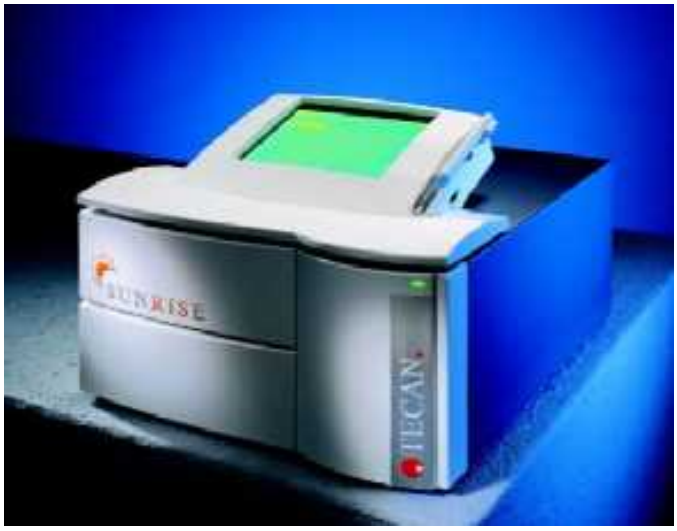
TECAN

Instructions For Use for

SUNRISE Absorbance Reader



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CE

Tecan Affiliates and Service Centers

Austria
Tecan Austria GmbH
Untersbergstrasse 1a
A-5082 Grödig / Salzburg
Austria
Tel.: +43 62 46 89 33
Fax: +43 62 46 72 770

Austria
Tecan Sales International GmbH
Untersbergstrasse 1a
A-5082 Grödig / Salzburg
Austria
Tel.: +43 62 46 89 33
Fax: +43 62 46 72 770

Asia
Tecan Asia (Pte) Ltd.
80, Marine Parade #13-04
Singapore 449269
Singapore
Tel.: +65 44 41 886
Fax: +65 44 41 836

Belgium
Tecan Benelux B.V.B.A.
Vaartdijk 55
B-2800 Mechelen
Belgium
Tel.: +32 15 42 13 19
Fax. +32 15 42 16 12

France
Tecan France S.A.
Parc d'Activités de Pissaloup
Batiment Hermes II
Rue Edouard Branly
F-78190 Trappes
France
Tel.: +33 1 30 68 81 50
Fax: +33 1 30 68 98 13

Germany
Tecan Deutschland GmbH
Theodor-Strom-Straße 17
D-74564 Crailsheim
Germany
Tel.: +49 79 51 94 170
Fax: +49 79 51 50 38

Italy
Tecan Italia S.r.l.
Via F.lli Cervi
Palazzo Bernini
Centro Direzionale Milano2
20090 Segrate (Mi)
Italy
Tel.: +39 02 215 21 28
Fax: +39 02 215 97 441

Japan
Tecan Japan Co. Ltd
Meiji Seimei Fuchu Building 10F
1-40 Miyamachi
Fuchu City, Tokyo
Japan
Tel.: +81 42 334 88 55
Fax: +81 42 334 04 01

Netherlands
Tecan Benelux B.V.B.A.
Industrieweg 30,
NL-4283 Giessen,
Netherlands
Tel.: +31 018 34 48 17 4
Fax: +31 018 34 48 06 7

Spain
Tecan Spain
Sabino de Arana, 32
E-08028 Barcelona
Spain
Tel.: +34 93 490 01 74
Fax: +34 94 411 24 07

Sweden
Tecan Nordic AB
Box 208, SE-431 23
Mölndal
Sweden
Tel: +46 31 75 44 000
Fax: +46 31 75 44 010

Switzerland
Tecan Sales Switzerland AG
Seestrasse 103
CH-8708 Männedorf
Switzerland
Tel: +41 922 8 922
Fax: +41 922 8 923

United Kingdom
Tecan UK
Theale Court
11-13 High Street
Theale
UK-Reading RG7 5AH
United Kingdom
Tel.: +44 11 89 300 300
Fax: +44 11 89 305 671

USA
Tecan US
P.O. Box 13953
Research Triangle Park,
NC 27709
USA
Tel.: +1 919 361 5200
Fax: +1 919 361 5201

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.
We would appreciate any comments on this publication.

Manufacturer

Tecan Austria GmbH
Untersbergstraße 1A
A-5082 Grödig/Salzburg
AUSTRIA / EUROPE
Telephone: 0043 (0)6246/8933
FAX: 0043 (0) 6246/72770
E-mail: office.austria@tecan.com

Copyright Information

Declaration for EU Certificate

See the back of this publication.

SUNRISE Absorbance Reader Intended Use

See chapter 2.2.1 Sunrise Intended Use.

About the Instructions For Use

This publication is intended as ***Instructions For Use*** for the SUNRISE 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
- Clean and maintain the instrument

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 Absorbance Reader as a standard. Warranty invalid if instrument is opened or modified.

Warnings, Cautions and Notes

There are various types of notices used in this publication. These notices highlight important information or warn the user of a potentially dangerous situation. The notices used in this publication appear below:

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 FOLDED.

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

WARNING
INDICATES LASER. DO NOT STARE INTO THE BEAM!

Symbols

	Manufactured by
	Date of manufacture
	Communauté Européenne
	In vitro diagnostic medical device
	Laser
	Biohazardous

Abbreviations

Abbreviation	
A	Ampere
Abs	Absorbance
C	Celsius
CE	Communauté Européenne
cm	Centimeter
F	Fahrenheit
Hz	Hertz
IVD	In vitro diagnostics
IVD-D	In vitro diagnostics Directive
kg	Kilogram
l; L	Liter
MB	Megabyte
µL	Microliter
mL	Milliliter
nm	Nanometer
REF	Reference Number/ Order Number
SN	Serial Number
TYPE	Name and type of instrument
V	Volts
VA	Volt ampere
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 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.
3. Observe all WARNINGS and CAUTION statements in this publication.
4. Never open SUNRISE while the instrument is plugged into a power source.
5. Observe proper laboratory safety precautions, such as wearing protective clothing and using approved laboratory safety procedures.

WARNING

IF THE SUNRISE ABSORBANCE READER 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:
SUNRISE Absorbance Reader is intended for use with only external software.

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 for in vitro diagnostics.

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 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:

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

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

I_o = emitted light

I = detected light

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 fitted into Tecan robotic systems.

The SUNRISE Absorbance Reader is an optical 96-well microplate reader for the measurement of absorbance and turbidimetry of samples from the biological or non-biological origin according to the specifications described in this document, intended for professional use only.

The SUNRISE Absorbance Reader is available with options Touchscreen, tuneable wavelength, temperature control and barcode scanner.

The Tecan Sunrise Absorbance Reader when used with the appropriate Magellan software is declared suitable for in-vitro diagnosis (IVD) purposes (Directive 98/79/EC of the European Community).

Magellan is a reader control and data reduction software package, also 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 compliance with the IVD Directive. A range of policies and standard operating procedures according to local regulations must also be established.

Make sure that the instrument and the software are suitable for use with the reagents, chemicals and microplates used (see 7.2 Optimizing for Maximum Performance and 7.3 Performance Tests).

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 Magellan or XFluor4 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 Sunrise Intended Use

The Sunrise Absorbance Reader is an optical 96-well microplate reader for the measurement of absorbance including turbidimetry (optical density) of samples from biological or non-biological origin according to the specifications described in this manual intended for professional use in:

- *in-vitro* diagnostic environments with tests like:
  - Enzyme Immuno Assays (EIA), e.g. for diagnostic of infectious diseases, autoimmune diagnostic, allergy screening,
  - Agglutination Assays, e.g. for blood typing assays,
  - Enzyme Assays, e.g. haemostaseology assays and
  - Enzyme Linked Probe Hybridization Assays (ELPHA), e.g. HLA-typing assays,

  which have been validated according to the IVD directive or other relevant regulations or
- *pharmaceutical*, biotechnological and life science industry, for research use, for food analysis and veterinary applications.

The *Sunrise Absorbance Reader* has been validated for use with representative applications from the above list. The validation shows the general ability of the *Sunrise Absorbance Reader* to use the above mentioned methods.

Note
If the* Sunrise Absorbance Reader *or Magellan software are modified in any way the instrument loses its guarantee and will no longer be IVD compliant.

Note:
The operating authority must use only CE-labeled test kits for clinical diagnostic applications. The operating authority must assure that the combination of a particular CE-labeled test kit used with the CE-labeled Sunrise Absorbance Reader as been validated according to the IVD directive or to other relevant national or local regulations.

If the *Sunrise Absorbance Reader* is used with any other software other than Magellan, additional validation must be carried out by the operating authority to ensure the safety of the results. The operating authority is fully responsible for any results obtained using software other than Magellan with the *Sunrise Absorbance Reader*.

2.2.2 Sunrise Variations

All variations of the Sunrise Absorbance Reader and its Options are compliant with the IVD directive and part of the CE declaration of conformity.

Sunrise Hardware Variations

The following table shows the compatibility of the filter slides with each Sunrise hardware variation:

Sunrise Variations	4 Filter Slide	6 Filter Slide	Gradient Filter Slide
Standard	X		
6 Filter	X	X	
Tuneable Wavelength	X		X

Sunrise Options

The Sunrise options work with all hardware variations and accessories and can be used in any combination:

Sunrise Options
Temperature Control
Touch screen
Barcode

Sunrise Accessories

The Sunrise accessories work with all hardware variations and options and can be used in any combination:

Sunrise Accessories	IVD Compliant		Research Use Only	None/ Unrelated[3]
	Included in CE[1]	Separate CE[2]		
4 Filter Slide	X			
6 Filter Slide	X			
Gradient Filter	X			
Sunrise Instrument Settings				X
XFluor 4			X	
Magellan		X		
Magellan TS		X		
QC Pac 1				X
QC Pac 2				X

[1] IVD compliant. Included in the CE declaration for the instrument.

[2] IVD compliant. CE declaration is separate from that of the instrument.

[3] Can be used in an IVD environment. CE declaration does not exist or it is unrelated to IVD compliance.

2.2.3 Available Options for SUNRISE

The SUNRISE is a modular system, so you can create your own tailor-made instrument that meets exactly your needs. Options such as a Touchscreen combined with a WindowsCE based on-board software, free wavelength selection, temperature control and a bar code scanner can be added onto the basic system which is dedicated to remote controlled computer operation.

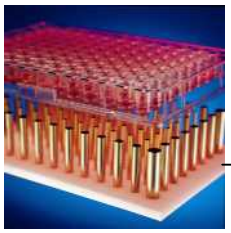
Factory Installed Options

Touchscreen

B037302

Tuneable wavelength from 400 – 700 nm

B037306

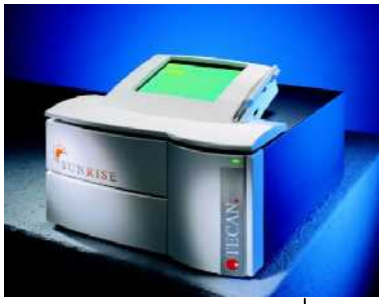


Temperature Control

B037303

6 Filter
B03641002

SUNRISE Absorbance Reader



Upgrade in Field Possible

Barcode scanner

B037304

Barcode Upgrade Kit

S 039 386

2.3 Specifications

The tables below lists the specifications for the instruments.

2.3.1 General

For all instrument options:

PARAMETERS	CHARACTERISTICS
Mains Power Input	100 - 120 & 220 - 240 V ± 10% 50/60 Hz (Auto sensing)
Consumption	Stand by mode: approx. 50 VA Operational mode: max. 110 VA
Fuse Rating	2 x F 2.0 A / 250 V (Fast Blow)
Outside Dimensions	Width: 33,5 cm Depth: 32,0 cm Height: 17,0 cm
Weight	6 kg
Ambient Temperature:	
Operation	15°C to 35°C (59°F to 95°F)
Storage	-40°C to 60°C (-40°F to 140°F)
Relative Humidity:	
Operation	20 % to 90 %
Storage	5 % to 95 %
Overvoltage 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 Abs

2.3.2 SUNRISE Standard Instrument (Standard Filter)

PARAMETERS	CHARACTERISTICS
Measurement time:	
dual wavelength	8 seconds
single wavelength	6 seconds
Wavelength Range	
Standard	340 - 750 nm
Filter Wavelength Accuracy	Central wavelength +/- 2 nm
Filter Bandwidth	
At 50% transmission:	10 +/- 2nm
Measurement Range:	
340 – 399 nm	0 - 3.000 Abs
400 – 750 nm	0 - 4.000 Abs
Resolution:	0.001 Abs.
Accuracy:	
(492 nm) 0.000 - 2.000 Abs	Better than +/- 1.0 % +/- 0.010 Abs.
(492 nm) 2.000 - 3.000 Abs	Better than +/- 1.5 % +/- 0.010 Abs.
Precision:	
(492 nm) 0.000 - 2.000 Abs.	Better than +/- 0.5 % +/- 0.005 Abs
(492 nm) 2.000 - 3.000 Abs.	Better than +/- 1.0 % +/- 0.005 Abs
Linearity:	
(340 - 399 nm) 0.000 - 2.000 Abs.	Better than +/- 2 %
(400 - 750 nm) 0.000 - 2.000 Abs.	Better than +/- 1 %
2.000 - 3.000 Abs.	Better than +/- 1.5 %
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.
Light source:	Halogen lamp 20 W
All connected devices must be approved and listed as per EN 60950, UL 1950 or CSA C22.2 No. 950 for Data Processing Devices.	
Computer interface:	
Serial RS 232 C	300 - 38,400 baud
Printer	Only functions with the Touchscreen option.

2.3.3 SUNRISE Touchscreen Instrument

PARAMETERS	CHARACTERISTICS
Screen Size	240 x 320 pixel
Operating System	WindowsCE
Operating Software:	MagellanCE
Storage	8 / 32 MB (SUNRISE Memo Card)
Computer interface:	
Serial RS 232 C	300 - 38,400 baud
Printer	Only functions with the Touchscreen option.
Serial RS 232 C to the Touchscreen	Only for the XChange program.
MagellanCE software	See Magellan Manual

2.3.4 SUNRISE Tuneable Wavelength (Gradient Filter)

PARAMETERS	CHARACTERISTICS
Measurement time:	
dual wavelength	8 seconds
single wavelength	6 seconds
Wavelength Range	
Gradient filter	400 - 700 nm
Standard filter	340 - 399 nm & 700 - 750 nm
Measurement Range:	
400 – 750 nm	0 - 4.000 Abs.
340 – 399 nm	0 - 3.000 Abs
Resolution:	0.001 Abs.
Accuracy:	
(492 nm) 0.000 - 2.000 Abs	Better than +/- 1.5 % +/- 0.010 Abs.
Precision:	
(492 nm) 0.000 - 2.500 Abs	Better than +/- 1.0 % +/- 0.005 Abs
Linearity:	
(492 nm) 0.000 - 2.500 Abs.	Better than +/- 2 %
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
Filter Wavelength Accuracy	Central wavelength +/- 2 nm
Filter Bandwidth	
At 50% transmission:	
450 nm	10 – 16 nm
550 nm	10 – 14 nm
650 nm	10 – 18 nm

2.3.5 SUNRISE 6 Filter

See 2.3.2 SUNRISE Standard Instrument (Standard Filter)

2.3.6 Temperature Control

Peltier-based temperature control.

PARAMETERS	CHARACTERISTICS
Temperature Range:	Room temperature up to 42°C increments of 0.1°C
Accuracy	+/- 0.2°C
Preheating Time	20 min.

2.3.7 Barcode Laser Scanner

WARNING

LASER RADIATION – DO NOT STARE INTO THE BEAM!
CLASS II / 2 LASER PRODUCT.

The Class II / 2 Laser Scanner corresponds to the following norms:

- DIN EN 60825-1 : 2001
- CDRH 21 CFR 1040.10

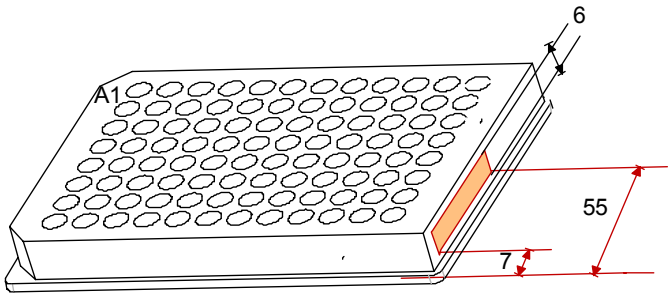
PARAMETERS	CHARACTERISTICS
Classification	Class II / 2 Laser Product
Input Power	5V DC +/- 10%
Emission Duration	> 0.25s
Scan Rate	42 +/- 3 Scans / second (bi-directional)
Laser Power	< 1mW
Definition of depth	Max. 40cm
Resolution	0.15cm
Min. Print Contrast	25% at 675nm
Ambient Light	Sun Light: 40000 Lux
	Halogen Light: 1500 Lux

2.3.8 Microplates

Only 96-well format microplates (v-shaped, flat and round including strip-wells) can be used with the Sunrise Absorbance Reader.

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

The barcode sticker has to be positioned on the right hand side of the plate, 7 mm from the front-right edge. The barcode may be up to 48 mm long.

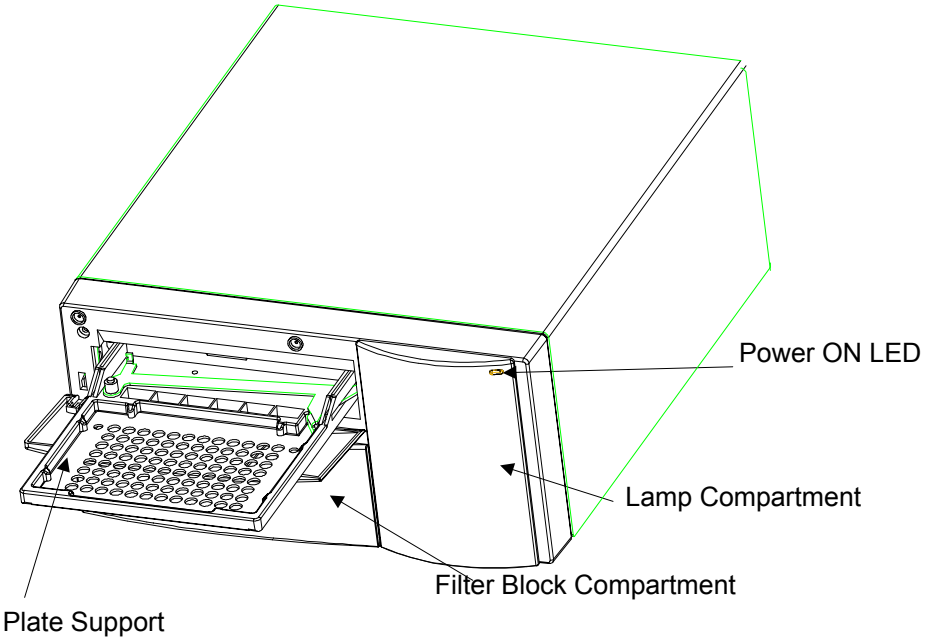


The SUNRISE barcode reader supports the following barcode types:

- CODE 39
- Interleaved 2 of 5
- UPC A, UPC E0, UPC E1
- EAN8, EAN 13
- Codabar
- CODE 128

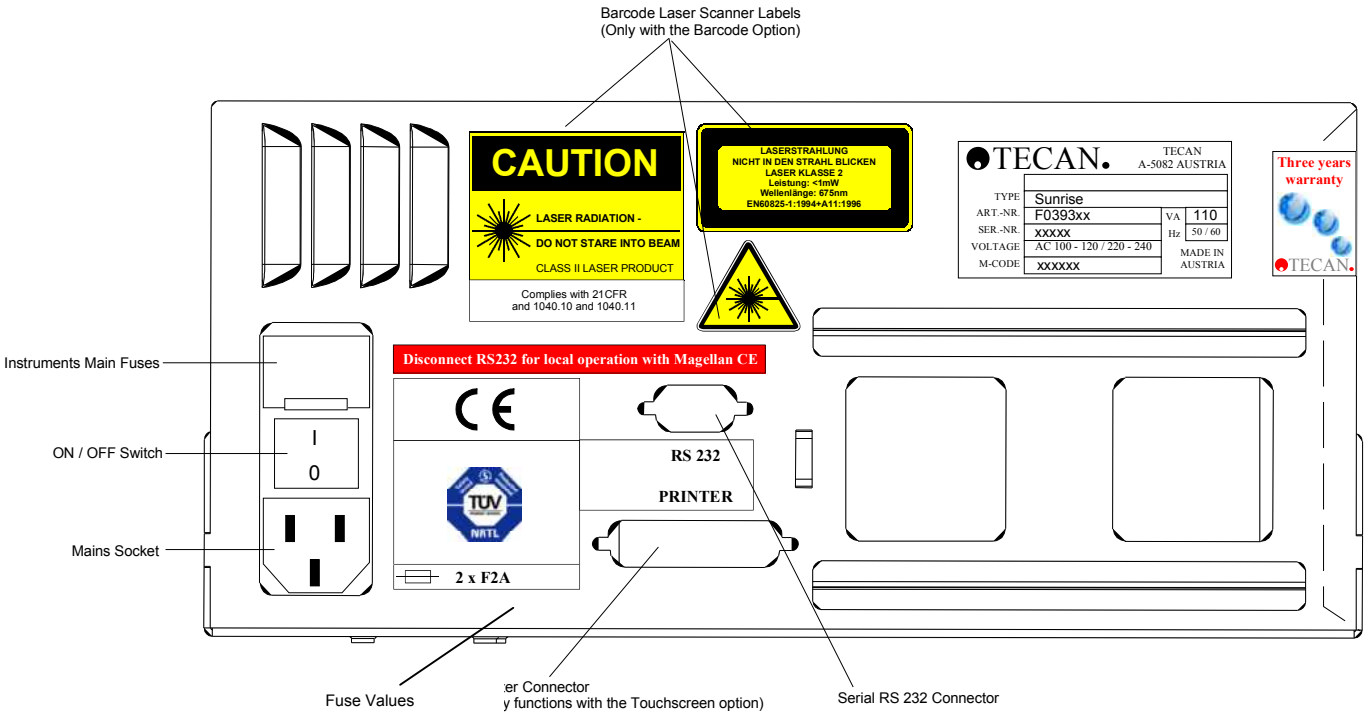
2.4 Instrument Description

The illustration below shows the components of the instruments.



2.4.1 Back Panel Connections

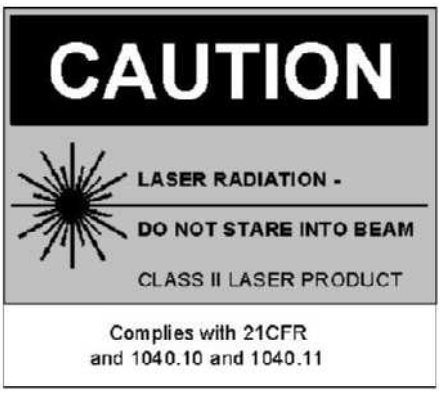
The illustration below shows the connections located in the back panel of the instrument.



All connected devices must be approved and listed as per EN 60950, UL 1950 or CSA C22.2 No. 950 for Data Processing Devices

Barcode Laser Scanner Labels

Label reproductions on the instrument housing and interior:



Note:
If any labels become damaged or removed, contact you local Tecan representative for replacement labels.

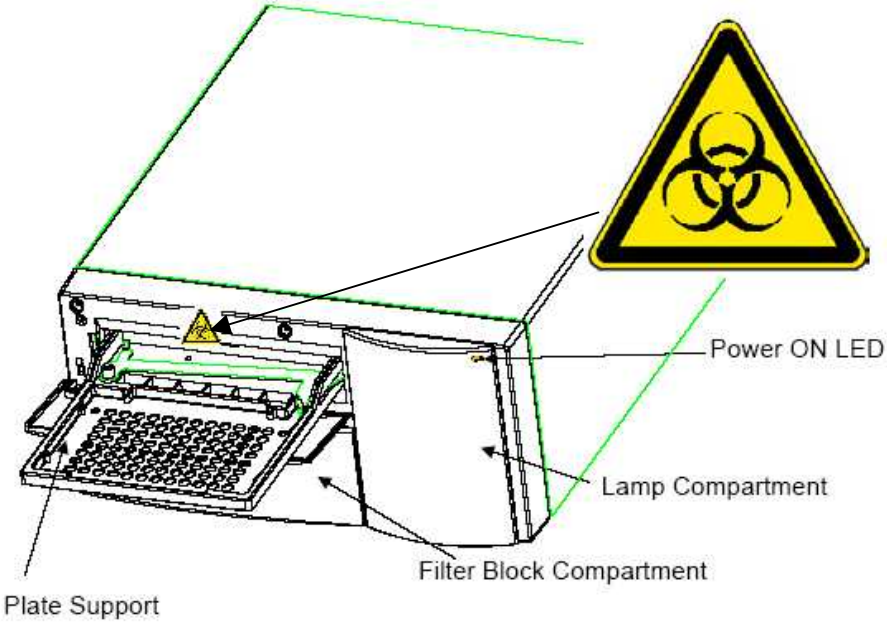
2.4.2 Handling the Microplate

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, *MagellanCE*, etc.)

WARNING

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



2.5 Filter Carriage Description

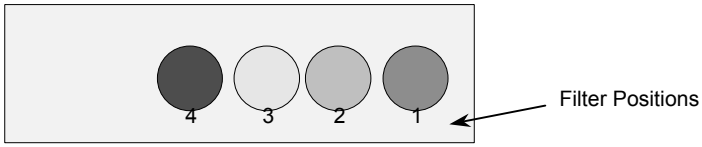
The SUNRISE instrument can use the following types of filter carriages:

SUNRISE Standard and SUNRISE Gradient Filter (with tuneable wavelength option).

2.5.1 SUNRISE Standard Filter Carriage

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

SUNRISE Standard Filter 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.

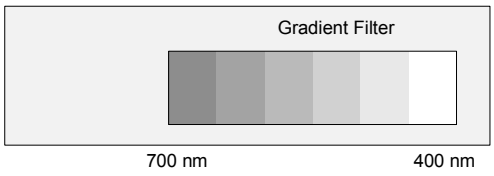
Note:
For more information about the definition of the new and customized filter slides, see 3.8 Defining the SUNRISE Instrument Settings.

2.5.2 SUNRISE Gradient Filter Carriage

SUNRISE Gradient filters cannot be used with a standard instrument.

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.

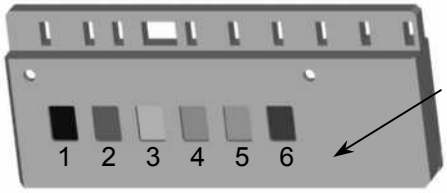
Note:
When another Gradient filter is inserted into the instrument, the instrument must be re-calibrated. This re-calibration procedure can only be performed by the manufacturer or by a service engineer.

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.

Gradient filters cannot be used with the Standard SUNRISE Absorbance Reader.

2.5.3 SUNRISE 6 Filter Carriage

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



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 SUNRISE 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, all the measurement positions are used.

Note:
For more information about setting the measurement mode, see 3.8 Defining the SUNRISE 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 Instrument Accessories

The table below contains the order numbers for instrument accessories:

Part Name	Part Order Number
Halogen lamp	3 709 008
Reader to external computer cable	3 350 005
QC Pac 1 for SUNRISE	B 037 371
QC Pac 2 for SUNRISE	B 037 372
Additional filter slide (Standard 4-Filter)	B 036 301
Memory card	B 037 359 01
Flash card for Magellan Windows CE (English)	S 039 351
TS - Pen	B 037 360
Barcode Upgrade Kit	S 039 386

2.8 Software for the SUNRISE Absorbance Reader

Part of the Software CD:

Software	Functionality
Magellan	Instrument control and data reduction software. (IVD version available, which has been declared suitable for in-vitro diagnosis (IVD) purposes (Directive 98/79/EC of the European Community).
XFluor4	Instrument control and transfer of raw data to Excel. (Not suitable for in-vitro diagnosis (IVD) purposes)
SUNRISE Instrument Settings	Enables settings of SUNRISE instrument (SUNRISE, SPECTRA, ATC mode, etc.).
Rdr Download	Enables download of new firmware from PC to reader.
SunDiag	For error diagnosis, a print out of the instrument status for service purposes can be produced.

Note:
SUNRISE Absorbance Reader is intended for use with only external software.

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

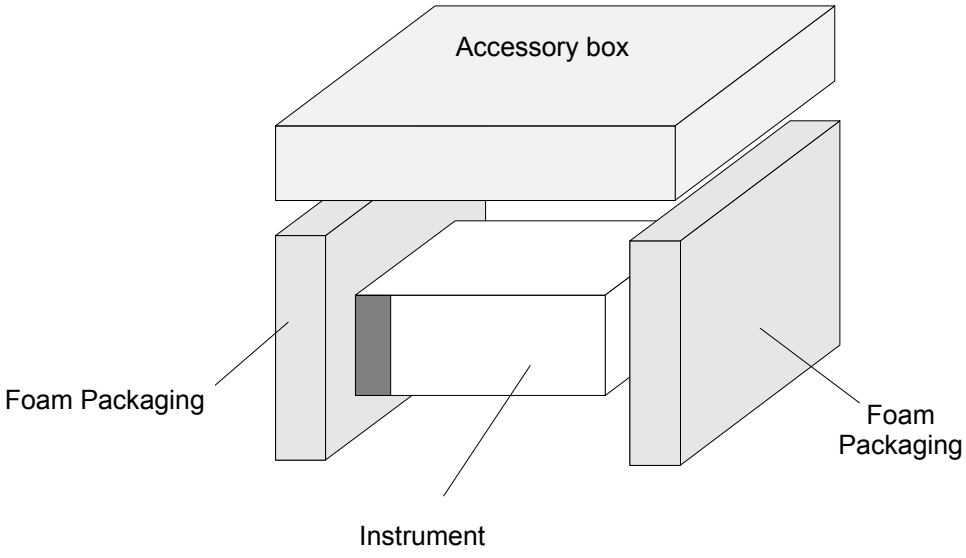
This chapter contains the necessary information for installing the instrument.

The installation procedures involve 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 Absorbance Reader, XFluor4 Instructions for Use
- Spare fuses
- A software CD, which also contains the XFluor4 program and Magellan demo program (30 day working license).



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 accessories 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 MAINS FUSES SHOULD ONLY BE REPLACED WITH THE SAME TYPE AND RATING OF FUSES.

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	-40°C to 60°C (-40°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 interfacing cable.
   The interfacing cable is connected into the 9 pin serial interface socket, in the back panel.
3. Ensure that the mains power switch in the back panel of the instrument is in the off position.
4. Insert the power cable into the mains power socket in the back panel.
5. Switch the instrument on using the mains 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 Magellan or XFluor4 Instructions for Use, which can be found on the Software CD.

3.8 Defining the SUNRISE Instrument Settings

This program enables the user to define the settings of:

- Instrument modes
- 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:

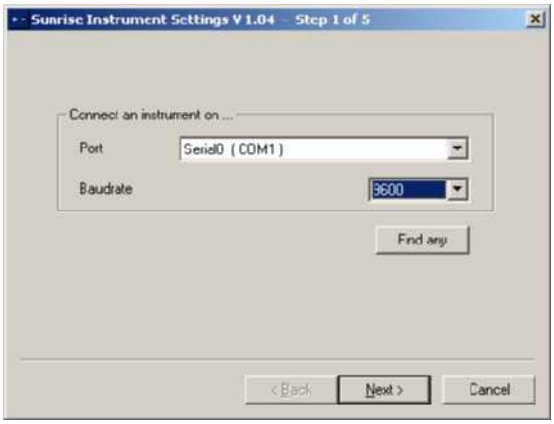
1. Insert Tecan Detection Suite CD into the required CD ROM drive.
2. The Setup dialog box is displayed. Click the Service and Settings button. Click the Setup button for the SUNRISE Instrument Settings. The installation program is started, which installs SUNRISE Instrument Settings onto your computer
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**.

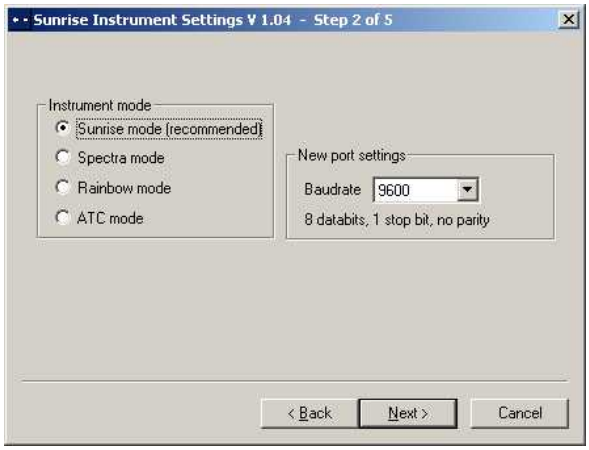
The following dialog box appears:



In the SUNRISE Instrument Settings dialog box, select the communication port and the baudrate. Click **Next**.

3.8.3 Define Instrument Mode

The following dialog box appears:

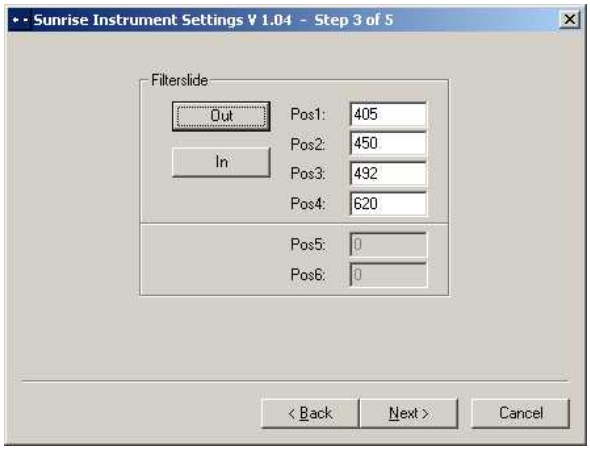


To use an instrument with software designed for previously manufactured Tecan readers, select the appropriate instrument mode and baudrate. Click **Next**.

SUNRISE mode	It is recommended to use the SUNRISE mode with 9600 baud.
Spectra mode	Simulates a SPECTRA Reader.
Rainbow mode	Simulates a Rainbow Reader
ATC mode	Simulates an ATC Reader.

3.8.4 Define Filter

The following dialog box appears:



Click the Filterslide **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 Filterslide **In** button and the filter is inserted.

Pos1 - 4 shows the filter values for the currently loaded absorbance filters.

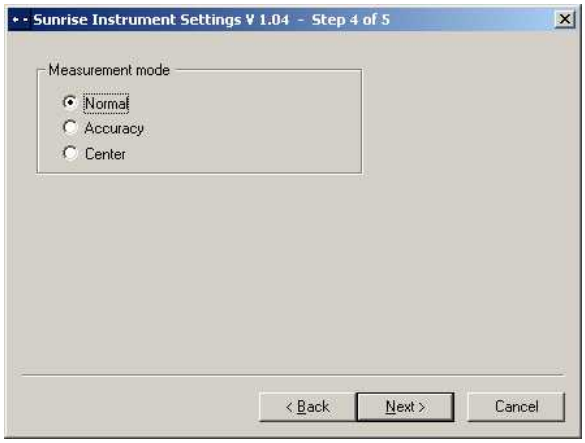
Note:
The instrument is able to recognize predefined filter slides and you must not attempt to change the filter values. However, if the filters in the filter slide have been changed (by a service engineer) or if a new undefined customized filter slide is to be used, the filter slides need to be defined.

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.

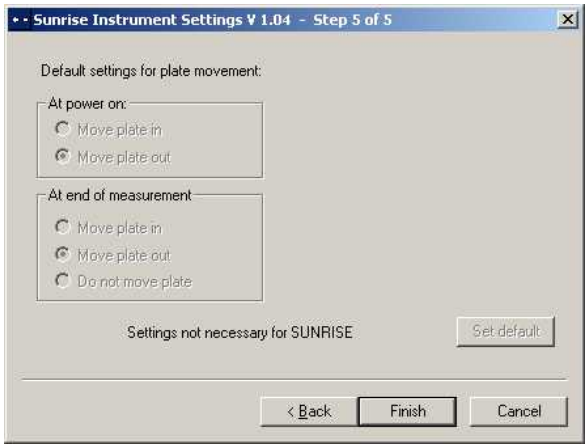
3.8.5 Define Measurement Mode

The following dialog box appears:



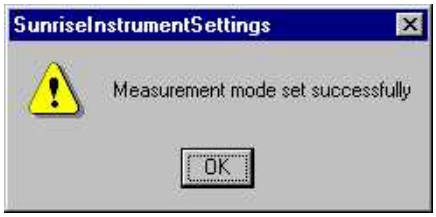
Select the appropriate measurement mode.

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



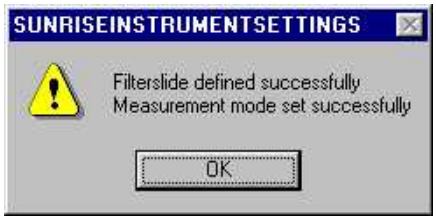
These settings are not available to the SUNRISE Absorbance Reader.

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 has been defined, then the following dialog box appears at the end of the program.



4. SUNRISE Touchscreen

4.1 Introduction

The SUNRISE Touchscreen option consists of:

- A screen that includes a touch panel
- A Touchscreen pen
- Operating software MagellanCE
- SUNRISE Memo card

The Touchscreen option enables the user to control the reader and evaluates obtained data, using the onboard software. The WindowsCE™ based software, MagellanCE, offers the user the possibility for full instrument control, data reduction and storage. It also supports numerous applications as ELISA's or Kinetic studies. Enhanced curve fitting and screening tools, as well as the possibility to combine several assays on one plate, makes it an ideal tool for various laboratory purposes. The Touchscreen offers a clear and easy overview of all available data.

The MagellanCE provides the user with Wizards for all operating procedures and guides the user through the software program via step-by-step commands.

Disclaimer:
Magellan has been carefully devised and checked. With the exception of negligence or intention, Tecan takes no liability for any damages that occur as a result of the software.

Caution
If the instructions given in this manual are not correctly performed, the instrument may be damaged or the procedure may not be correctly performed and the safety of the instrument cannot be guaranteed.

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.

Caution
Before starting measurements, make sure that the microplate position A1 is inserted correctly.

™ *Windows is registered trademark of the Microsoft Corporation.*

4.2 Area of Application for the Touchscreen Option

See 2.2 Area of Application.

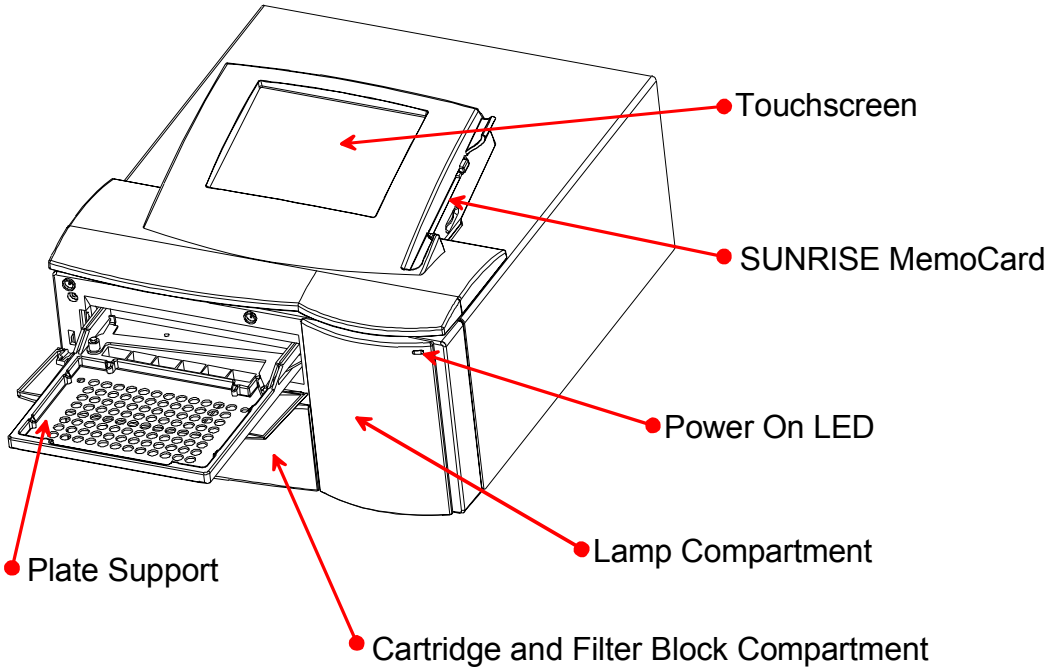
4.3 Specifications

The table below lists the specifications for the Touchscreen.

PARAMETERS	CHARACTERISTICS
Size	240 x 320 pixel
Operating System	WindowsCE
Operating Software:	MagellanCE
Storage	8 / 32 MB (SUNRISE Memo Card)

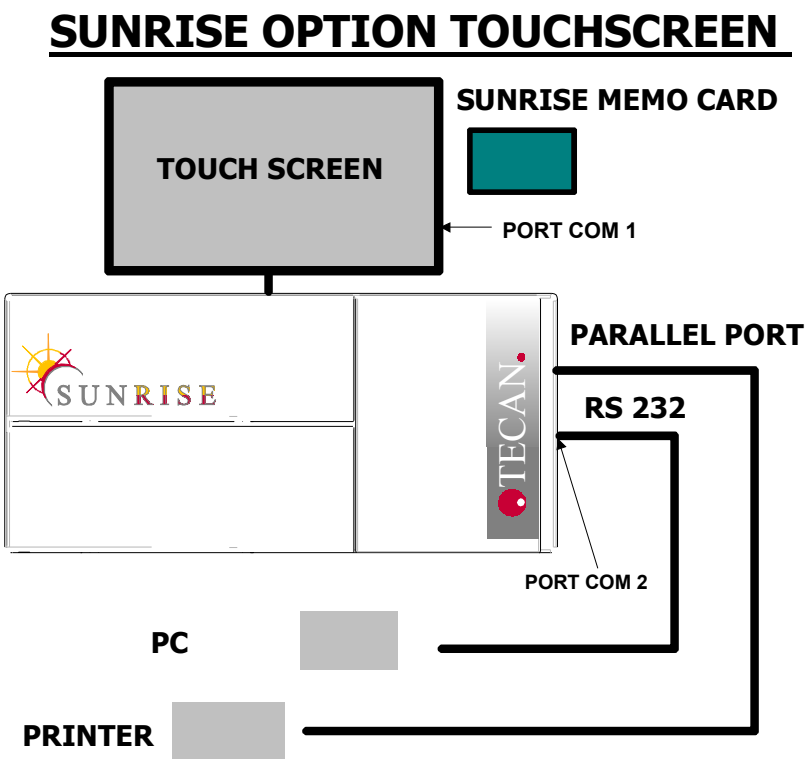
4.4 Instrument Description

The illustration below shows the components of the instrument.



4.4.1 Data Handling

The illustration below shows the concept of data handling of the instrument.



The standard memory module for onboard operation is the SUNRISE memo card. The SUNRISE memo card offers a capacity of 8 / 32 MB to save results and defined methods. According to the size, between 300 / 1200 and 400 / 1600 files can be stored permanently on the card. Additional cards can be ordered for memory extension. Data can also be transferred to a PC either by transferring the card to a PC and downloading the files or by using the data exchange module of Magellan software (use of this module requires no license.)

This module enables the user to exchange data between the reader and a connected PC via the RS232 port (COM1).

Additionally, the SUNRISE can be connected to the personal computer (PC) and by-pass the onboard software (Port COM 2).

4.4.2 Printer Compatibility

The SUNRISE Touchscreen supports the following industry standard printer languages:

1. Hewlett-Packard PCL3 Compatible devices
2. Epson ESC/P2 Compatible devices

Not only Hewlett-Packard printers support PCL3, but also the majority of the laser printers. Please contact your printer provider or look up the printer specifications on the Internet homepage of the printer manufacturer for further information.

Please note:
Printer languages up to PCL5E are compatible with PCL3. PCL6 is not longer compatible with PCL3.
For further information see the Hewlett-Packard homepage.

For example, the SUNRISE Touchscreen supports the following printers:

Hewlett-Packard Deskjet	300, 400, 500, 600, 660, 672, 680, 690, 870, 880 895, 340C, 350C, 640C, 840C, 930C, 950C, 970 CXI, 990 CXI
Hewlett-Packard Laserjet	4L, 4P, 4M, 4MP, 4si, 5L, 5P, 5M, 5MP, 5si, 6L, 6P, 6MP, 4000
Epson Stylus Color	400, 600, 740, 750, 800, & 900 series
Epson Stylus	Photo & Photo 700
Canon Bubblejet	30, 50, 70, 80, 250, 1000, 2000, 4300, 4400

4.5 Operating the Touchscreen

4.5.1 Introduction

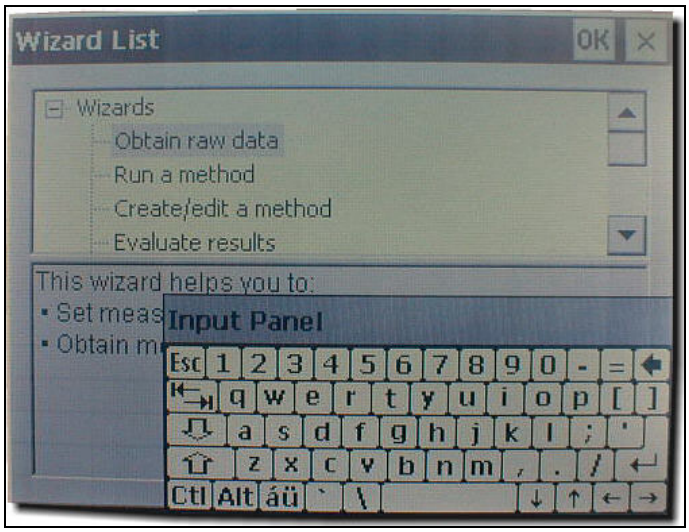
The Touchscreen can be operated either by simply touching the touch panel with the finger or using the Touchscreen pen, which is included in the package.

Note:
Some of the functions on the touch panel are rather small, so it is recommended to use the Touchscreen pen.

Caution
Before starting measurements, make sure that the microplate position A1 is inserted correctly.

4.5.2 Starting the Software

- Make sure that the SUNRISE Memo card is inserted in the Touchscreen.
- Switch the instrument on.
- The Wizard and a keyboard are displayed on the touch panel. The keyboard is always displayed. When it is not required, it can be shifted to the side of the panel with the Touchscreen pen or with a finger.
- The Wizard structure guides the user through every step. The starter screen is displayed:



4.5.3 Special Features of MagellanCE

Input Panel

Some *Input Panel* keys have special functions:

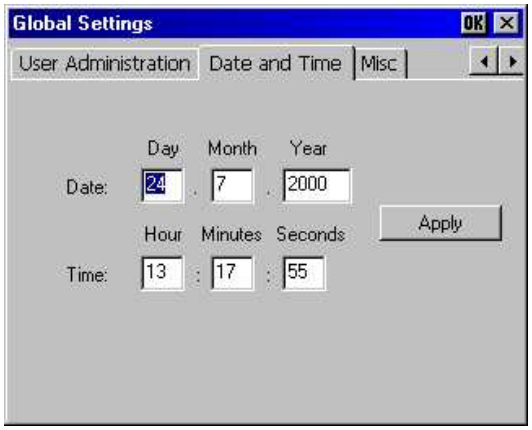
 Caps lock key selected	Click to view the capital character keys. All letters will be capitalized.
 Caps key selected	The first letter typed will be in capitals, the following letters will be in lowercase.
Caps lock and Caps key selected	The first letter typed will be in lowercase, the following letters will be in capitals.
Caps lock and Caps key *not* selected	All letters will be in lowercase.
 Special characters key	Click to view the special character keys.
Esc key	Click to close the current window.

Date / Time

In the *Wizard List* dialog box under *Other Wizards,* select **Options**.

The *Global Settings* dialog box is made up of 5 tabs:
Export, Workspace Name, User Administration, Date and Time and *Misc.*

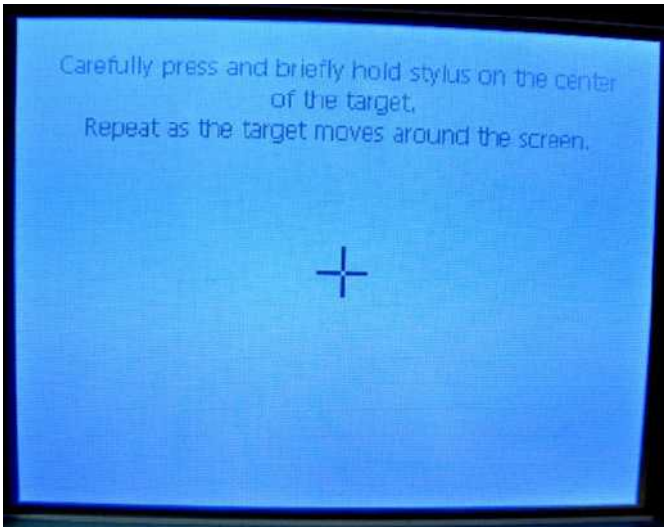
To set the date and time, select the **Date and Time** tab.



Enter the current date and time and click **Apply**.

Exit to Recalibrate screen

The Touchscreen can be recalibrated, if the screen is not responding properly to the Touchscreen pen. Select **Exit to Recalibrate screen** from the Settings menu and follow the instructions. The program will be exited and restarted.



5. Error Messages and Trouble Shooting

5.1 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.

5.1.1 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 Errors		
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.

Error Messages	Description	Trouble Shooting
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.
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 other 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 other 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 other optical defect	Check lamp and if the lamp is working and positioned correctly, contact your local service engineer.

Error Messages	Description	Trouble Shooting
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.
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.

5.1.2 Table of Error Messages and Trouble Shooting for SPECTRA Mode

Error Messages	Description	Trouble Shooting
Filter	The filter slide has not reached the required position or is not defined.	Check that the filter slide is correctly inserted into the instrument. Contact your local service engineer, if the error continues.
Transport	Microplate transport error	Ensure that the microplate is inserted correctly and that nothing is blocking the transport system. Contact your local service engineer, if the error continues.
Lamp low	Optical system error	This message is displayed when the instrument detects that the optical system is not receiving enough light. Possible causes could be: defective halogen lamp, halogen lamp incorrectly positioned, optical system is not clean, filter alignment out of range. Contact your local service engineer, if the error continues.
Lamp high	Optical system error	This message is displayed when the instrument detects that the optical system is receiving too much light. Possible causes could be: defective halogen lamp, halogen lamp incorrectly positioned. Contact your local service engineer, if the error continues.
System	Internal firmware or flash EPROM error	Contact your local service engineer.
Abort	Lamp or other optical defect	Check lamp and if the lamp is working and positioned correctly, contact your local service engineer.

6. Maintenance & Cleaning

6.1 Introduction

This chapter contains the following procedures on how to:

- Replace the lamp
- Replace the filter carriages
- Replace the mains input fuses
- Clean the instrument
- Disinfect the instrument

WARNING

REMOVE THE MICROPLATE BEFORE DOING ANY MAINTENANCE.

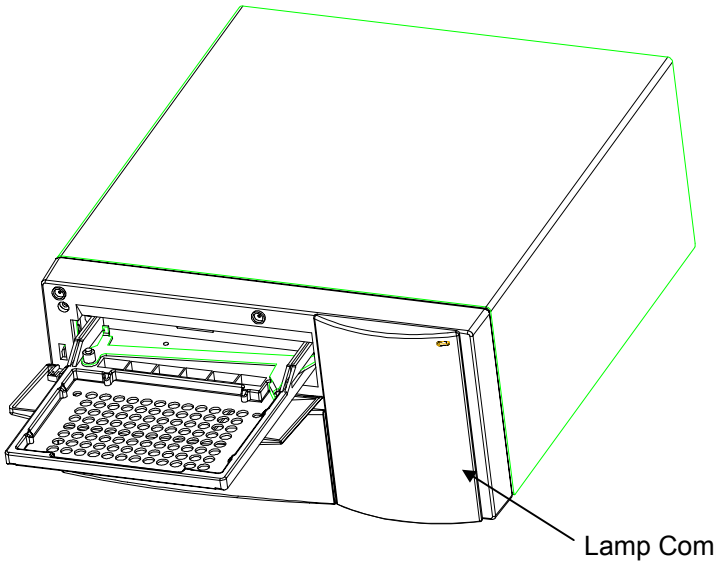
6.2 Lamp Replacement

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

The following steps must be followed to replace the lamp:

Before starting to replace the lamp leave the instrument to cool down for at least thirty minutes.

1. Switch off the instrument and disconnect it from the mains supply.



2. Remove the lamp compartment cover by gently pulling it from the underside.
3. Push the locating spring bar, on top of the lamp, to the left.
4. Carefully remove the lamp from the lamp holder.

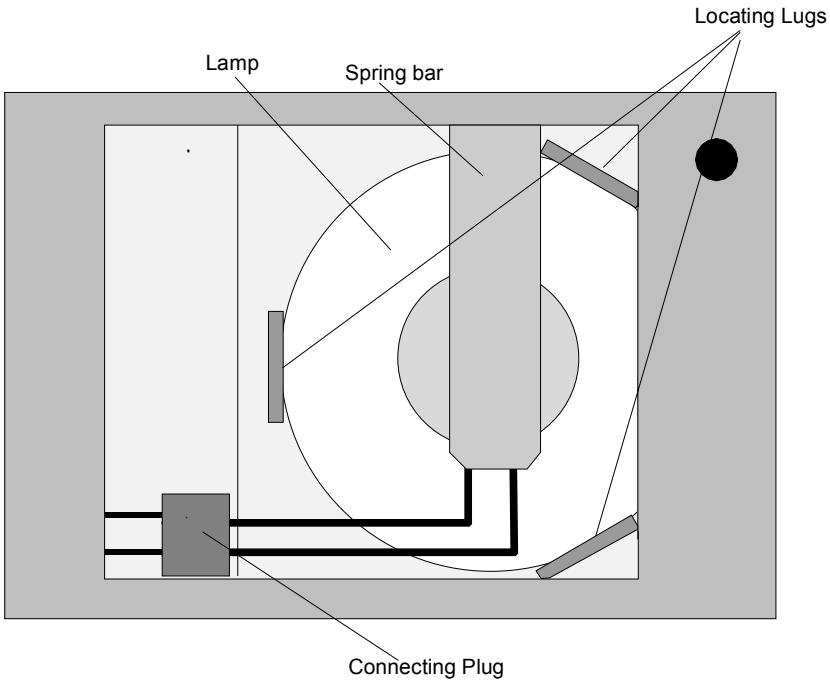
WARNING

TO PREVENT BURNS, ENSURE THAT THE LAMP IS COLD.

5. Disconnect the lamp power cables from the lamp power connector.
6. Replace the old lamp.
7. Reconnect the lamp power connector.
8. Replace the lamp into the lamp holder.

Please note that the lamp is held in place by three lugs, between which the lamp is to be inserted.

Insert the lamp so that the cables are at the bottom.



10. Lock the lamp into place using the spring bar.
11. Before closing the cover plate, ensure, that the lamp is properly seated, in the three lugs.
12. Close the lamp compartment cover.

Caution

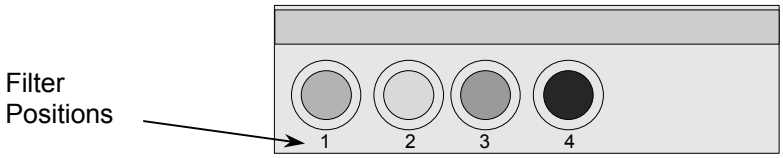
Do not touch the reflective surface and the bulb. Any fingerprints on these surfaces must be removed with acetone or methylated spirits.

6.3 Filter Replacement

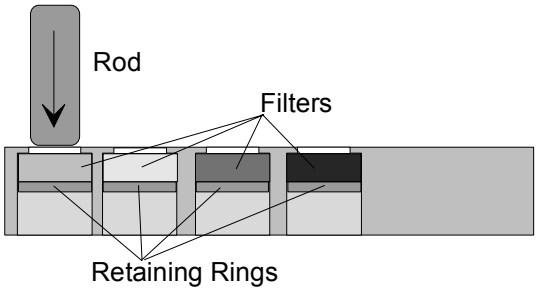
6.3.1 Standard Filter Carriages

The filters of the standard filter 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.



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.



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.

Caution
When handling the filters, be careful that they do not become scratched or soiled with fingerprints or dust.

6.3.2 Gradient Filter Carriages

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 *Standard* filter 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.

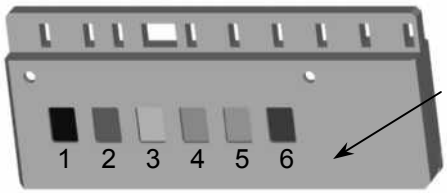
To change the filter carriage, please follow the procedure outlined in the appropriate software Instructions for Use.

6.3.3 6 Filter Carriages

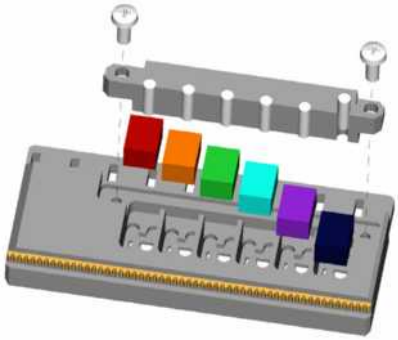
The filters of the standard filter carriages can be replaced using the following procedure:

To replace all of the filters:

1. Remove the filter carriage from the instrument.
2. Place the filter carriage on a clean flat surface, so that the Philips 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.

To replace a single filter:

1. Follow steps 1 and 2 above.
2. Remove the retaining pin of the filter to be replaced with needle-nose pliers.
3. Remove the filter. *Be careful not to scratch it or soil it with fingerprints or dust.*
4. Insert the new filter and replace the retaining pin.

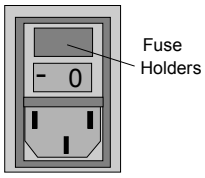
6.4 Fuse Replacement

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 MAINS 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 screw driver 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.



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.

6.5 Cleaning the Instrument

Liquid Spills

If any liquid is spilled in the instrument, it should be immediately removed to prevent liquid running into the optical system and causing a loss of accuracy or the error message **Lamp Low** due to one or more of the diode lenses not being clean.

Cleaning the Touchscreen

The Touchscreen may be cleaned periodically using a tissue moistened with a mild detergent solution.

6.6 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 are maybe shorter.

6.6.1 Daily

- No daily maintenance is required.

6.6.2 Weekly

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

Caution
Never use Acetone as it will damage the covers.

6.6.3 Every Six Months

- Clean the filters using a optical cleaning solution.
  (Lens tissue recommended)

6.6.4 Yearly (Service Engineer Required)

- Check the lamp and mirror unit.
- Check if diode counts are in the necessary range.
- Start Position test.
- Perform duration test for about 100 cycles.
- Perform the QC Pac 2 test (see QC Pac 2 Instructions for Use).

6.6.5 Every Four Years

- Replace the lamp and the filters.

6.7 Instrument Disinfection

All parts of the instrument that come into contact with the patient sera or positive control samples must be treated as potentially infectious areas.

Note:
It is advisable to wear gloves when performing the measurement procedure and also when making adjustments to the instrument.

It is very important that the instrument is thoroughly disinfected before it is removed from the laboratory or any servicing is performed on it.

Before the instrument is returned to the distributor for servicing, it must be disinfected and a disinfection certificate completed by the operating authority. If a disinfection certificate is not supplied, the instrument may not be accepted by the servicing center or it may be held by the customs authorities.

6.7.1 Disinfection Procedure

If the laboratory has no specific disinfection procedure, the following procedure should be used to disinfect the instrument.

The instrument should be disinfected using one of the following solutions:

Lysetol Manufacturer: Schülke & Mayr Ges.m.b.H.

Aseptisol Manufacturer: Bode Chemie Hamburg

If neither of these solutions are available 70% ethanol should be used as an alternative.

WARNING

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

Caution:

The disinfectant can negatively influence the performance of your instrument, if it is applied inside the instrument.

The following procedure should be used to disinfect the instrument.

1. Wear protective gloves, protective glasses and protective clothing.
2. Prepare an autoclaveable bag for all disposables used during the disinfection procedure and label it with autoclave tape.
3. Disconnect the instrument from the mains power supply to avoid any risk of explosion.
4. Disconnect the instrument from the computer.
5. Carefully spray the disinfectant solution (or use a disposable soft tissue paper towel soaked in the disinfectant) on all outer surfaces of the instrument.
6. After a minimum contact time of 10 minutes, repeat the previous step of this procedure.
7. After a contact time of five hours wipe the instrument using a soft paper towel and a mild detergent or distilled water to remove all traces of the disinfectant.
8. Wipe dry the outer surfaces of the instrument.
9. Pack the instrument and its accessories.
10. Disinfect your hands and clean them with a mild detergent.
11. **Complete a disinfection declaration and attach it to the outside of the box so that it is clearly visible.** See below for an example of the disinfection declaration.

See below for an example of the disinfection declaration, which must be completed before the instrument is returned to the distributor for servicing.

6.8 Disinfection Declaration

The following label MUST be completed by the operating authority and attached to the top of the package in which the instrument is returned, before sending the instrument to the servicing center for repair.

I declare that the instrument in this package has been decontaminated or disinfected to remove or inactivate any biological material, which could be dangerous to the service personnel, or that it has never been exposed to any hazardous biological material.

Name:.....

Firm: .....

Address: .....

.....

.....

Country:.....

Signature:.....

6.9 Disposal of Instrument

6.9.1 Introduction

Follow laboratory procedures for biohazardous 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.

6.9.2 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.

6.9.3 Disposal of Operating Material

WARNING

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

6.9.4 Disposal of the Sunrise 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.**

7. Performance Testing / Quality Control

7.1 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 performance of the instrument.

7.2 Optimizing for Maximum Performance

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

It has been found through experience 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:

7.2.1 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 effected by any external light.

7.2.2 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.
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 any type of microplate. The best results are obtained when a clear flat-bottom microplates are used in the specifications.

   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 that what is described in the specifications.

   Make sure that the type of microplate used with the Sunrise Absorbance Reader is suitable for the respective application. This applies particularly to IVD applications.
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.
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 microliters 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.

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. This is especially necessary when performing measurements for IVD applications.

7.2.3 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.

7.3 Performance Tests

The following test can be done 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.

7.3.1 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

Only use QC PAC 2 for SUNRISE instruments. The former version of the QC PAC 2 (for SPECTRA instruments) is not compatible with the instrument.

7.3.2 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.

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	

7.3.3 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

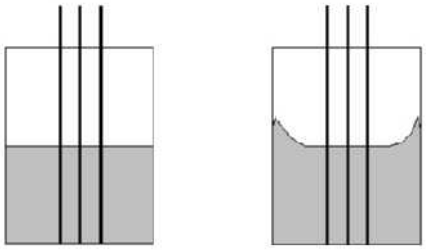
3 positions, 8 measurements per position.

Positions are 0.4375 mm apart.

Accuracy Mode

3 positions, 55 measurements per position.

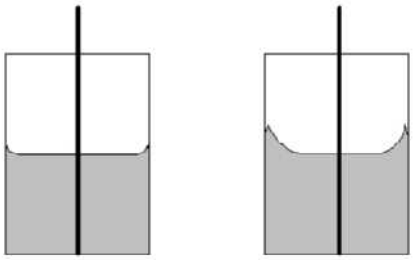
Positions are 0.4375 mm apart.



Normal meniscus High meniscus

Center Mode

1 position, 22 measurements.



Normal meniscus High meniscus

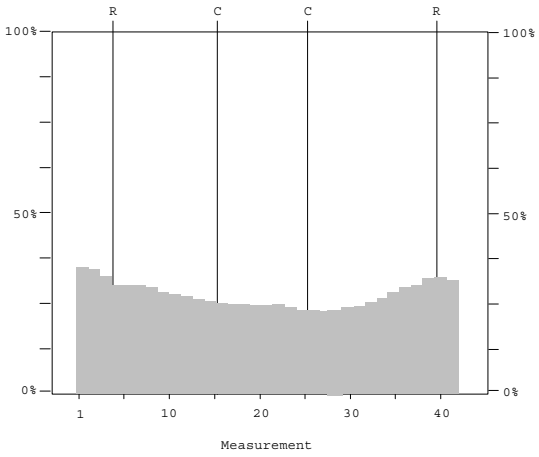
Agglutination Method

For agglutination measurements, an external software package such as Software 2000 must be used. Depending on the software used, the SUNRISE Absorbance Reader must be set to SUNRISE or SPECTRA mode using the SUNRISE Instrument Settings software. The SUNRISE Absorbance Reader is able to read up to 40 measurement points per well.

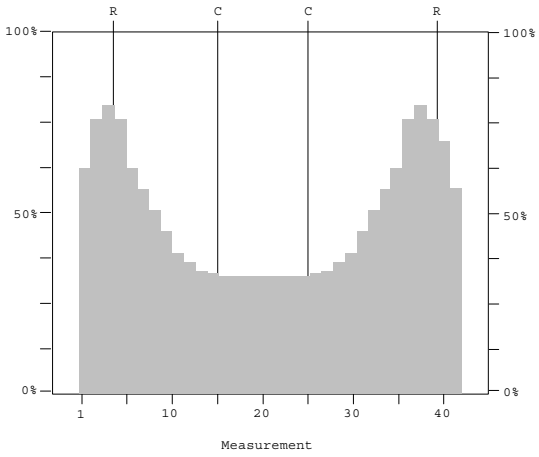
Note:
Instruments with option tuneable wavelength selection are not able to perform agglutination measurements.

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

Normal Liquid



Liquid with High Meniscus



If the printout has less than sixteen measurement points in the middle of the well, that 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

Average = 0.945, Highest = 0.971, Lowest = 0.926

Tolerances = (0.945 ± 0.5 % and ± 0.005)

Highest value within tolerance = 0.955

Lowest value within tolerance = 0.935

Ensure 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.

7.4 Quality Control Testing

7.4.1 Precision Testing

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 dilution's of the solution in each well so that a range of optical densities is obtained. Ensure that the wells contain at least 200 microliters.

Program a test to use 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 and the percentage difference between the average, highest and lowest values

Readings 0.000 to 2.000 Abs

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

Readings 2.001 to 3.000 Abs

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

Readings above 3.000 Abs

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

7.4.2 Instrument Accuracy

The accuracy of the instrument can be checked using different absorbance level neutral density filters and a reference spectrophotometer.

Measure the absorbance of the filters using both the instrument and the spectrophotometer at different wavelengths and compare the results obtained.

Ensure that the instrument is using the Accurate measurement mode.

The percentage inaccuracy is then calculated by the following formula:

$$\%\ \text{inaccuracy} = \frac{\text{OD.(instrument)} - \text{OD.(spectrophotometer)}}{\text{OD.(spectrophotometer)}}\ \text{X}\ 100$$

The inaccuracy using standard filter should be not greater than:

+/- 1.0 % +/- 0.0010 OD (at 492 nm, 0.000 - 2.000 OD).

Example

The following neutral density filters were measured at 405 and 492 nm wavelengths.

Filters used 0.451, 1.199, 1.586.

Wavelength	Spectrophotometer	Instrument	% Inaccuracy
405	0.463	0.465	0.43
	1.199	1.208	0.75
	1.589	1.601	0.76
492	0.662	0.663	0.16
	1.698	1.702	0.24
	2.253	2.279	1.15

7.4.3 Instrument Linearity

The instrument's linearity can be checked by using a dilution series of a solution. For example: a dilution series of Methyl Orange in 0.1 % Tween 20 solution for measurements at 492 nm.

For other wavelengths, different solutions must be used.

The diluted solutions are then measured on a reference spectrophotometer.

A graph of OD against predicted concentration is drawn and the best straight line through the points is then plotted.

The absorbance values obtained for the dilutions are then compared with the graph and a calculated concentration of the dilution, is determined from the straight line.

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

Ensure that the instrument is using the Accurate measurement mode.

The microplate is then measured and a linear graph of OD against concentration is drawn from the average of the measured OD values and the predicted concentration for each dilution.

The absorbance values obtained for the dilutions are then compared with the graph and a calculated concentration of the dilution, is determined from the straight line.

The calculated concentrations are then compared from both the spectrophotometer and the instrument.

The percentage inaccuracy of the instrument is calculated by the formula

$$\% \text{ inaccuracy} = \frac{\text{cCONC (instrument)} - \text{cCONC (spectrophotometer)}}{\text{cCONC (spectrophotometer)}} \times 100$$

cCONC = calculated concentration

The inaccuracy should be not greater than:

Using standard filter	**492 nm**	0.000 - 2.000 Abs	**+/- 1 %**
		2.000 – 3.000 Abs	**+/- 1.5 %**
Using gradient filter	**492 nm**	0.000 - 2.500 Abs	**+/- 2 %**

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TECAN AUSTRIA GMBH, Untersbergstrasse 1a, A-5082 Grödig / Salzburg, Austria
T +43 62 46 89 33, F +43 62 46 72 770, office.austria@tecan.com, www.tecan.com

TECAN.

Declaration of Conformity

Product Type: Microplate Absorbance Reader
Model Designation: ***Sunrise RC/TS – TC/TW/BC/6Filter***

Manufacturer: Tecan Austria G.m.b.H.
Untersbergstraße 1A
A-5082 Grödig Austria/ Europe

The product complies with the requirements of the following European directive:

- **In Vitro Diagnostic Directive 98/79/EC**

Applied Standards:

EN 591:2001	Instructions for use for in vitro diagnostic instruments for professional use
EN 980: 2003	Graphical symbols for use in the labelling of medical devices
EN 1658:1996	Requirements for marking of in vitro diagnostic instruments
EN 13485:2003	Quality systems - Medical devices - Particular requirements for the application of EN ISO 9001:1994
EN ISO 14971:2000	Medical devices – Application of risk management to medical devices
EN 61010-1-1: 2001	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
EN 61010-2-101: 2002	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
EN 61326-1:1997/A2:2001	Electrical Equipment for Measurement, Control, and Laboratory Use - EMC Requirements Part 1: General Requirements
EN 60825-1:2001	Safety of laser products - Part 1: Equipment classification, requirements and user's guide

Furthermore, the product complies with the following Standards, which are not within the scope of the above EC-Directive:

EN 60068-2-6	Environmental testing. Part 2: Tests; Test Fc: Vibration (sinusoidal)
EN 60068-2-27	Environmental testing. Part 2: Tests; Test Ea and guidance: Shock
EN 60068-2-29	Environmental testing. Part 2: Tests; Test Eb and guidance: Bump
EN 60068-2-31	Environmental testing. Part 2: Tests; Test Ec: Drop and Topple
EN 60068-2-32	Environmental testing. Part 2: Tests; Test Ed: Free fall

National Recognized Testing Laboratory (USA, Canada):
UL 61010A-1
CAN/CSA-C22.2 No. 1010 .1-92
CAN/CSA-C22.2 No. 1010 .1-B-92

U.S. Food and Drug Administration / Center of Radiological Health
Accession No. 991 265 9

Place, Date: Grödig, December 5th, 2003

Legally binding signature:

Name:	Armin Dallüge	Alois Krutzenbichler
Function:	**General Manager**	**Head of Research & Development**