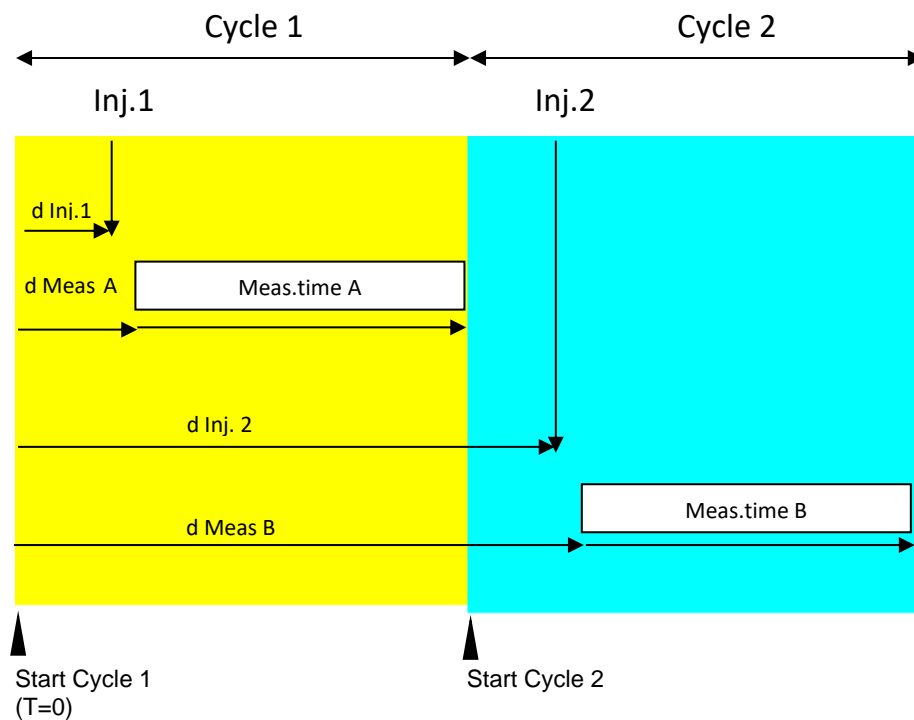
Fig. 7-2:Calculation of delay and measurement times

Where*:*

d Inj. 1   delay 1st injection starting with cycle 1
d Meas. A delay measurement A starting with cycle 1
Inj. 1   injection 1
d Inj. 2   delay 2nd injection starting with cycle 1
d Meas. B delay measurement B starting with cycle 1
Inj. 2   injection 2

For measurement order ABAB, cycle 2 is always started automatically.

If only <u>one</u> injector is installed (**Injector 1**), but you would like to perform injections in **cycle 1**, set the delay time for **Injector 2** so high that it extends into **cycle 2**.

Measurement order: AABB

IMPORTANT

DUAL Assay AA…BB

The measurement sequence AA…BB in the protocol **DUAL ASSAY** may be considered as <u>two individual runs carried out in succession. This applies for the injector operation, too.</u> The respective injector parameters will be carried out in sequence 1 and sequence 2 in succession. The software measures and calculates the results as defined in the protocol.

2.3.4   Comparison of Assay Protocol Types

To help you get a quick overview of the different protocol types, we have summarized their functions in the table below:

	Quick Measurement	**Single Assay**	**Dual Assay**
Function		Measurement of several samples with replicates	Measurement of sample series A and B
Blank	no	yes	yes
Replicates	no	flexible	same number for A and B
Number of samples	any	flexible	same number for A and B
Calculations	none	>1 replicate: average value %CV	>1 replicate: average value %CV
Miscellanous	Meas. sequence	Meas. sequence	different calculation formulas for A and B

2.3.5   Set up and run an Assay Protocol

1. To set up or edit an Assay protocol, press the respective buttons **<New>** or **<Edit>** and insert the assay settings.

1st cycle settings:
Injector 1 and Measurement A enabled

2nd cycle settings:
Injector 2 and Measurement B enabled

Blank measurement : disabled
Meas. start by Door close: enabled

Fig. 7-3: Example of a New/Edit dialog for the Dual Assay

2. Insert all settings according to your assay description.

3. To start the measurement, press the **<Start>** button. The measurement window will open.

    Alternatively a protocol in the protocol main window can be started after selection by using the start button or wiping **<protocol name>** to the left.

4. Follow the instructions on the screen to perform injections and/or measurements. Use the action button according to the description in chapter 2.2.
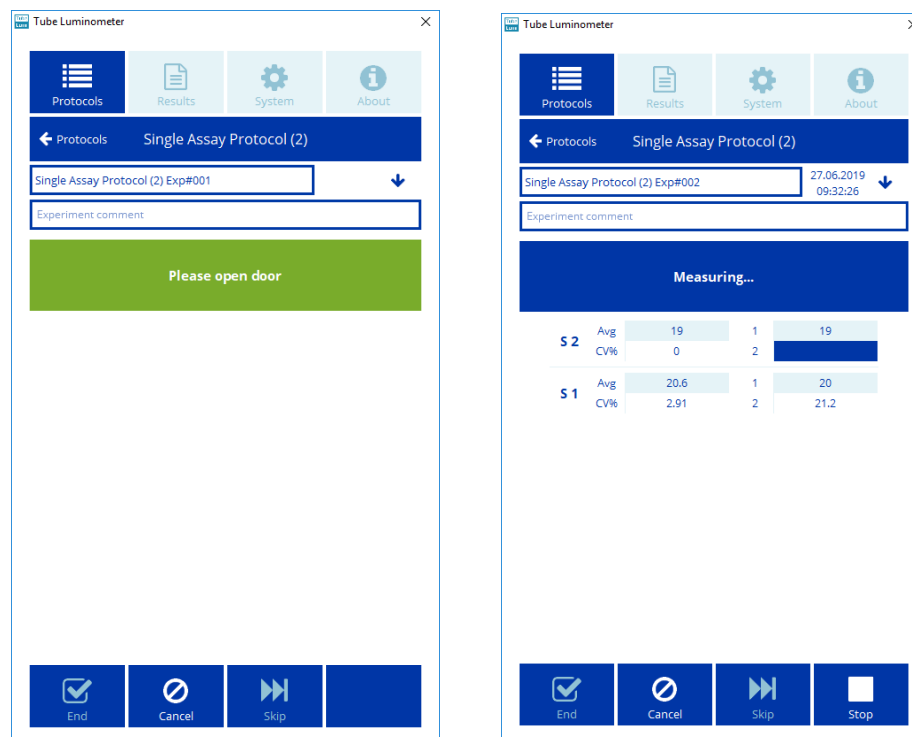
Fig. 7-4: Examples of measurement windows

5. Measurement data are stored in the main menu **<Results>**.

2.4 Results

All measurement file are stored automatically. View the result list in the menu **<Results>.**

View results

- To view a result file, tab on the file name to enable it and on the **<View >**button.

- In the **<Results>** menu, wiping can be used to switch between **<results file name>**, table **<View>** and **<Graph>.**

Print or export

- Measurement data may be printed or exported. Printer settings may be selected in the submenu **<Printer>**of the **<Results>** menu.

- In cases of data export, insert a USB stick at the side of the computer, tap the button **<Export>** and select between CSV(Excel), HTML and PDF.

2.5   System

The system menu allows settings for software language (default is English), date and time, selection of separators for decimals and thousands, and network and printer settings.

Network or USB printing requires a printer with PCL6 or Postscript 3 protocol.

2.6   About

The About menu contain all necessary information about the Tube Luminometer Software, the hardware and the contact information of Berthold Technologies.

3   Models without Control Unit

Some Sirius 2 models (ID No. 84018-04/-05/-06) are operated by Windows PC software. These models are delivered without control unit.

The software is provided on a USB stick which is part of the accessories.

3.1   Technical Data of PC Operating Software

PC software	MS Windows® application for control, measurement and evaluation
Platform/Required Hardware	Microsoft Windows compatible PC, Pentium like processor, RS232 or USB port
Operating System	Windows®7, Windows®10, 32 and 64 bit
Additional Software	Microsoft Excel^{TM} (optional)
Standard configuration	Protocol Manager, Quick Measurement
Additionally available	Single Assay, Dual Assay, Single Kinetics, Multiple Kinetics, Cut-off Assay

3.2   Software Installation

The description is valid for Windows 10. The general sequence is similar for other tube luminometer software/OS combinations as well. Differences may occur in file or folder names or similar.

IMPORTANT

Software installation

The luminometer must not be connected to PC while installing the software or the driver.

Step1: Installation of the Operating Software

1. Close all Windows applications and insert the USB stick provided with the accessories into a USB slot of your PC.

2. Double-click the FB12/ Sirius software V2.0 Setup.exe file to start the setup program. Administrator rights are necessary for installation. An installation wizard guides you through the software installation. Usually the default settings may be taken over. Follow the instructions until completion of installation.

3. The FB12/Sirius software icon will be available on your desktop after installation.

Step 2: Installation of Driver Software

4. The driver software is a separate file not provided by the software package. You will find the driver software in the subfolder USB_drivers. Install the driver, then.

5. Connect the instrument to PC via USB cable and switch it on.

Step 3: Verification

6. Open the software by double-clicking the FB12/ Sirius icon on your desktop. The protocol manager will open.

7. Open the **<Options>** dialog and check **<Find luminometer>**. Information about the instrument and the selected COM port is shown.

8. Start the Quick Measurement protocol with **<Run>** to open the measurement window. "RX" appears on the right side of the status line.

9. The system is now ready to use.

3.3 Priming Injectors

Depending on your order, the instrument is delivered with one or two injectors. A priming menu for washing and priming of the injectors is part of the software.

1. Connect the reagent bottle to the white tubing of the respective injector to be primed. Do not mix up the tubing!

2. Click the **<Priming injectors>** button in your protocol manager to open the priming dialog box.

3. Mark the check box of the respective injector.

4. Set the injection direction. Select between **[To Tube]** and **[To Bottle].** It is recommended to select **[To Tube].**

5. Set the **[Number]** of Strokes and the **[Volume]** of a single stroke.

6. The **[Total volume]** is calculated automatically:

    [Volume] x [Strokes] = [Total volume]

7. To avoid leavings of air, reagents or water in the injector system, the **[Total Volume]** should not be lower than 750µl. It is recommended to operate a second priming cycle with a new empty tube for every injector, to make sure that residua have been eliminated.
    Recommended maximum total volume (µl) for priming of a single injector:

    75x12mm tubes : ≤3000µl
    55x12mm tubes: ≤2000µl
    Microfuge tubes 2ml: ≤1000µl
    Microfuge tubes 1,5ml: ≤750µl

8. Click on **<Prime>**. The injectors are initialized and the lines are washed/primed.

3.4   Assay Protocols

The protocol manager provides 6 protocol types:

Protocol type	Description
Quick Measurement	simple measurement without any calculation
Single Assay	measures any number of samples and replicates, display of average values and standard deviation
Dual Assay	measures a sample twice directly one measurement after the other
Cut Off Assay	Cut-off measurements for qualitative classification of patient samples
Single Kinetics	shows the course of light emission over a specific period of time
Multiple Kinetics	several samples are measured in parallel over a defined period of time and for a defined number of times

3.4.1   Setup an Assay Protocol

1. Select your protocol type and confirm with **<Create>**.

2. Please refer to chapter 2.3.1 for information about the total reaction volume. Do not exceed the specified volume for your tube format.

3. Enter **[Delay time]**- and **[Measurement time]**, decide how you want to **[Start measurement]** and whether the **[First sample is background]** or not, enter **[Number of samples]** and **[Number of replicates]** and set **[Injectors]** parameters, if necessary.

4. Name the protocol and save it. The new protocol will be shown in the list of **[Runnable protocols]** on the Protocol manager screen.

5. Runnable protocols may be edited or deleted, pressing the respective buttons **<Edit>** or **<Delete>.**

3.4.2 Run an Assay Protocol

1. Choose your protocol in the lower window of the protocol manager and press **<Run>**. The measurement window will open.

2. Insert your first sample and start the measurement according to the settings in your protocol with "door close" (typically selected) or via "start button". Exchange the sample tube and close door/ press start button again to start the next measurement.

3. **<Save>** your results, **<print>** or transfer them to **<Excel>** by using the respective buttons.

3.5 Data Storage

Measured data are stored by default in the **[Default data storage directory]**. Find the information in the **<Options>** dialog.

To open a measured file, click on the **<Retrieve Data>** button on the protocol manager screen.

3.6 About

The **<About>** menu contains the name and the version number of the PC Software for Sirius 2 models without control unit. If questions appear, contact Berthold Technologies. Refer to the contact data in chapter 1.1.

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4 Further Information

Quality control

It is considered good laboratory practice to run laboratory samples according to instructions and specific recommendations included in the package insert of the reagent kit or the standard laboratory protocol for the test to be conducted. A failure in the performance of Quality Control checks could result in erroneous test data.

Samples should be obtained, treated and stored following the instructions and recommendations of the kit insert.

It is recommended to run known internal quality standards or samples attendant to the measurement runs or to use the LED TestTube, offered by Berthold Technologies, for instrument validation measurements.

NOTICE

System validation

The whole system of luminometer, assay and evaluation software must be validated by the user.

⚠ CAUTION

Further calculations

The system only provides RLU/s values. Further calculations and evaluations based on these RLU/s values are the sole responsibility of the user.

Cleaning/Decontamination

- Follow the instructions in the safety manual / chapter 5.4

5 Warranty and Technical Issues

5.1 Special Spare Parts

Special spare parts, to be purchased from the manufacturer or his local representative only, are listed in the safety manual, chapter 5.2.

5.2 Warranty Statement

The instrument is sold in accordance with the general conditions of sale of Berthold Technologies GmbH & Co KG and its affiliates and representatives.

Berthold Technologies warrants this product to be free of defects in material and workmanship for a period of 12 months from the date of delivery, ex works Bad Wildbad.

Berthold Technologies or its authorized representative will repair or replace, at its option and free of charge, any product that under proper and normal use proves to be defective during the warranty period.

Berthold Technologies shall in no event be liable or responsible for any incidental or consequential damage, either direct or indirect.

The above warranty shall not apply if:

- the product has not been operated in accordance with the operating manual
- the product has not been regularly and correctly maintained
- the product has not been repaired or modified by a Berthold Technologies authorized representative or user
- parts other than original Berthold Technologies parts are used
- the product and parts thereof have been altered without written authorization from Berthold Technologies GmbH & Co KG
- the product has not been returned properly packed in the original Berthold Technologies packaging

This warranty does not apply to any third party product involved in the application.

5.3 Customer Service

Customer service will be provided in the first instance by the network of Berthold Technologies representatives. In the event of any problem experienced with your instrument, the first recourse should be your local Berthold Technologies representative. For further problems requiring hardware or software expertise, contact the Technical Support group at Berthold Technologies GmbH & Co KG. Here are the contact data::

> Berthold Technologies GmbH & Co KG
> Technical Support
> Calmbacher Str. 22
> 75323 Bad Wildbad/ Germany
> Phone: +49 7081 177 114
> Fax: +49 7081 177 301
> Email: service@berthold.com

Please have the following relevant information available:

- serial numbers, part number, revision: see production label on instrument
- software and firmware versions
- monitor and log files, if available.

5.3.1 Return Shipment to Berthold Technologies

In case of an instrument return shipment please refer to our website and follow the instructions:

https://www.berthold.com/en/company/service/form-rma-return-material-authorization/

An RMA number is required to ship an instrument for repair and identify your instrument when it arrives.

Confirmation on Decontamination

If you return an instrument to Berthold Technologies for servicing purposes which is not properly decontaminated, there will be a health risk for Berthold Technologies employees.

We therefore need your confirmation that the instrument was decontaminated and cleaned properly before shipping. Follow the instructions on cleaning, decontamination and preparations for transport in the Safety Manual and confirm the decontamination in the online-form.

6 Index

Modifications due to technical advancement reserved.

This product uses the FreeRTOS.org real time kernel – The freeRTOS.org source code can be obtained by visiting http://www.FreeRTOS.org

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