



Instructions for Use for

SUNRISE

Microplate Absorbance Reader



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Tecan Customer Support

If you have any questions or need technical support for your Tecan product, contact your local Tecan Customer Support organization. Go to <http://www.tecan.com/> for contact information.

Prior to contacting Tecan for product support, prepare the following information for the best possible technical support (see name plate):

- Model name of your product
- Serial number (SN) of your product
- Software and software version (if applicable)
- Description of the problem and contact person
- Date and time when the problem occurred
- Steps that you have already taken to correct the problem
- Your contact information (phone number, fax number, e-mail address, etc.)



WARNING

**CAREFULLY READ AND FOLLOW THE INSTRUCTIONS PROVIDED
IN THIS PUBLICATION BEFORE OPERATING THE INSTRUMENT.**

Notice

Every effort has been made to avoid errors in text and diagrams; however, Tecan Austria GmbH assumes no responsibility for any errors, which may appear in this publication.

It is the policy of Tecan Austria GmbH to improve products as new techniques and components become available. Tecan Austria GmbH therefore reserves the right to change specifications at any time *with appropriate verification, validation, and approvals*. We would appreciate any comments on this publication.



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Declaration for EU Certificate

See the last page of these Instructions for Use.

SUNRISE Microplate Absorbance Reader Intended Use

See chapter 2.2.1 Intended Use.

About the Instructions for Use

Original instructions. This publication is intended as **Instructions for Use** for the SUNRISE Microplate Absorbance Reader, which is designed to measure the light absorbance (optical density) of samples in 96 well microplates. It is intended as reference and instruction for the user.

This document instructs how to:

- Install the instrument
- Operate the instrument
- Clean and maintain the instrument

Every time SUNRISE is mentioned the SUNRISE Microplate Absorbance Reader is intended.

Warranty

3 Year Warranty

As an expert for microplate instrumentation Tecan proves its commitment to quality and offers a unique 3-year warranty for your SUNRISE Microplate Absorbance Reader as a standard. Warranty will be invalid if the instrument is opened or modified.

Warnings, Cautions and Notes

The following types of notices are used throughout this publication to highlight important information or to warn the user of potentially dangerous situations:



Note

Gives helpful information.



CAUTION

INDICATES A POSSIBILITY OF INSTRUMENT DAMAGE OR DATA LOSS IF INSTRUCTIONS ARE NOT FOLLOWED.



WARNING

INDICATES THE POSSIBILITY OF SEVERE PERSONAL INJURY, LOSS OF LIFE OR EQUIPMENT DAMAGE IF THE INSTRUCTIONS ARE NOT FOLLOWED.



WARNING

INDICATES THE POSSIBLE PRESENCE OF BIOLOGICALLY HAZARDOUS MATERIAL. PROPER LABORATORY SAFETY PRECAUTIONS MUST BE OBSERVED.



ATTENTION

NEGATIVE ENVIRONMENTAL IMPACTS ASSOCIATED WITH THE TREATMENT OF WEEE

- DO NOT TREAT ELECTRICAL AND ELECTRONIC EQUIPMENT AS UNSORTED MUNICIPAL WASTE.
- WASTE OF ELECTRICAL AND ELECTRONIC EQUIPMENT MUST BE COLLECTED SEPARATELY.















FOR CALIFORNIA RESIDENTS ONLY:

WARNING

THIS PRODUCT CAN EXPOSE YOU TO CHEMICALS SUCH AS LEAD WHICH IS KNOWN TO THE STATE OF CALIFORNIA TO CAUSE CANCER AND BIRTH DEFECTS OR OTHER REPRODUCTIVE HARM.

FOR MORE INFORMATION GO TO:
WWW.P65WARNINGS.CA.GOV/PRODUCT.

Symbols

	Manufacturer
	Date of manufacture
	CE conformity marking
	United Kingdom Conformity Assessed marking shows that the labeled product is following the applicable regulation in Great Britain.
	Consult instructions for use
	Catalogue number
	Serial Number
	Unique Device Identification The UDI symbol identifies the data carrier on the label.
	WEEE symbol
	China RoHS symbol
	TÜV SÜD MARK
	Biological risks

Abbreviations

Abbreviation	
A	Ampere
Abs.	Absorbance
ADC	Analog digital converter
ASCII	American Standard Code for Information Interchange
ASTM	American Society for Testing and Material
C	Celsius
CE	CE conformity marking
cm	Centimeter
F	Fahrenheit
Hz	Hertz
IVD	In vitro diagnostics
kg	Kilogram
l; L	Liter
LED	Light emitting diode
LIS	Laboratory Information System
MB	Megabyte
ml	Milliliter
nm	Nanometer
OD	Optical Density
RC	Remote control
REF	Reference Number/ Order Number
SN	Serial Number
ST	Standard
TW	Tuneable wavelength
TYPE	Name and type of instrument
USB	Universal serial bus
V	Volt
VA	Volt ampere
VGA	Video Graphics Array
VOLTAGE	Voltage

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1. Safety

1.1 Instrument Safety

1. Always follow basic safety precautions when using this product to reduce the risk of injury, fire, or electrical shock.
2. Read and understand all information in the Instructions for Use (IFU). Failure to read, understand, and follow the instructions in this document may result in damage to the product, injury to operating personnel, or poor instrument performance. Tecan is not responsible for damage or injuries resulting from incorrect handling of the device.
3. Observe all WARNING and CAUTION statements in this document.
4. Always disconnect the device from the main power supply prior to cleaning and disinfection.
5. Never open the instrument's housing.
6. Observe proper laboratory safety precautions such as wearing protective clothing (e.g., gloves, lab coat, and safety glasses) and the application of approved laboratory safety procedures.



CAUTION

IF THE INSTRUCTIONS GIVEN IN THIS PUBLICATION ARE NOT CORRECTLY FOLLOWED, THE INSTRUMENT MAY BECOME DAMAGED OR PROCEDURES MAY NOT BE CORRECTLY PERFORMED AND THE SAFETY OF THE INSTRUMENT CANNOT BE GUARANTEED.

It is assumed that the instrument operators, because of their vocational experience, are familiar with the necessary safety precautions for handling chemicals and bio-hazardous substances.

Adhere to the following laws and guidelines:

- National industrial protection law
- Accident prevention regulations
- Safety data sheets of the reagent manufacturers



WARNING

DEPENDING ON THE APPLICATIONS, PARTS OF THE SUNRISE MAY COME IN CONTACT WITH BIOHAZARDOUS/INFECTIOUS MATERIAL.

MAKE SURE THAT ONLY QUALIFIED PERSONNEL OPERATE THE INSTRUMENT. IN CASE OF SERVICE OR WHEN RELOCATING OR DISPOSING OF THE INSTRUMENT, ALWAYS DISINFECT THE INSTRUMENT ACCORDING TO THE INSTRUCTIONS GIVEN IN THIS DOCUMENT.

OBSERVE PROPER LABORATORY SAFETY PRECAUTIONS SUCH AS WEARING PROTECTIVE CLOTHING WHEN WORKING WITH POTENTIALLY INFECTIOUS SUBSTANCES.

1. Safety



WARNING

THE INSTRUMENT COMPLIES WITH THE EMISSION AND IMMUNITY REQUIREMENTS DESCRIBED IN IEC 61326-2-6; HOWEVER, THE ELECTROMAGNETIC ENVIRONMENT SHOULD BE EVALUATED PRIOR TO THE OPERATION OF THE INSTRUMENT.

IT IS THE OPERATOR'S RESPONSIBILITY TO ENSURE THAT A COMPATIBLE ELECTROMAGNETIC ENVIRONMENT FOR THE INSTRUMENT IS MAINTAINED, SO THAT THE INSTRUMENT PERFORMS AS INTENDED.

DO NOT OPERATE THE INSTRUMENT IN CLOSE PROXIMITY TO SOURCES OF STRONG ELECTROMAGNETIC RADIATION (E.G. UNSHIELDED INTENTIONAL RF SOURCES) AS THIS MAY INTERFERE WITH THE PROPER FUNCTION OF THE INSTRUMENT AND MAY ALSO LEAD TO INCORRECT RESULTS.



WARNING

IF THE SUNRISE INSTRUMENT OR THE MAGELLAN SOFTWARE ARE MODIFIED IN ANY WAY, THE PERFORMANCE OF THE READER MAY BE NEGATIVELY AFFECTED, THE WARRANTY WILL NO LONGER BE VALID AND THE INSTRUMENT WILL NOT BE CE CONFORM.

2. General

2.1 Introduction



Note

The SUNRISE Microplate Absorbance Reader, equipped with option Remote Control, is intended for use with external software only.



CAUTION

BEFORE STARTING MEASUREMENTS, MAKE SURE THAT THE MICROPLATE POSITION A1 IS INSERTED CORRECTLY.

The SUNRISE instruments are fully automatic, microprocessor-controlled readers designed for professional use, enabling the user to measure the light absorbance (optical density) of samples in 96 well microplates according to the specifications described in this publication.



Note

Results obtained using the SUNRISE are influenced by the proper use of the instrument and microplates, according to the instructions given in this document, as well as the liquid compounds used (reagents, chemistry). The instructions for use, for storage and for other manipulations in connection with samples or reagents must be strictly followed. Taking this fact into consideration, results must be interpreted carefully.

By reading twelve wells simultaneously, the instrument is able to measure a microplate in approximately six seconds.

The obtained transmission values are converted into OD values according to the following formula:

$$\text{Transmission } T = \frac{I}{I_0}$$

I_0 = incident light

I = detected light (after the sample)

The absorption (Optical Density) is the logarithm of the reciprocal transmission.

$$\text{OD} = \text{Log} \frac{1}{T}$$

With an innovative range of options, this versatile microplate reader gives diagnostic and research laboratories all the features for numerous purposes.

Based on a new design concept EPAC, the excellent optical performance and high quality of the SUNRISE will guarantee fast, reproducible, and accurate measurements.

The SUNRISE is designed to be used as a stand-alone device as well as an integrated module on Tecan robotic systems.

The SUNRISE Microplate Absorbance Reader is an optical 96-well microplate reader for the measurement of absorbance and turbidimetry of samples from the

2. General

biological or non-biological origin according to the specifications described in this document, intended for professional use only.

The SUNRISE Microplate Absorbance Reader is available with the options **Tuneable wavelength** and **Temperature control**.

Magellan is a reader control and data reduction software package, and also can be used for concentration and titer determination.



Note

It is important to note that the proper installation of the instrument and Magellan software alone will not ensure regulatory compliance. A range of policies and standard operating procedures according to local regulations must also be established.

Make sure the instrument and the software are suitable for use with the reagents, chemicals and microplates that are being used (see 6.2 Optimizing for Maximum Performance and 6.3 Operational Qualification).



CAUTION

IF THE INSTRUCTIONS GIVEN IN THIS PUBLICATION ARE NOT CORRECTLY FOLLOWED, THE INSTRUMENT MAY BECOME DAMAGED OR PROCEDURES MAY NOT BE CORRECTLY PERFORMED AND THE SAFETY OF THE INSTRUMENT CANNOT BE GUARANTEED.



Note

For more information about the operating instructions, see the Magellan Instructions for Use.



WARNING

CAREFULLY READ AND UNDERSTAND ALL INFORMATION IN THIS DOCUMENT. FAILURE TO READ, UNDERSTAND AND FOLLOW THE INSTRUCTIONS IN THIS PUBLICATION MAY RESULT IN DAMAGE TO THE PRODUCT, INJURY TO OPERATING PERSONNEL OR POOR INSTRUMENT PERFORMANCE.

2.2 Area of Application

2.2.1 Intended Use

The SUNRISE instrument is a 96-well absorbance reader for the measurement of light absorbance (optical density) of liquid media. The instrument has been designed as a general-purpose laboratory instrument for professional use.

Software and instrument have been validated for measurement and for the evaluation of qualitative and quantitative Enzyme-linked Immunosorbent Assays (ELISA).



Note

If the SUNRISE or the Magellan software is modified in any way, the warranty will no longer be valid, and the instrument will lose regulatory conformity.



Note

Results obtained using the SUNRISE are influenced by the proper use of the instrument and microplates, according to the instructions given in this document, as well as the liquid compounds used (reagents, chemistry). The instructions for use, storage, and applications involving samples or reagents must be followed strictly. Results must therefore be interpreted carefully.

2. General

2.2.2 User Profile

Professional User - Administrator Level

The administrator is a person who has suitable technical training and corresponding skills and experiences. If the product is used as intended, the person is able to recognize and avoid dangers.

The administrator has extensive skills and is able to instruct the end user or the routine user in assay protocols in connection with a Tecan product within the bounds of the intended use.

Computer application skills and good English skills are required.

End User or Routine User

The end user or routine user is a person who has suitable technical training and corresponding skills and experiences. If the product is used as intended, the person is able to recognize and avoid dangers.

Computer application skills and good language skills for the respective national language at the installation site and English are required.

Service Technician

The service technician is a person who has suitable technical training and corresponding skills and experiences. If the product needs to be serviced or maintained, the person is able to recognize and avoid dangers.

Computer application skills and good English skills are required.



Note

Training dates, their duration and frequency are available at your customer support.


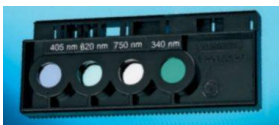



***Address and phone number can be found in Internet:
<http://www.tecan.com/customersupport>***

2.2.3 Options of SUNRISE

The SUNRISE is a modular system, so you can create your own tailor-made instrument that meets exactly your needs.

The options **Wavelength selection** and **Temperature control** are available.

SUNRISE Options

Option Level	Description		
User Interface	Remote control (RC) 		
Optics	4-Filter (ST) 	6-Filter (6F) 	Tuneable wavelength (TW)  This option is not used for clinical diagnostics in China.
	Options Temperature control (TC) 		

2.3 Specifications

The tables below list the specifications for the instruments in SUNRISE mode.

2.3.1 General

For all instrument options:

PARAMETERS	CHARACTERISTICS
Main power input	100 - 120 & 220 - 240 V, 50/60 Hz (Auto sensing)
Consumption	Operational mode: max. 110 VA
Fuse rating	2 x F 2.0 A / 250 V (Fast Blow)
Outside dimensions	Width: 28.5 cm (11.22 inch) Depth: 34.0 cm (13.39 inch) Height: 14.5 cm (5.71 inch)
Weight	
Max. (incl. all options)	8.6 kg
Ambient temperature:	
Operation	15°C to 35°C (59°F to 95°F)
Storage	-20°C to 60°C (-4°F to 140°F)
Relative humidity:	
Operation	20 % to 90 %
Storage	5 % to 95 %
Over voltage category	II
Pollution degree	2
Method of disposal	Contaminated waste
Environment	See 3.5 Environmental Requirements for more information.
Stability: Normal measurements	After 15 minutes warm up time max. +/- 0.001 OD

2.3.2 SUNRISE Instrument Configuration with 4Filter Option

PARAMETERS	CHARACTERISTICS
Measurement time: dual wavelength single wavelength	8 seconds 6 seconds
Wavelength range: Standard filter	340 - 750 nm
Measurement range: 340 - 399 nm 400 - 750 nm	0 - 3.000 OD 0 - 4.000 OD
Resolution:	0.001 OD
Accuracy: (492 nm) 0.000 - 2.000 OD (492 nm) 2.000 - 3.000 OD	< (1.0 % + 0.010 OD) * < (1.5 % + 0.010 OD) *
Precision: (492 nm) 0.000 - 2.000 OD (492 nm) 2.000 - 3.000 OD	< (0.5 % + 0.005 OD) * < (1.0 % + 0.005 OD) *
Linearity: (340 - 399 nm) 0.000 - 2.000 OD (400 - 750 nm) 0.000 - 2.000 OD 2.000 - 3.000 OD	< 2 % < 1 % < 1.5 %
(340 - 399 nm) 0.000 - 2.000 OD (400 - 750 nm) 0.000 - 2.000 OD (400 - 750 nm) 2.000 - 3.000 OD	R ² ≥ 0.999 R ² ≥ 0.999 R ² ≥ 0.999
* better than x % of measurement value plus corresponding OD value. Note: All deviations from the measurement value are meant in positive and negative direction.	
Wavelength selection: Standard filter	Narrow band interference filters. Up to four filters can be mounted in a filter carriage. The instrument can use up to eight different filter carriages.
Filter wavelength accuracy	Central wavelength +/- 2 nm
Filter bandwidth At 50% transmission:	10 +/- 2 nm
Light source:	Halogen lamp 20 W
<i>All connected devices must be approved and listed as per IEC 60950-1 Information Technology Equipment – Safety and equivalent local standards.</i>	
Computer interface: Serial RS 232 C	300 - 38,400 baud

2.3.3 SUNRISE Instrument Configuration with 6Filter Option

See 2.3.2 SUNRISE Instrument Configuration with 4Filter Option .

2. General

2.3.4 **SUNRISE Instrument Configuration with Tuneable Wavelength Option (Gradient Filter Carriage)**

PARAMETERS		CHARACTERISTICS
Measurement time: Dual wavelength Single wavelength		16 seconds 8 seconds
Wavelength range: Gradient filter Standard filter		400 - 700 nm 340 - 399 nm & 700 - 750 nm
Measurement range: 340 - 399 nm 400 - 750 nm		0 - 3.000 OD 0 - 4.000 OD
Resolution:		0.001 OD
Accuracy: (492 nm)	0.000 - 2.000 OD	< (1.5 % + 0.010 OD) *
Precision: (492 nm)	0.000 - 2.500 OD	< (1.0 % + 0.005 OD) *
Linearity: (492 nm)	0.000 - 2.500 OD	< 2 %, $R^2 \geq 0.999$
Wavelength selection: Gradient filter		Special gradient filter any wavelength between 400 and 700 nm in 1 nm steps. The instrument can use up to eight different filter carriages
* better than x % of measurement value plus corresponding OD value Note: All deviations from the measurement value are meant in positive and negative direction.		
Filter wavelength accuracy		Central wavelength +/- 2 nm
Filter bandwidth At 50% transmission:		
450 nm		8.5 - 16 nm
550 nm		10 - 15 nm
650 nm		10 - 18 nm
Light source:		Halogen lamp 20 W
<i>All connected devices must be approved and listed as per IEC 60950-1 Information Technology Equipment – Safety and equivalent local standards.</i>		
Computer interface: Serial RS 232 C		300 - 38,400 baud

2.3.5 *SUNRISE Instrument Configuration with Option Temperature Control*

Peltier-based temperature control.

PARAMETERS	CHARACTERISTICS
Temperature range:	Room temperature up to 42°C increments of 0.1°C
Accuracy	typical +/- 0.2°C (max. +/- 0.5°C)
Preheating time	30 min

The SUNRISE specification of the temperature control unit (typical accuracy +/- 0.2°C) applies if everything (reader, microplate, reagents, samples) has already target temperature.

There is no specification for the heating up period and we are aware that within this period not all wells are heated up equally. This effect will be seen especially when reagents are not preheated.

During preheating the plate transport with a 96 well microplate loaded has to be inside of the instrument. Only in this way a homogenous temperature is received in the instrument. The microplate must not be the same as the one used for measurement but should be clean to keep influences on the following measurement low.

Every time the plate transport is moved it will take up to 1 min to reach again a homogenous temperature inside of the instrument.

Bear in mind that if non-preheated microplate and/or reagents are added, temperature control will take a certain time depending on the temperature difference between microplates.

We recommend a longer measurement interval (e.g., 1 min) to increase homogenous temperature distribution. Keep the difference between target temperature and the temperature of microplate with reagents and samples lower than 20 °C (68 °F).

2.3.6 *Microplates*

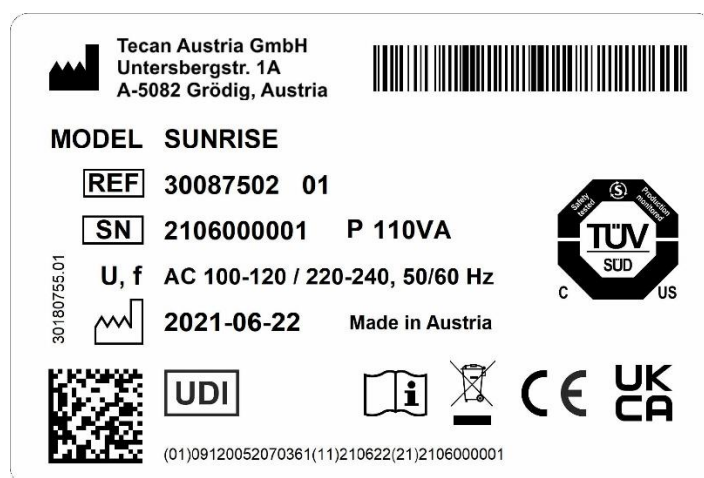
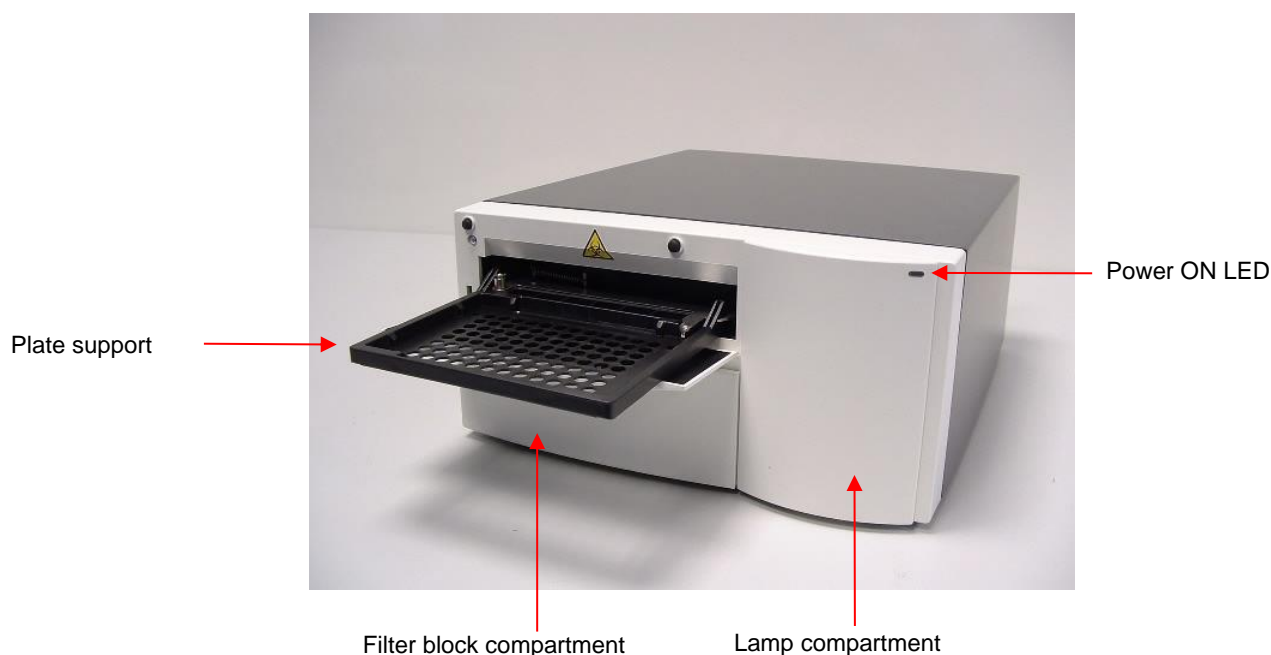
Only 96-well format microplates without lid (V-shaped, flat, or round including strip-wells) with transparent bottom can be used with the SUNRISE Microplate Absorbance Reader.

PARAMETERS	CHARACTERISTICS
Max. overall plate height	14.35 mm +/- 0.76 mm (0.5650 inches +/- 0.0299 inches)
Diameter of wells	7.0 mm (0.276 inches)
Pitch size (center to center)	9.0 mm (0.3543 inches)
Bottom shape	V-shaped, Flat and Round bottom

2. General

2.4 Instrument Description

The illustration below shows the components of the instruments.

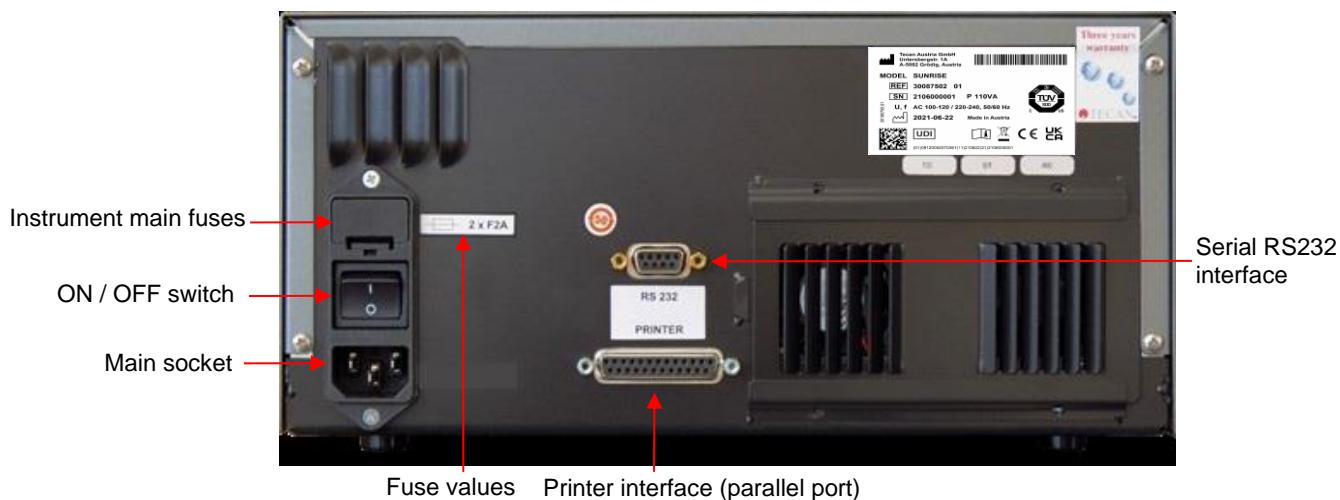


Contents of the name plate (e.g., model name and article number) may vary depending on the specific model.

For an overview of the various instruments for which these Instructions for Use are valid, see the Declaration of Conformity on the last page of this document.

2.4.1 Back Panel Connections

The illustration below shows the connections located in the back panel of the instrument.



All connected devices must be approved and listed as per IEC 60950-1 Information Technology Equipment – Safety and equivalent local standards.

2.4.2 Handling the Microplate

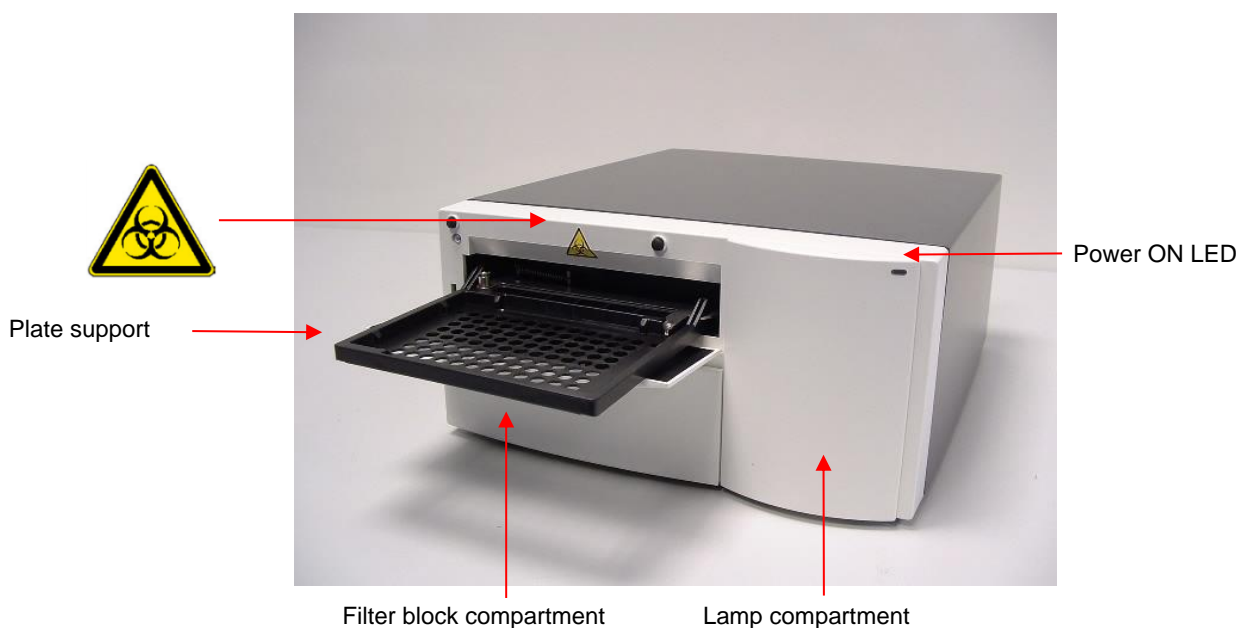
Insert or remove the microplate only when the plate support is fully ejected (as illustrated below) and the plate transport motor is not active.

For details, see the corresponding *Instructions for Use* of the selected SW product (Magellan).



WARNING

WHEN HANDLING THE MICROPLATE ALWAYS USE DISPOSABLE GLOVES AND PROTECTIVE CLOTHING.



2.5 Filter Carriage Description

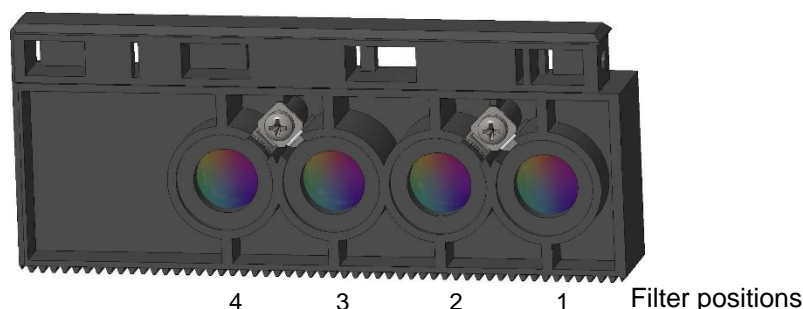
The SUNRISE instrument can use the following types of filter carriages:

SUNRISE 4Filter, 6Filter and Gradient Filter (with tuneable wavelength option).

2.5.1 4Filter Carriage

The SUNRISE 4filter carriage has up to four narrow band interference filters that have a fixed wavelength.

4Filter Carriage



When a wavelength is selected, the entered wavelength is compared against the list of entered filter values for this filter carriage.

If the required filter is fitted in the filter carriage, the filter carriage is moved so that the required filter is in the light beam.



Note

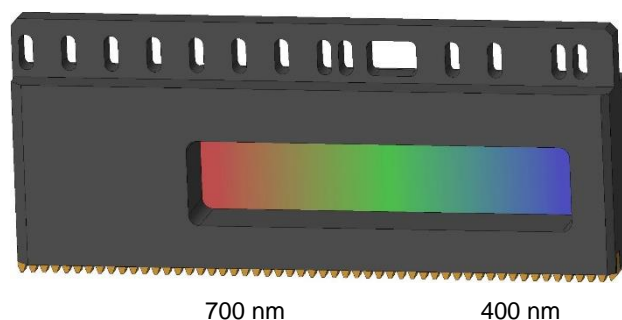
For more information about the definition of the new and customized filter slides, see 3.8 Defining the Instrument Settings.

2.5.2 Gradient Filter Carriage

SUNRISE gradient filters can only be used with the SUNRISE tuneable wavelength option.

The SUNRISE gradient filter carriage is fitted with a gradient filter that allows the selection of any wavelength from 400 to 700 nm.

Gradient Filter Carriage



The gradient filter carriages are calibrated by the manufacturer and each one is unique.



Note

When another gradient filter is inserted into the instrument, the instrument must be re-calibrated. This re-calibration procedure can only be performed by the manufacturer or by a service engineer.

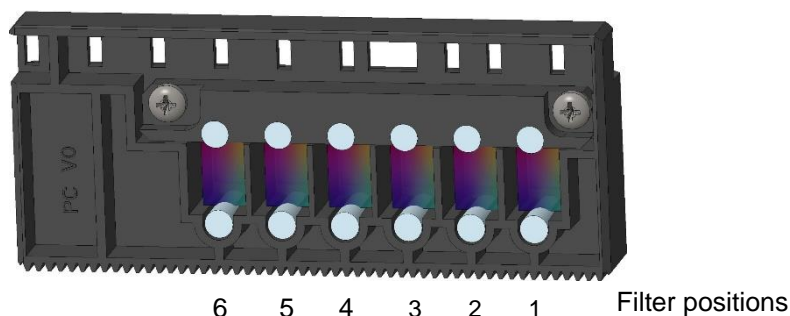
When a wavelength is selected, the entered wavelength is compared against the calibration table. The filter carriage is moved the required distance, so that the required section of the gradient filter is in the light beam.

2.5.3 6Filter Carriage

The SUNRISE 6filter carriages can only be used with the SUNRISE 6filter option.

The SUNRISE 6filter carriage has up to six narrow band interference filters that have a fixed wavelength.

6Filter Carriage



When a wavelength is selected, the entered wavelength is compared against the list of defined filter values for this filter carriage.

If the required filter is fitted in the filter carriage, the filter carriage is moved, so that this specific filter is in the light beam.



Note

For more information about the definition of the new and customized filter slides, see 3.8 Defining the Instrument Settings.

2.6 Instrument Features

Microplates can be measured using the following features:

- Various measurement modes
- Single or dual wavelength measurements
- Microplate shaking

2.6.1 Measurement Modes

The instrument can be set to use the following measurement modes:

Normal	The plate transport is moved quickly under the measurement diodes so that a fast measurement is obtained. Each well is measured at three points, 8 times for each point.
Accuracy	The plate transport is moved very slowly under the measurement diodes so that a very accurate measurement is obtained. Each well is measured at three points, 55 times for each point.
Center	This option measures the optical density only in the center of each well. It is recommended for U-bottom wells or for liquids with high meniscus. Each well is measured at one point, 22 times.

With the **Normal** and **Accuracy** measurement modes, the optical density is measured at three positions across the wells and the average measured optical density value from the three measurements is used as the optical density of the well.



Note

The accurate measurement cycle should always be used when measuring high optical densities.

The **Center** measurement mode should be used if the liquid in the microplate produces a high meniscus, as an incorrect optical density could be obtained if the optical density is measured at three positions. If an agglutination measurement is performed, up to 40 measurement positions per well are used.



Note

For more information about setting the measurement mode, see 3.8 Defining the Instrument Settings.

2.6.2 Microplate Shaking

The SUNRISE is able to shake the microplate before it is measured. Use external software (for example: Magellan) to set the shaking modes.

The microplate can also be shaken between each of the kinetic measurement cycles.



WARNING

WHEN USING A 96 WELL PLATE IN HIGH SHAKE MODE, SPILLAGE MAY OCCUR IF THE WELLS ARE FILLED WITH MORE THAN 300 µL.

The shaking widths and frequencies for the 4 SUNRISE shake modes are as follows:

Shake Mode	Shake Width	Shake Frequency
HIGH	2.8 mm	12.3 Hz
NORMAL	4.4 mm	9.2 Hz
LOW	4.4 mm	7.8 Hz
WIDE	14.2 mm	2 Hz

2.7 Software for the SUNRISE Microplate Absorbance Reader

Software	Functionality
Magellan	Instrument control and data reduction software (also available for Clinical laboratory use)
SUNRISE Instrument Settings	Enables settings of the SUNRISE instrument (SUNRISE mode).



Note

The SUNRISE Microplate Absorbance Reader, equipped with option Remote Control, is intended for use with external software only.



Note

For more information about the software features, see the appropriate individual Instructions for Use. For example, refer to the Magellan Reference Instructions for Use.

3. Installation Procedure

3.1 Introduction

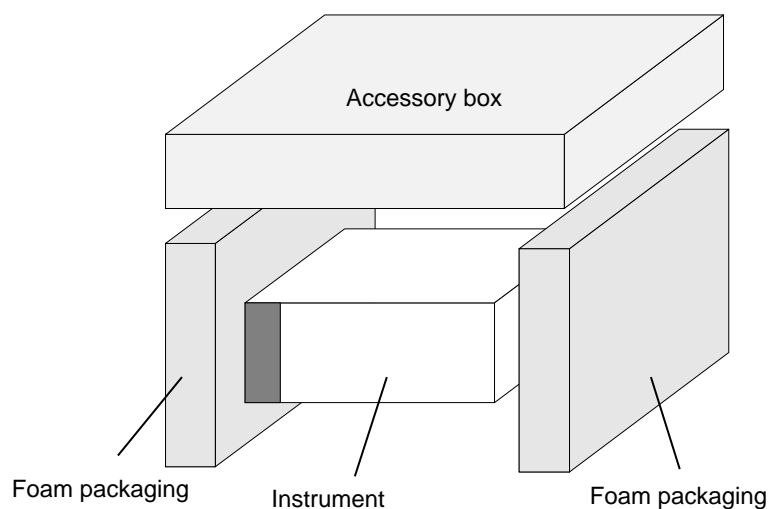
This chapter contains the necessary information for installing the instrument.

The installation procedure involves unpacking, environmental requirements, power requirements and interfacing.

3.2 Unpacking and Inspection

The delivered instrument is shipped in one carton, which includes:

- Power cable
- Computer connection cable
- Instructions for Use for SUNRISE Microplate Absorbance Reader as pdf-files on a data-carrier
- Spare fuses



3.3 Unpacking Procedure

1. Visually inspect the container for damage, before opening it.
Report any damage immediately.
2. Place the carton in an upright position and open it.
The cartridge, filter block and plate transport compartments are fixed with adhesive tape. The location of the adhesive tape is indicated with a red arrow.
3. Lift the instrument out of the carton and place it on a flat surface, free from dust, vibration and away from direct sunlight.
4. Visually inspect the instrument for loose, bent, or broken parts.
Report any damage immediately.
5. Compare the instrument's serial number, attached on the rear panel of the instrument, against the serial number of the instrument on the delivery (shipping) note.
6. Check the instrument spare parts and tools against the delivery (shipping) note.
7. Open the plate support area cover and remove the foam strip that is used as the microplate transport lock.
8. Please save all packing materials, as it may be required for storage or later transportation.

3.4 Power Requirements

The instrument is auto sensing for the supplied voltage, and therefore does not have to be set for the correct voltage.

Connect the instrument only to an electricity supply system with protective earth.



WARNING

TO PREVENT THE RISK OF FIRE, THE MAIN FUSES SHOULD ONLY BE REPLACED WITH THE SAME TYPE AND RATING OF FUSES.



CAUTION

DO NOT REPLACE DETACHABLE MAIN POWER SUPPLY CORDS WITH INADEQUATELY RATED CORDS.

3.5 Environmental Requirements

The instrument should be placed on a flat, level surface that is free from dust, solvents and acidic vapors.

Vibration and direct sunlight must be avoided, to ensure correct results.

Ambient Temperature:	
Operation	15°C to 35°C (59°F to 95°F)
Storage	-20°C to 60°C (-4°F to 140°F)
Relative Humidity:	
Operation	20 % to 90 %
Storage	5 % to 95 %

3.6 Instrument Installation Procedure

The following procedures detail the necessary steps to be followed when installing the instrument.



CAUTION

BEFORE THE INSTRUMENT IS INSTALLED AND SWITCHED ON, IT SHOULD BE LEFT TO STAND FOR AT LEAST THREE HOURS, SO THERE IS NO POSSIBILITY OF CONDENSATION CAUSING A SHORT CIRCUIT.

When the requirements above have been met, installation is carried out using the following procedure:

1. Place the instrument into the required position.

Ensure that the distance between the back panel of the instrument and the wall is at least 10 cm.

2. Connect the instrument to the external computer with the required interface cable.

The interface cable must be plugged into the 9-pin serial interface socket, in the back panel.

For connection to the external computer with a COM port use the serial – serial interface cable.

For connection to the external computer with a USB port use the serial RS232 adapter – serial interface cable and a USB adapter.

3. Ensure that the main power switch in the back panel of the instrument is in the off position.
4. Insert the power cable into the main power socket in the back panel.
5. Switch the instrument on using the main power switch in the back panel and wait for 15 minutes.

The instrument is now ready to measure microplates.

3.7 Installation of Instrument Control Software



Note

For more information about installing the software, see the Magellan Instructions for Use.

3.8 Defining the Instrument Settings

This program enables the user to define the settings of:

- Instrument modes (no longer supported)
- Filter definition
- Measurement modes



CAUTION

IF USED IN THE IVD ENVIRONMENT, ONLY THE AUTHORIZED PERSON IS ALLOWED TO CHANGE AND DEFINE THE “SUNRISE INSTRUMENT SETTINGS”.

3.8.1 Installation of “SUNRISE Instrument Settings” Software

The “SUNRISE Instrument Settings” software is installed using the following procedure:

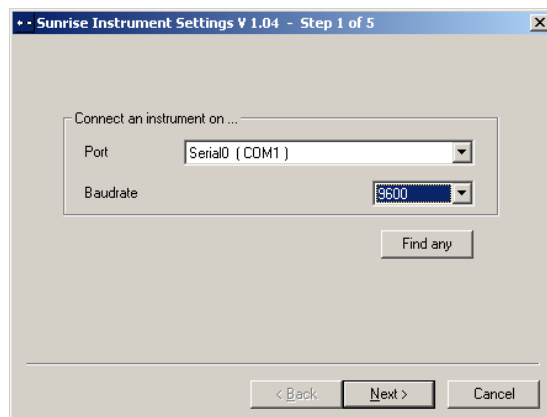
1. Insert Tecan Detection Suite CD into the required CD ROM drive.
2. The setup dialog box is displayed. Click the service and settings button. Click the setup button for the “SUNRISE Instrument Settings”. The installation program is started, which installs “SUNRISE Instrument Settings” onto your computer
3. A series of dialog boxes will appear, read each one, enter any necessary information and click **Next** to continue.
4. The files are then installed, and the program icon is created.
5. When the **Installation Complete** dialog box appears, click **Finish** and the “SUNRISE Instrument Settings” program is ready to be used.

3.8.2 Starting the “SUNRISE Instrument Settings”

In case an instrument is already connected to one of Tecan's programs, close the program or disconnect the instrument.

The “SUNRISE Instrument Settings” software is started by clicking the “SUNRISE Instrument Settings” icon on the desktop if present or go to **Start – Programs – Tecan** – and select “SUNRISE Instrument Settings”.

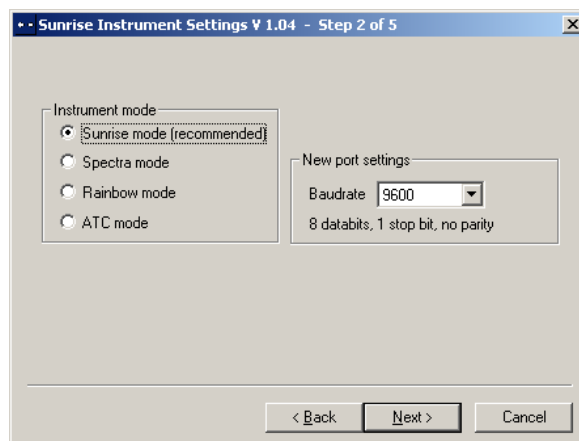
The following dialog box appears:



In the “SUNRISE Instrument Settings” dialog box, select the communication port and the baud rate. Click **Next**.

3.8.3 Define Instrument Mode

The following dialog box appears:



To use an instrument with software designed for previously manufactured Tecan readers, select the appropriate instrument mode and baud rate. Click **Next**.

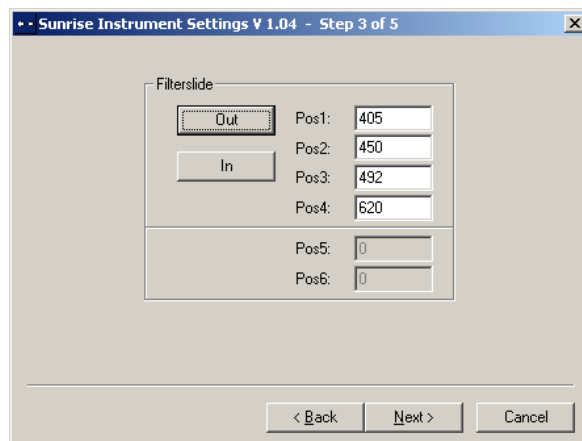
SUNRISE mode	It is recommended to use the SUNRISE mode with 9600 baud
Spectra mode	No longer supported
Rainbow mode	No longer supported
ATC mode	No longer supported

3. Installation Procedure

3.8.4 Define Filter

Before inserting the filter make sure that the slots are free of dust and dirt.

The following dialog box appears:



Click the Filter-slide **Out** button to move the filter out of the instrument.

To insert a Filter-slide, open the filter compartment manually and slot the filter in so that the filter end of the slide is inserted first. (Do not force the Filter-slide into the instrument beyond the point of resistance).

Click the Filter-slide **In** button and the filter is inserted.

Pos 1 - 6 shows the filter values for the currently loaded absorbance filters.



Note

The instrument is able to recognize predefined filter slides and you must not attempt to change the filter values. However, if the filters in the Filter-slide have been changed (by a service engineer) or if a new undefined customized Filter-slide is to be used, the filter slides need to be defined.

To define the filter values for a new Filter-slide, enter the required wavelengths in the text boxes. Click **Next**.

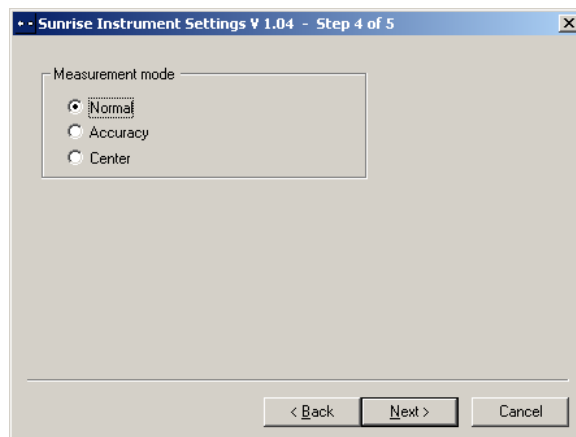


Note

The wavelength range for the SUNRISE is 340 - 750 nm.

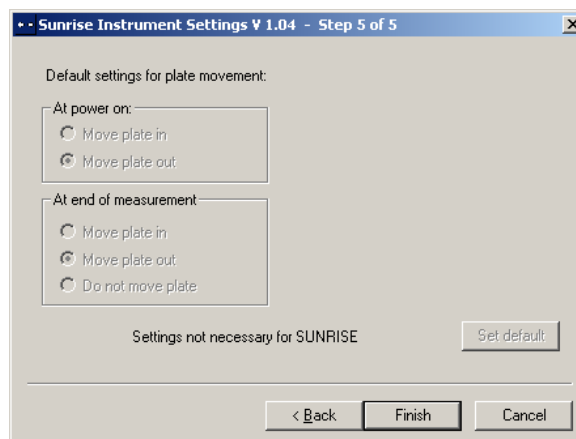
3.8.5 Define Measurement Mode

The following dialog box appears:



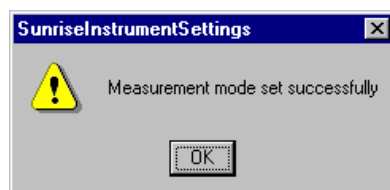
Select the appropriate measurement mode.

Click **Next** and the following dialog box appears:



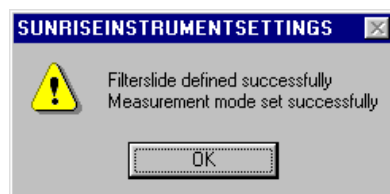
These settings are not available for the SUNRISE Microplate Absorbance Reader.

Click **Finish** and the following dialog box appears:



The measurement mode has now been set successfully.

If the filter values for the new Filter-slide have been defined, then the following dialog box appears at the end of the program.



4. Error Messages and Trouble Shooting

4.1 Introduction

The internal microprocessor controls and checks all electronic functions as well as measurements, operations and results. If the microprocessor detects a fault or an incorrect operating procedure, an error message is displayed on the computer.

4.1.1 Table of Error Messages and Trouble Shooting for SUNRISE Mode

The following table gives a brief description of the error messages and the trouble shooting actions.



Note

If other error messages appear that are not mentioned in the table below, contact your local service engineer.

Error Message	Description	Trouble Shooting
System Error		
Out of memory in module...	Internal firmware error	Switch instrument off and then on again. Contact your local service engineer, if the error continues.
Not implemented	Internal firmware error	Switch instrument off and then on again. Contact your local service engineer, if the error continues.
Timer event not active	Internal firmware error	Switch instrument off and then on again. Contact your local service engineer, if the error continues.
Wrong Transport Positioning		
Transport lost steps due to invalid shaking section	Transport	Check that the microplate is inserted correctly, and nothing is blocking the transport system. Contact your local service engineer if the error continues.
Transport lost steps	Wrong detection of the positioning switches.	Check that the microplate is inserted correctly, and nothing is blocking the transport system. Contact your local service engineer if the error continues.
Transport inserted steps	Wrong detection of the positioning switches.	Check that the microplate is inserted correctly, and nothing is blocking the transport system. Contact your local service engineer if the error continues.

4. Error Messages and Trouble Shooting

Error Message	Description	Trouble Shooting
System Error		
Transport lost steps during calibration	Wrong detection of the positioning switches.	Check that the microplate is inserted correctly, and nothing is blocking the transport system. Contact your local service engineer if the error continues.
Wrong Transport Parameters		
Transport frequency too low	Software error	Wrong combination of selected measurement parameters.
Transport frequency too high	Software error	Wrong combination of selected measurement parameters.
Optical Problems		
Transport couldn't find full dark edge during calibration	Lamp or another optical defect	Check lamp and if the lamp is working and positioned correctly, contact your local service engineer.
Lamp low	The optical system is receiving not enough light	Check lamp and if the lamp is working and positioned correctly, contact your local service engineer.
Timeout waiting for lamp on	Lamp or another optical defect	Check lamp and if the lamp is working and positioned correctly, contact your local service engineer.
Timeout waiting for measurement finished	Lamp or another optical defect	Check lamp and if the lamp is working and positioned correctly, contact your local service engineer.
Filter Errors		
Already inserted	Filter already inserted	Check if the filter is properly inserted.
No filter carriage detected	The instrument does not detect the filter carriage	Insert filter. If a filter has been already inserted, check the filter carriage for dirt or damage. Contact your local service engineer if the error continues.
No measurement filter defined	The measurement filter is not defined	Define filter.
No reference filter defined	The reference filter is not defined	Define filter.
Illegal filter carriage position	Internal firmware or electrical error	Check the filter carriage for dirt or damage. Contact your local service engineer if the error continues.
Wavelength ... nm not available	The defined reference or measurement filter is not available on the inserted filter carriage	Change filter carriage or check filter values for incorrect input.
Filter carriage not defined, Type, Number...	Wrong, damaged or not defined filter carriage inserted	Check the filter carriage to see if it is correct or check the filter carriage for dirt and damage.
ADC Electronic Error		
Offset 340 not adjusted	Electronic error on ADC board or optical problem	Start Lamp Adjust program in the Setup program. Contact your local service engineer if the error continues.

Error Message	Description	Trouble Shooting
System Error		
Offset 400 not adjusted	Electronic error on ADC board or optical problem	Start Lamp Adjust program in the Setup program. Contact your local service engineer if the error continues.
No wavelength defined	Electronic error on ADC board or optical problem	Start Lamp Adjust program in the Setup program. Contact your local service engineer if the error continues.
Area 400 not adjusted	Electronic error on ADC board or optical problem	Start Lamp Adjust program in the Setup program. Contact your local service engineer, if the error continues.
Area 340 not adjusted	Electronic error on ADC board or optical problem	Start Lamp Adjust program in the Setup program. Contact your local service engineer if the error continues.
E2Pot Overflow	Electronic error on ADC board or optical problem	Start Lamp Adjust program in the Setup program. Contact your local service engineer if the error continues.

4.2 Definition of 'Overflow'

If the result of the absorbance measurement is outside the instrument specifications (e.g., >4.0 OD) an overflow may occur and the measured OD value of the current well will be replaced by 'OVER'. This is done by the controlling software and not by the instrument itself. Depending on the controlling software used, OD values outside of the instrument specifications might be shown or replaced by OVER. Please be aware that OD values which are outside the instrument specifications are not reliable.

5. Maintenance & Cleaning

5.1 Introduction

This chapter contains the following procedures:

- Replace the filter carriages
- Replace the main input fuses
- Clean the instrument
- Disinfect the instrument



WARNING
BEFORE DOING ANY MAINTENANCE REMOVE THE MICROPLATE.

5.2 Filter Replacement



CAUTION
WHEN HANDLING THE FILTERS, BE CAREFUL THAT THEY DO NOT BECOME SCRATCHED OR SOILED WITH FINGERPRINTS OR DUST.

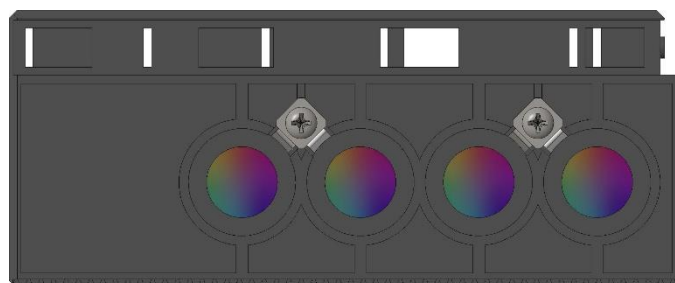
The direction of the arrow on the filter glass and the direction of the beam must be identical. Put in the filter glass accordingly. If you can read the print on the filter glass when the beam comes from the bottom, it is inserted correctly.

Use only framed or black filters and insert them flush to avoid scattered light.

5.2.1 Filter Carriages for 4Filter Option

The filters of the 4filter carriages can be replaced using the following procedure:

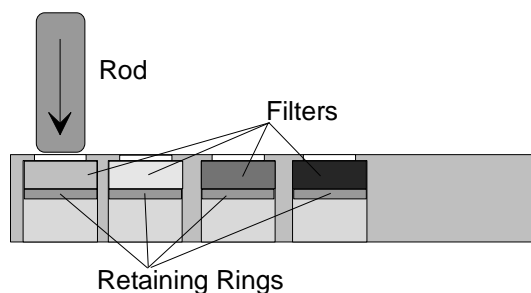
1. Remove the filter carriage from the instrument.
2. Place the filter carriage on a clean flat surface.



4 3 2 1 Filter positions

3. Using a wooden or rubber rod (ensure that the ends are rounded so that the corners do not scratch the filters) carefully push the filter and retaining ring out of the filter carriage.

5. Maintenance & Cleaning



4. Turn the filter carriage over and insert the new filter and the retaining ring.
5. Carefully push the filter and retaining ring into the filter carriage, using a wooden or rubber rod.

5.2.2 Gradient Filter Carriages for Tuneable Wavelength Option



Note

The instrument specifications can only be guaranteed if genuine Tecan parts are used.

Using the option tuneable wavelength selection, the instrument is fitted with a special gradient filter, which allows the selection of any wavelength of light between 400 and 700 nm. For measurements in the ranges of 340 - 399 nm and 700 - 750 nm the appropriate 4filter carriage, containing the required wavelength filters, must be inserted into the instrument.

The filter carriage can be exchanged for another carriage, which contains other filters; the instrument can store the data for up to eight filter carriages.

To change the filter carriage, please follow the procedure outlined in the appropriate software Instructions for Use.



Note

The SUNRISE specifications are different if the instrument is equipped with the 4filter option, 6filter option or tuneable wavelength option.

Validation of the system has to be performed with those filters, which finally are actually used during measurement.

Specifications for SUNRISE with 4Filter Option / 6Filter Option

PARAMETERS		CHARACTERISTICS
Accuracy:		
(492 nm)	0.000 - 2.000 OD	< (1.0 % + 0.010 OD) *
(492 nm)	2.000 - 3.000 OD	< (1.5 % + 0.010 OD) *
Precision:		
(492 nm)	0.000 - 2.000 OD	< (0.5 % + 0.005 OD) *
(492 nm)	2.000 - 3.000 OD	< (1.0 % + 0.005 OD) *
Linearity:		
(400-750 nm)	0.000 - 2.000 OD	< 1 %
(400-750 nm)	2.000 - 3.000 OD	< 1.5 %
(400 - 750 nm)	0.000 - 2.000 OD	R ² >= 0.999
(400 - 750 nm)	2.000 - 3.000 OD	R ² >= 0.999

Specifications for SUNRISE with Gradient Filter of Tuneable Wavelength Option

PARAMETERS	CHARACTERISTICS
Accuracy: (492 nm) 0.000 - 2.000 OD	< (1.5 % + 0.010 OD) *
Precision: (492 nm) 0.000 - 2.500 OD	< (1.0 % + 0.005 OD) *
Linearity: (492 nm) 0.000 - 2.500 OD	< 2 %, $R^2 \geq 0.999$

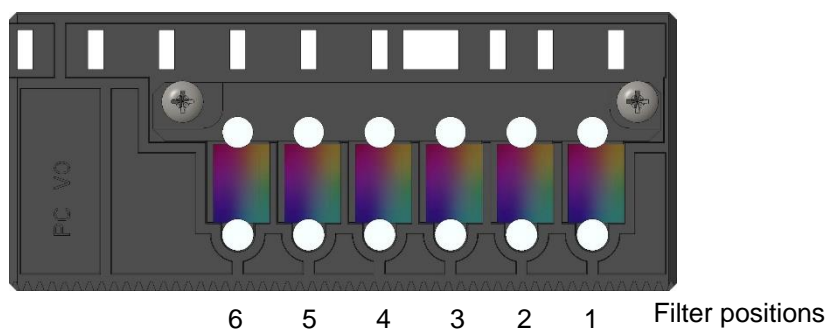
* better than x % of measurement value plus corresponding OD value

Note: All deviations from the measurement value are meant in positive and negative direction.

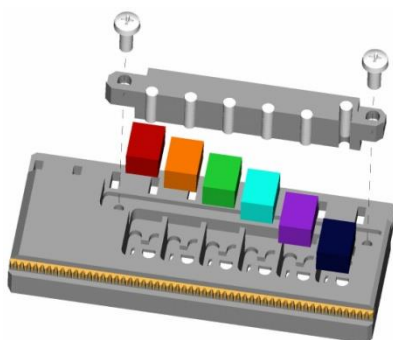
5.2.3 6Filter Carriages for 6Filter Option

The filters of the 6Filter carriages can be replaced using the following procedure:

1. Remove the filter carriage from the instrument.
2. Place the filter carriage on a clean flat surface, so that the Phillips head screws are visible.



3. Remove the two screws and then remove the retaining bar that holds the retaining pins.
4. Remove the filters. Be careful not to scratch the filters or soil them with fingerprints or dust.



5. Insert the new filters and replace the retaining bar. Replace and tighten the screws while pressing the retaining bar to the filters.

5.3 Fuse Replacement

The following steps must be performed to replace the fuse, which is located above the power cable connection, in the rear panel of the instrument.



WARNING

TO PREVENT THE RISK OF FIRE, THE MAIN FUSES SHOULD ONLY BE REPLACED WITH THE SAME TYPE AND RATING OF FUSES.

1. Switch off the instrument and unplug the power cord.
2. Open the plastic cover of the fuse compartment by inserting a screwdriver into the slot in the top of the cover and pushing the cover out.
3. The fuse holders are located above the on/off switch.



Fuse holders

4. Pull the fuse holder(s) out and replace the defective fuse(s) with the spare fuse(s).

Ensure that the fuse(s) has/have the correct rating.

F 2.0 A / 250 V (Fast Blow)

5. Replace the fuse holder(s), ensure that the arrow points in the correct direction and close plastic cover of the fuse compartment.
6. Reconnect the power cord and switch the instrument on



WARNING

IF THE FUSE CONTINUES TO BLOW, PLEASE CALL FOR SERVICE.

5.4 Cleaning the Instrument

**WARNING**

PRIOR TO CLEANING DISCONNECT THE INSTRUMENT FROM THE MAIN POWER SUPPLY TO AVOID ANY RISK OF FIRE AND EXPLOSION.

**WARNING**

THE CLEANING PROCEDURE SHOULD BE PERFORMED IN A WELL-VENTILATED ROOM BY AUTHORIZED TRAINED PERSONNEL WEARING DISPOSABLE GLOVES AND PROTECTIVE GLASSES AND CLOTHING.

5.4.1 Cleaning the Device

Clean the outside of the device and the plate transport only with a dry or moist cloth. If very dirty, clean it with a cloth moistened with a maximum of 70% ethanol or mild detergent. Wipe dry with a lint-free cloth.

5.4.2 Liquid Spills

If any liquid is spilled on the instrument, it should be immediately removed to prevent liquid running into the optical system causing loss of performance or the error message **Lamp Low** due to one or more of the diode lenses not being clean. Contact your local service representative in order to clean and check the instrument.

**WARNING**

IF LIQUID SPILLED ON THE PLATE SUPPORT IS POTENTIALLY INFECTIOUS IT SHOULD BE DISINFECTED ACCORDING TO THE RELEVANT NATIONAL LAWS AND REGULATIONS.

**Note**

For disinfection solutions and procedure see chapter 5.6 Instrument Disinfection..

5.5 Preventive Maintenance Plan for SUNRISE

This preventive maintenance plan is for standard throughput instruments. For instruments that are used in high throughput, the maintenance intervals might be shorter.

5.5.1 *Daily*

- No daily maintenance is required.

5.5.2 *Weekly*

- Clean the cover and the plate transport with a mild detergent.



CAUTION
NEVER USE ACETONE AS IT WILL DAMAGE THE COVERS.

5.5.3 *Every Six Months*

- Clean the filters using an optical cleaning solution (lens tissue recommended)

5.5.4 *Yearly (Customer or Service Technician)*

- Either done by customer:
- Perform the QC Pac 2 Test (see QC Pac Instructions for Use)
- Or done by service technician:
- Perform extended operational quality check

5.5.5 *Every Four Years (Service Technician Required)*

- Replace the lamp and the filters
- Perform extended operational quality check

5.6 Instrument Disinfection

All parts of the instrument that came into contact with biological samples, patient samples, positive control samples or hazardous material must be treated as potentially infectious areas.



WARNING

THE DISINFECTION PROCEDURE AND THE DISINFECTANTS SHOULD CONFORM TO THE RELEVANT NATIONAL LAWS AND REGULATIONS.



WARNING

IT IS VERY IMPORTANT THAT THE INSTRUMENT IS THOROUGHLY DISINFECTED BEFORE IT IS REMOVED FROM THE LABORATORY OR BEFORE ANY SERVICE IS PERFORMED ON IT.

Before the instrument is returned to the distributor or to a service center, all outer surfaces and the plate transport must be disinfected, and a disinfection declaration must be completed by the operating authority. If a disinfection declaration is not supplied, the instrument may not be accepted by the distributor or service center, or custom authorities may hold it.

5.6.1 Disinfection Solutions

The outer surfaces and the plate transport of the instrument should be disinfected using a surface disinfection solution such as:

- Microcide SQ® (Global Biotechnologies Inc, Portland, Maine)
- Terralin® protect (Schülke & Mayr GmbH, Norderstedt)



WARNING

PRIOR TO DISINFECTION DISCONNECT THE INSTRUMENT FROM THE MAIN POWER SUPPLY TO AVOID ANY RISK OF FIRE AND EXPLOSION.

5.6.2 Disinfection Procedure

If the laboratory has no specific disinfection procedure, the following procedure should be used to disinfect the outer surfaces and the plate transport of the instrument.



WARNING

THE DISINFECTION PROCEDURE SHOULD BE PERFORMED IN A WELL-VENTILATED ROOM BY AUTHORIZED TRAINED PERSONNEL WEARING DISPOSABLE GLOVES AND PROTECTIVE GLASSES AND CLOTHING.

5. Maintenance & Cleaning



CAUTION
THE SURFACE DISINFECTANT CAN NEGATIVELY INFLUENCE THE PERFORMANCE OF YOUR INSTRUMENT, IF IT IS APPLIED OR ACCIDENTALLY GETS INSIDE THE INSTRUMENT.



CAUTION
MAKE SURE THAT THE MICROPLATE HAS BEEN REMOVED FROM THE INSTRUMENT BEFORE STARTING DISINFECTION.

Observe the following issues during disinfection:

1. Wear protective gloves, protective glasses and protective clothing.
2. Prepare a suitable container for all disposables used during the disinfection procedure.
3. Move the plate transport into the load position.
4. If applicable, remove the microplate from the plate transport.
5. Disconnect the instrument from the main power supply and let it cool down to ambient temperature to avoid any risk of fire and explosion.
6. Disconnect the instrument from the computer.
7. Carefully apply the disinfectant solution according to the manufacturer's instructions for use on the plate transport of the instrument.
8. After the required contact time (according to the manufacturer's instructions for use) wipe the plate transport using a soft paper towel moistened with a mild detergent or distilled water to remove all traces of the disinfectant.
9. Move the plate transport into the instrument by gently pressing the front end of the plate transport until the plate transport door is completely closed.
10. Carefully apply the disinfectant solution according to the manufacturer's instructions for use on all outer surfaces of the instrument.
11. After the required contact time (according to the manufacturer's instructions for use) wipe the instrument using a soft paper towel moistened with a mild detergent or distilled water to remove all traces of the disinfectant.
12. Wipe dry the outer surface of the instrument with a soft paper towel.
13. Disinfect your hands and clean them with a mild detergent.
14. Pack the instrument.
15. Dispose of the container with the disposables according to the relevant national laws and regulations.
16. Complete the disinfection declaration and attach it to the outside of the box so that it is clearly visible.



CAUTION
THE PLATE TRANSPORT SHOULD ONLY BE MOVED MANUALLY IF THE INSTRUMENT IS DISCONNECTED FROM THE MAIN POWER SUPPLY.

See below for the disinfection declaration, which must be completed before the instrument is returned to the distributor/ service center.

5.7 Disinfection Declaration

The following Disinfection Declaration **MUST** be completed by the operating authority and attached on top of the package in which the instrument is returned, before sending it to the distributor or service center.

– Disinfection Declaration –

I declare that the outer surfaces and the plate transport of the instrument in this package have been disinfected to remove or inactivate any biological material, patient samples, positive control samples or hazardous material, which could be dangerous to any personnel, or that it has never been exposed to any hazardous biological material.

Contact person:

Company/ institution:

Function:

Phone/ Fax:

E-mail:.....

Date of disinfection:

Date, name:

Signature:

5.8 Disposal of Instrument

5.8.1 Introduction

Follow laboratory procedures for bio-hazardous waste disposal, according to national and local regulations.

This chapter gives instructions on how to lawfully dispose of waste material accumulating in connection with the SUNRISE.



CAUTION

OBSERVE ALL FEDERAL, STATE AND LOCAL ENVIRONMENTAL REGULATIONS.



ATTENTION

NEGATIVE ENVIRONMENTAL IMPACTS ASSOCIATED WITH THE TREATMENT OF WEEE

- **DO NOT TREAT ELECTRICAL AND ELECTRONIC EQUIPMENT AS UNSORTED MUNICIPAL WASTE.**
- **WASTE OF ELECTRICAL AND ELECTRONIC EQUIPMENT MUST BE COLLECTED SEPARATELY.**

5.8.2 Disposal of Packing Material

According to Directive 94/62/EC on packaging and packaging waste, the manufacturer is responsible for the disposal of packing material.

Returning Packing Material

If you do not intend to keep the packing material for future use, e.g. for transport and storage purposes:

Return the packaging of the product, spare parts and options via the field service engineer to the manufacturer.

5.8.3 Disposal of Operating Material



WARNING

BIOLOGICAL HAZARDS CAN BE ASSOCIATED WITH THE WASTE MATERIAL (MICROPLATE) OF THE PROCESS RUN ON THE SUNRISE MICROPLATE ABSORBANCE READER.

TREAT THE USED MICROPLATE, OTHER DISPOSABLES, AND ALL SUBSTANCES USED, IN ACCORDANCE WITH GOOD LABORATORY PRACTICE GUIDELINES.

INQUIRE ABOUT APPROPRIATE COLLECTING POINTS AND APPROVED METHODS OF DISPOSAL IN YOUR COUNTRY, STATE OR REGION.

5.8.4 Disposal of the Instrument

Please contact your local Tecan service representative before disposing of the instrument.



CAUTION

ALWAYS DISINFECT THE INSTRUMENT BEFORE DISPOSAL.

Pollution degree

2 (IEC/EN 61010-1)

Method of disposal

Contaminated waste



WARNING

DEPENDING ON THE APPLICATIONS, PARTS OF THE SUNRISE MAY HAVE BEEN IN CONTACT WITH BIOHAZARDOUS MATERIAL.

- **MAKE SURE TO TREAT THIS MATERIAL ACCORDING TO THE APPLICABLE SAFETY STANDARDS AND REGULATIONS.**
- **ALWAYS DECONTAMINATE ALL PARTS BEFORE DISPOSAL.**

6. Quality Control

6.1 Introduction



CAUTION

IF AT ANY TIME THE ANALYTICAL PERFORMANCE OF THE SUNRISE IS QUESTIONED THE USER SHOULD FOLLOW THE INSTRUCTIONS GIVEN FOR QUALITY CONTROL OR CONTACT THE LOCAL SERVICE CENTER.



CAUTION

BEFORE STARTING MEASUREMENTS, MAKE SURE THAT THE MICROPLATE POSITION A1 IS INSERTED CORRECTLY.

This chapter gives the instructions on how to obtain the best performance and accuracy from this instrument.

Also included are instructions on how to easily check the operational quality of the instrument.

6.2 Optimizing for Maximum Performance

The instrument has been fully factory tested to ensure that its performance is within the specified limits.

Experience has shown that operating technique and laboratory conditions cause the greatest amount of inaccuracy.

The greatest accuracy can be obtained from the instrument by observing the recommendations below:

6.2.1 *Instrument Location*

The instrument should be placed on a level, flat surface that is free from dust, solvents and acidic vapors.

The instrument must be protected from vibrations and direct light, particularly sunlight.

When performing the measurements, always close the plate support cover to ensure that the results are not affected by any external light.

6.2.2 *Operating Procedure*

General

1. The best repeatability is obtained, when the measurement wavelength corresponds to the maximum absorbance wavelength of the particular solution.

It is important to use the maximum absorbance wavelength, if the absorbance curve of the sample is over a narrow wavelength band.

6. Quality Control

2. After each microplate has been measured, please refer to the test kit package for information regarding the validation procedure.
3. When very accurate results are required, ensure the **Accurate** measurement mode is used.

Microplates

1. The instrument can be used with those types of microplates which are described in the specifications in chapter 2.3.6 Microplates. The best results are obtained when clear flat-bottom microplates are used.

Depending on the type of microplate being used, the measurement result may vary.

Take care especially when using round bottom plates or the strip frames because it is possible that the measurement results might differ slightly to what is described in the specifications.

Make sure that the type of microplate used with the SUNRISE Microplate Absorbance Reader is suitable for the respective application.

2. Use only perfectly clean microplates.
3. Do not allow dust to settle onto the solutions or the microplate, if the microplate is left to stand for a time before the measurement.

It is recommended to use a cover for protection.

4. Inaccuracies in the amount of solution pipetted has a greater effect on the results obtained, when small amounts of solutions are used.

It is recommended that a minimum of 200 µl is used in each well.

5. The form of the meniscus of the solution can cause inaccuracies in the results, particularly if small amounts of solution are used (see 6.3.3 High Meniscus Liquids).



CAUTION

MAKE SURE THE SUITABILITY OF THE MICROPLATE USED IN COMBINATION WITH THE AMOUNT OF SOLUTION, MENISCUS PROPERTIES AND THE MEASUREMENT MODE IS APPROPRIATE FOR THE CURRENT APPLICATION.

6.2.3 Self-Check Procedure

Before each microplate is measured, the self-check calibration procedure is performed to ensure that the instrument is working correctly and to calibrate the optical system.

When the self-check procedure starts, a digital value for each measurement channel is taken without the lamp and with the lamp on, using each of the selected measurement filters.

A calibration curve for each measurement channel is calculated.

6.3 Operational Qualification (OQ)

The following test can be performed to ensure that the instrument is working correctly, and accurate results are being obtained.

The repeatability and accuracy of the instrument may vary with the type of solution and microplate used.

To eliminate this effect, the instruments are tested in the factory with a calibration plate, which removes the influence of the solution and any variation due to the positioning of the microplate when it is being measured.

6.3.1 QC PAC 2

QC PAC 2 provides an automated check of reader performance including accuracy, linearity, precision, and alignment with NIST traceable standards. It also detects damaged or mislabeled filters. For more information, see QC PAC 2 Instructions for Use.



CAUTION

USE ONLY "QC PAC 2 FOR SUNRISE INSTRUMENTS". THE FORMER VERSION OF THE QC PAC 2 (FOR SPECTRA INSTRUMENTS) IS NOT COMPATIBLE WITH THE INSTRUMENT.

6.3.2 Microplate Test

If the optical densities of the wells in the microplate are not consistent, the results obtained with this type of microplate will be influenced.

This inconsistency can be checked by reading an empty microplate.

The OD values obtained from the measurement of the empty microplate should be in a narrow range. For example: ± 0.010 OD.

If the OD values are not within this range this type of microplate should not be used.

By using dual wavelength measurements, the influence of the difference in OD values of the microplate is removed or reduced to a level that is within acceptable limits.

6. Quality Control

Acceptable Microplate

	1	2	3	4	5	6	7	8	9	10	11	12	
	-----	-----	-----	-----	-----	-----	-----	-----	-----	-----	-----	-----	
A	0.042	0.039	0.045	0.041	0.039	0.037	0.043	0.043	0.040	0.039	0.043	0.041	A
	-----	-----	-----	-----	-----	-----	-----	-----	-----	-----	-----	-----	
B	0.042	0.042	0.040	0.040	0.042	0.040	0.045	0.043	0.039	0.038	0.043	0.039	B
	-----	-----	-----	-----	-----	-----	-----	-----	-----	-----	-----	-----	
C	0.043	0.040	0.040	0.043	0.041	0.041	0.042	0.042	0.041	0.046	0.043	0.039	C
	-----	-----	-----	-----	-----	-----	-----	-----	-----	-----	-----	-----	
D	0.043	0.043	0.047	0.038	0.039	0.040	0.040	0.041	0.042	0.039	0.039	0.049	D
	-----	-----	-----	-----	-----	-----	-----	-----	-----	-----	-----	-----	
E	0.041	0.044	0.046	0.043	0.039	0.040	0.040	0.042	0.043	0.041	0.045	0.044	E
	-----	-----	-----	-----	-----	-----	-----	-----	-----	-----	-----	-----	
F	0.046	0.042	0.041	0.043	0.042	0.052	0.043	0.047	0.045	0.044	0.041	0.040	F
	-----	-----	-----	-----	-----	-----	-----	-----	-----	-----	-----	-----	
G	0.041	0.043	0.041	0.040	0.042	0.042	0.041	0.040	0.043	0.043	0.041	0.041	G
	-----	-----	-----	-----	-----	-----	-----	-----	-----	-----	-----	-----	
H	0.042	0.040	0.040	0.044	0.045	0.039	0.041	0.046	0.045	0.044	0.040	0.045	H
	-----	-----	-----	-----	-----	-----	-----	-----	-----	-----	-----	-----	
	1	2	3	4	5	6	7	8	9	10	11	12	

Unacceptable Microplate

	1	2	3	4	5	6	7	8	9	10	11	12	
	-----	-----	-----	-----	-----	-----	-----	-----	-----	-----	-----	-----	
A	0.104	0.105	0.110	0.134	0.136	0.168	0.147	0.140	0.163	0.154	0.167	0.188	A
	-----	-----	-----	-----	-----	-----	-----	-----	-----	-----	-----	-----	
B	0.119	0.107	0.110	0.151	0.133	0.168	0.153	0.138	0.165	0.167	0.167	0.178	B
	-----	-----	-----	-----	-----	-----	-----	-----	-----	-----	-----	-----	
C	0.111	0.117	0.121	0.141	0.146	0.136	0.156	0.150	0.158	0.173	0.170	0.182	C
	-----	-----	-----	-----	-----	-----	-----	-----	-----	-----	-----	-----	
D	0.112	0.101	0.113	0.153	0.146	0.127	0.139	0.143	0.152	0.165	0.163	0.170	D
	-----	-----	-----	-----	-----	-----	-----	-----	-----	-----	-----	-----	
E	0.105	0.109	0.114	0.135	0.120	0.131	0.142	0.138	0.143	0.161	0.163	0.163	E
	-----	-----	-----	-----	-----	-----	-----	-----	-----	-----	-----	-----	
F	0.096	0.106	0.110	0.138	0.132	0.128	0.128	0.149	0.158	0.155	0.161	0.172	F
	-----	-----	-----	-----	-----	-----	-----	-----	-----	-----	-----	-----	
G	0.097	0.110	0.112	0.125	0.133	0.125	0.120	0.132	0.145	0.155	0.168	0.156	G
	-----	-----	-----	-----	-----	-----	-----	-----	-----	-----	-----	-----	
H	0.095	0.090	0.096	0.144	0.129	0.124	0.129	0.139	0.131	0.150	0.151	0.161	H
	-----	-----	-----	-----	-----	-----	-----	-----	-----	-----	-----	-----	
	1	2	3	4	5	6	7	8	9	10	11	12	

6.3.3 High Meniscus Liquids

When measuring liquids that produce a high meniscus, the measured optical density can be incorrect as the instrument normally measures the optical density at three positions in the well and uses this average measured optical density as the optical density for the well.

Normal Mode

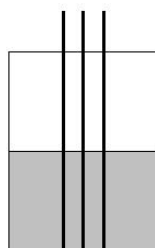
3 positions, 8 measurements per position.

Positions are 0.4375 mm apart.

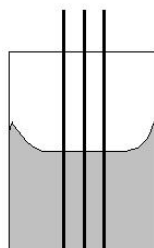
Accuracy Mode

3 positions, 55 measurements per position.

Positions are 0.4375 mm apart.



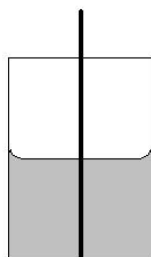
Normal meniscus



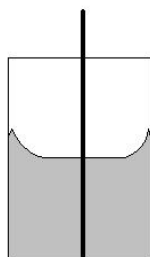
High meniscus

Center Mode

1 position, 22 measurements.



Normal meniscus



High meniscus

6. Quality Control

Agglutination Method

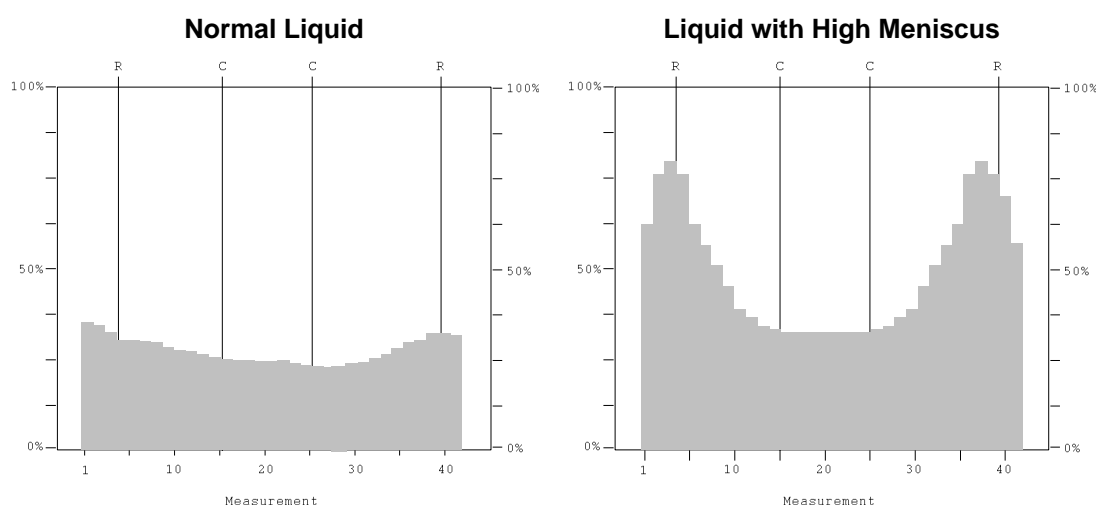
For agglutination measurements, an external software package must be used which is not provided by Tecan. The SUNRISE Microplate Absorbance Reader is able to read up to 40 measurement points per well.



Note

Instruments with option tuneable wavelength selection must not be used for agglutination measurements.

After the microplate has been measured, select a well and zoom it so that it is printed in large scale.



If the printout has less than sixteen measurement points in the middle of the well, which are at the same level, use the center measurement.

Manual Method

If the instrument is not able to perform agglutination measurements, measure the microplate five times.

Then rotate the microplate by 180 ° and then measure the microplate five times.

For a number of wells, calculate the average optical density value from all the measurements for these wells.

Compare the average value against the highest and lowest measured values.

Example

Measured Values

0.945, 0.956, 0.937, 0.926, 0.971, 0.936, 0.961, 0.939, 0.942, 0.938 OD

Average = 0.945 OD, highest value = 0.971 OD, lowest value = 0.926 OD

Tolerances for instruments with 4filter option:

$0.945 \pm (0.5 \% + 0.005 \text{ OD}) = 0.945 \pm 0.010 \text{ OD}$

Highest value within tolerance = 0.955 OD

Lowest value within tolerance = 0.935 OD

Make sure that the values are within the allowed tolerances. If not, use the center measurement mode.

Repeat the procedure using the center measurement, to ensure that the measured values are now within the required tolerances.

6.3.4 Instrument Precision with Liquid Samples

This procedure can be used to check the precision of the measurements from one microplate to another.

Fill a new microplate with a freshly prepared Methyl Orange in 0.1 % Tween 20 solution, use different dilutions of the solution in each well so that a range of optical densities is obtained. Make sure that the wells contain at least 200 µl.

Define a test run using the 492 nm filter and then measure the microplate at least three times.

For each well calculate the following:

- the average OD value
- the highest and lowest values
- the difference between the average, highest and lowest values

Example for a SUNRISE equipped with 4filter option

Readings 0.000 to 2.000 OD

The difference between the average and the highest and lowest values for the same well should be within +/- (1.0 % + 0.010 OD)

e.g., 1.000 +/- 0.020 OD

Readings 2.001 to 3.000 OD

The difference between the average and the highest and lowest values for the same well should be within +/- (1.5 % + 0.010 OD)

e.g., 2.400 +/- 0.046 OD

Readings above 3.000 OD

Readings above 3.000 OD are only used as an indication and the precision cannot be guaranteed.

6. Quality Control

6.3.5 Instrument Linearity with Liquid Samples

The linearity for the instrument and application at the wavelength used can be checked by using a dilution series of a solution.

The result depends on the purity of the dye used and the meniscus of the liquid in the wells.

As a reference, dilution series of Methyl Orange in 0.1 % Tween 20 solution for measurements at 492 nm can be used.

The dilution series should be within the range of 0.1 to 3.0 OD for a 4filter or 6filter instrument and within the range of 0.1 to 2.5 OD for a tuneable wavelength instrument.

For other wavelengths, different solutions must be used.

250 µl of each dilution are then pipetted into the microplate, a minimum of at least two samples should be used for each dilution to reduce the errors caused by pipetting.

Make sure that the instrument is using the accuracy measurement mode.

The microplate is then measured and a linear regression of OD against concentration is drawn from the average of the measured OD values.

Determine the unweighted residual square value R^2 of the regression line.

Typical residual square values for a standard application are equal or better than $R^2 = 0.998$.



Note

Data can vary due to pipetting inaccuracy, meniscus of the liquid and the application used.



Note

The limits of the instrument's linearity will be measured with the QC plate.

Example for a tuneable wavelength instrument

Readings 0.100 to 2.500 OD

Dilution Factor	Absorbance
1	2.621 OD
0.5	1.323 OD
0.25	0.679 OD
0.125	0.360 OD
0.0625	0.192 OD
0.03125	0.110 OD
0	0.025 OD

Equation for linear regression:

$$y = 2,5911x + 0,0298$$

Residual squared value: $R^2 = 1$

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Declaration of Conformity

We, TECAN Austria GmbH herewith declare under our sole responsibility that the product identified as:

Product Type: Microplate Absorbance Reader

Model Designation: *SUNRISE*

Article Number(s): 30087502, 30087504, 30087505, 30087506

Address: Tecan Austria GmbH
Untersbergstr. 1A
A-5082 Grödig, Austria

is in conformity with the provisions of the following European Directive(s) when installed in accordance with the installation instructions contained in the product documentation:

- EMC Directive
- Machinery Directive
- RoHS Directive

is in conformity with the relevant U.K. legislation for UKCA-marking when installed in accordance with the installation instructions contained in the product documentation:

- Electromagnetic Compatibility (EMC) Regulations
- Supply of Machinery (Safety) Regulations
- The Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations

The current applicable versions of the directives and regulations as well as the list of applied standards which were taken in consideration can be found in separate CE & UK declarations of conformity.

These *Instructions for Use* and the included *Declaration of Conformity* are valid for all SUNRISE instruments with the article numbers listed above. The model designation varies depending on the specific model with different article number.