ASURYAN ATEX USER MANUAL

Reference of Document: U-053

Document Version: A

Product Number: ASR01-ATEX – ASR03-ATEX

ASURYAN
UV-VIS SPECTROSCOPY



EN – User's Manual

In order to ensure the best use of your system, please make sure to:

- **carefully read this user manual**
- **respect all precautions of use**

Failure to adhere to safety instructions may compromise the equipment's guaranteed safety.



WARNING, DANGER! The operator should refer to this user's manual whenever this danger symbol appears.



WARNING! Risk of electric shock. The voltage on the parts marked with this symbol may be dangerous.



WARNING, UV radiation. The operator should refer to this user's manual whenever this danger symbol appears.



The product has been declared recyclable after analysis of its life cycle in accordance with the ISO 14040 standard.





Chauvin Arnoux has adopted an Eco-Design approach in designing this appliance. Analysis of the complete lifecycle has enabled us to control and optimize the effects of the product on the environment. This appliance exceeds regulation requirements with respect to recycling and reuse.



The CE marking indicates conformity with European directives LVD and EMC.



The crossed-out trash bin indicates that, in the European Union, the product must undergo selective disposal in compliance with Directive WEEE 2012/19/EU. This equipment must not be treated as household waste.

This equipment has been manufactured to the technical specifications of the product and conforms in all respect to the relevant standards and regulations in force and especially to safety according to EN-61010-1:2010 for overvoltage up to 300V category II. This equipment complies with the requirements of the European directive on machinery 2006/42/EC, with the low voltage directive 2014/35/EU, with the EMC directive 2014/30/EU and with the RoHS directive 2011/65/EU.
Failure to observe safety instructions may result in a risk of electric shock, fire, explosion, destruction of the equipment and installations. The operator and / or the responsible authority must read carefully and have a good understanding of the various precautions for use. A good knowledge and a full awareness of the risks of electrical hazards is essential for any use of this device.

If you use this device in a way that is not specified, the protection it provides may be compromised, putting you at risk.

The security of any system that could integrate this device is the responsibility of the system assembler.

This device can be used on category II installations, for voltages not exceeding 300 Vrms with respect to earth.

Do not use the device in networks of voltages or categories higher than those mentioned.

Respect the environmental conditions of use.

Do not use the device if it appears damaged, incomplete or improperly closed.

Before each use, check the condition of the insulators of the cords, case and accessories. Anything whose insulation is damaged (even partially) must be recorded for repair or disposal.

Before using your device, check that it is perfectly dry. If it is wet, it must be completely dried before any connection or putting into operation.

Specifically use the supplied cords and accessories.

Before opening doors, make sure the system is disconnected and unplugged.

Always use personal safety protections.

Any troubleshooting or metrological inspection procedure must be carried out by competent and authorized personnel.

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1 PRESENTATION

1.1 UV-Visible spectroscopy

The principle of UV-visible spectroscopy is based on the interaction between light and electrons in molecules. When UV or visible radiation (generally between 200 and 800 nm) passes through a solution containing a chemical compound, the electrons in the molecular orbitals can absorb the photons. This absorption allows certain electrons to move from a ground state (lower energy level) to an excited state. The spectrum obtained represents absorbance (quantity of light absorbed) as a function of wavelength. Each absorption peak corresponds to a specific electronic transition, providing information about the molecular structure. The main advantages of this method are its speed, simplicity and sensitivity.

The technology offers very high sensitivity (up to 10 to 100 times that of NIR or Raman spectroscopy), which is one of the reasons why the pharmacopeia recommend it for both qualitative and quantitative studies. Acknowledged as an indispensable tool in the laboratory for decades, the technology is gaining increasing popularity for in-line measurements in a production environment. This method is particularly useful for analysing unsaturated organic compounds, metal complexes or biomolecules.

The sensitivity of UV spectroscopy, coupled with its compatibility with multiple probes, multi-angles and/or multi-pathlengths, makes it the ideal instrument for many key applications in biochemical or pharmaceutical analysis.

Evaluation of concentration of molecule of interest during downstream processes: Thanks to the characteristic UV wavelengths of interest and its flexible measuring configurations, Asuryan is the ideal tool for a quantitative or qualitative analysis of a protein blends (proteins, vitamins) or complex liquid solutions, as well as for analyzing and monitoring powder dissolution to optimize process control.

Determination of color: UV-Vis technology offers a flexible solution for color monitoring in-line or in the laboratory, enabling the quantification of solutions' color according to various standard scales.

Detection of leaks in syringes: UV-Vis technology offers a flexible solution for checking Container Closure Integrity (CCI) in-line or in the laboratory, allowing quantification of the dye concentration directly through the glass of the syringe

Detection of particles or impurities/traces in suspensions or solutions: UV-visible sensibility is used to detect particles or traces of products in solution, even at very low concentrations, by measuring the level of absorbance. This method is invaluable for checking the purity of solutions, detecting contaminants or residual impurities, determining the effectiveness of a Cleaning In Place (CIP), or monitoring chemical reactions in liquid media.

Qualification of product of interest with high therapeutic value: Asuryan offers a means of in-line and/or at-line measurement and inspection suitable for biopharmaceutical production, through a variety of probes, making it possible to monitor the quality of the finished product (validation of bioproduction, filling, conservation, etc.







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1.2 The Asuryan system

The ASURYAN system, coupled with probe(s) or flow cell(s), is a comprehensive hardware solution dedicated to continuous and non-destructive measurements in the UV-Visible range, ideally suited for both the pharmaceutical and biotechnological sector in the quest for in-line monitoring or at-line R&D work.

The Asuryan UV-Vis solution is dedicated to critical applications in industries, such as:

- Chemical composition of products
- Downstream process monitoring
- Analysis of vaccines
- Vitamins for chemical industry products
- Nanoparticles in suspension (e.g. ZnO_2, CuO, TiO_2, etc.)
- Intralipid globule size and form of crystals

PERFORMANCE:

ASURYAN allows for fast spectral acquisitions and offers excellent stability thanks to a simultaneous measurement of the light source spectrum. Several spectrometers can be integrated into one Asuryan unit in order to perform measurements on multiple key phases of the process simultaneously, thus giving an immediate snapshot of your whole process.

FLEXIBILITY:

Compatible with pharmacopoeia standards (USP857, Ph.Eur. 2.2.25), Asuryan and his multi-channel system can be adapted to a large number of sensors (transflexion or transmission immersion probes with different optical trajectories, flow cells with multiple optical path lengths, multi-angle probes for inspecting complex media or ATR immersion probes for strongly absorbing products) to allow flexibility when measuring diverse products of interest in diverse media.

USER-FRIENDLY:

Our Asuryan Ready® software lets you modulate measurement acquisition, particularly in terms of the light source used (UV only, VIS only, UV + VIS combined), the integration time and the number of scans. It also provides multiple options for recording the spectra, analyzing the data and displaying the results and predictions. Our system can be used directly in stand-alone mode or is also able to communicate with PLCs and other monitoring tools using OPC-UA or TCP-IP. The acquired data can be analyzed with third-party chemometric software packages such as PLS_Toolbox and SIMCA.

DATA ANALYSIS AND CALIBRATION:

The Asuryan analyzer is equipped with a 21 CFR part 11 compliant in-house developed software. It can be controlled through communication protocols such as OPC-UA for full integration into a complete automated solution. In stand-alone version, the acquisition and processing software Asuryan Ready allows to define the acquisition parameters such as integration time and number of scans, display and export acquired data, develop and apply univariate calibration models and integrate chemometric models (eg PCA, PLS) from external software packages such as PLS_Toolbox (Eigenvector) or SIMCA-Q (Sartorius). Our team is composed of chemometricians with more than 10 years' experience in biotech and chemical industries. We can provide support for data analysis, experimental design, calibration, scale-up, calibration transfers, etc., and we also offer training in chemometrics.

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2 TECHNICAL SPECIFICATIONS

TECHNOLOGY	Continuous, non-destructive UV-Visible analysis of agrochemical, pharmaceutical and biotechnological media. With use of an external PC.
ILLUMINATION SOURCE	Deuterium (UV) and halogen (Vis) light bulb with optical shutter
SPECTROMETERS	1 or 3 measuring spectrometers and one additional internal light-source measurement spectrometer to correct for potential fluctuations
SPECTRAL RANGE (BANDS)	200 – 800 nm
SPECTRAL RESOLUTION (FWHM)	< 6.5 nm
ACQUISITION TIME	8 – 1000 ms
ANALYSES	Real-time display of the spectra of the sample measured, by means of the in-house developed Asuryan Ready software. Possibility to create and apply univariate models directly in the software. Possibility of importing models from PLS_Toolbox® (Eigenvector) and SIMCA-Q® (Sartorius). OPC-UA communication for automation.
TEMPERATURE	5 – 40 °C
RELATIVE HUMIDITY	5 – 90 %
LAB BENCH SYSTEM, DIMENSIONS	Stainless steel unit, H215 mm x W400 mm x D350 mm (excluding the dimensions of the external PC)
CERTIFICATION	CE

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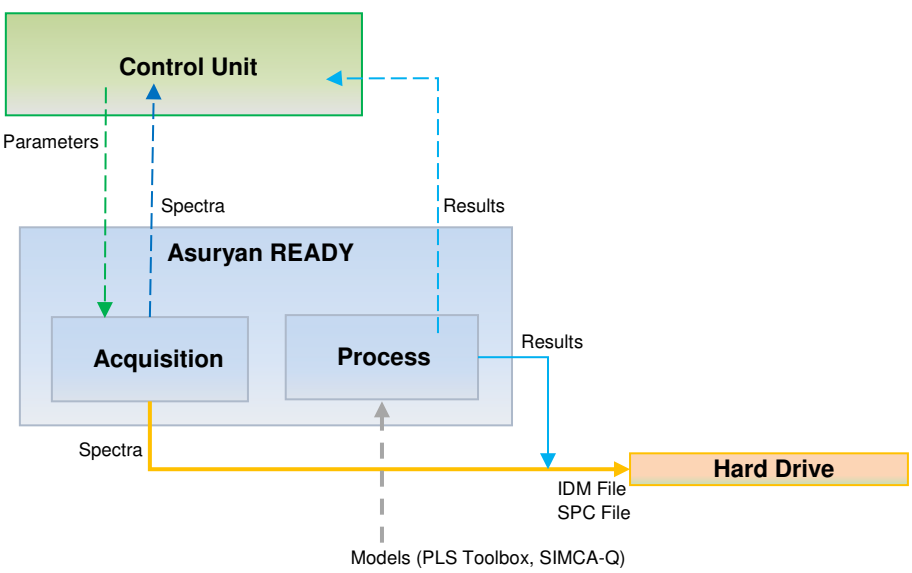
3 ASURYAN CONFIGURATIONS

The Asuryan system can be set up in two configurations: Stand Alone or Bench Data Acquisition Device.

Configuration	Controller	Document
Stand Alone	USER	The system is an independent device. Neither electrical signals nor data are exchanged between the Asuryan and external equipment. Asuryan Ready automatically saves the data in IDM format. Other formats are optional. Process values are calculated and displayed within the software, either from univariate models created directly inside Asuryan Ready or from multivariate models generated with an external modelling software.
Bench Data Acquisition Device	OPC-UA	The Asuryan computer communicates spectra to a Control unit, which handles setting the acquisition parameters and data saving. The data saving in Asuryan Ready is optional: the Control Unit must activate it. Process values are evaluated either by Asuryan Ready or by the Control Unit. The protocol to exchange data between the Control unit and the Asuryan Ready software is “Ethernet OPC-UA”



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4 SITE AND SAFETY INFORMATION

4.1 Safety

4.1.1 Mechanical

No potential hazard, no moving parts.

4.1.2 Electrical



Potential electrical shocks. The lamp works with high voltage of over 1000 V and with a high frequency of 250 KHz. This component is not accessible without tools. The maintenance of the lamp should be performed only by personnel trained by INDATECH (see the section 7 MAINTENANCE).

Danger zones have been cautiously labelled.

4.1.3 UV Radiation



The Asuryan produces UV radiation. Radiation from direct or reflected UV light may burn your skin and eyes. Protect your eyes by wearing safety goggles with clear or tinted glass. A mechanical shutter is placed on the light output optical fiber connector to block the light if nothing is connected.

Danger zones have been cautiously labelled.

4.2 Environmental Conditions

For inside use only.

4.2.1 Temperature

Conditions in operation mode: from 5 °C to 40 °C (from 41 °F to 104 °F).

4.2.2 Humidity

Excessive exposition to moisture may degrade components inside the enclosure. Humidity must be maintained in the range of 5% to 90%.

4.2.3 Magnetic field

Intense magnetic fields, such as those produced by superconducting magnet, can affect system performance. The instrument should be at least 5.5 m (18 ft) away from these fields. Minimize or eliminate exposure to magnetic fields wherever possible.

4.2.4 Altitude

Up to 2000 m.

4.3 Cleaning

Turn the equipment OFF and disconnect the unit completely.

Use a soft cloth, dampened with soapy water or a clean inox spray. Rinse with a damp cloth and dry rapidly with a dry cloth or forced air. Do not use solvents or hydrocarbons.

Do not use the instrument again until it is completely dry.

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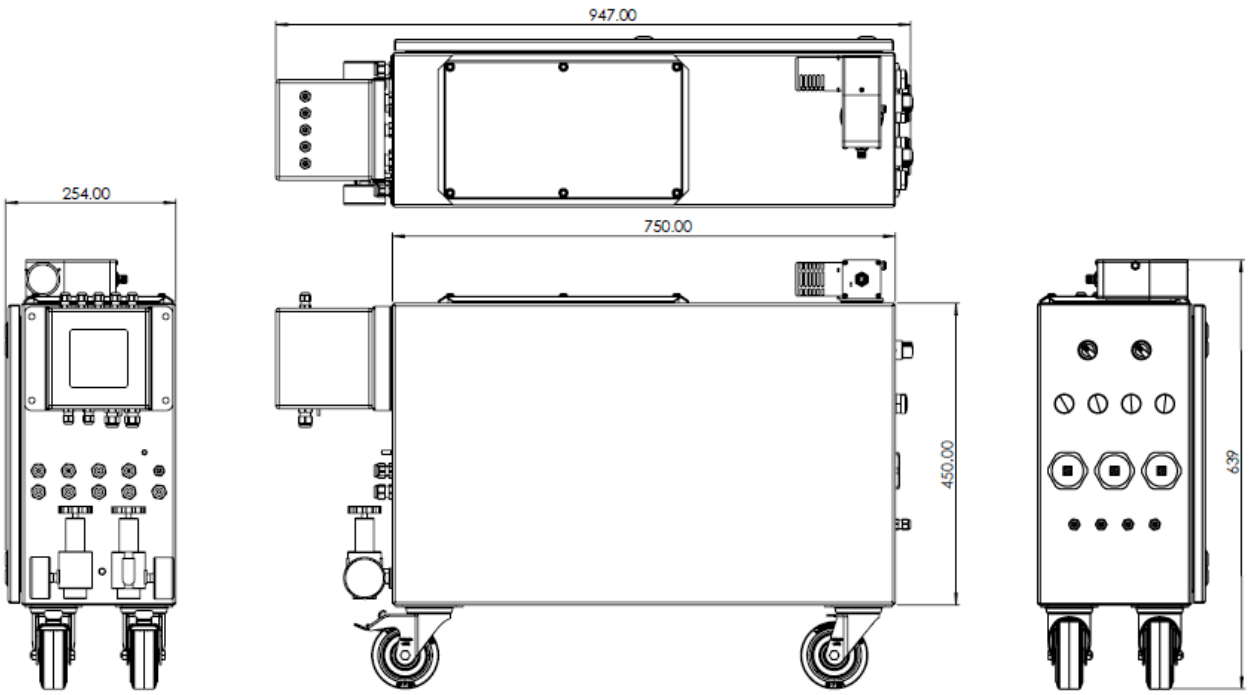
4.4 Electrical Requirements

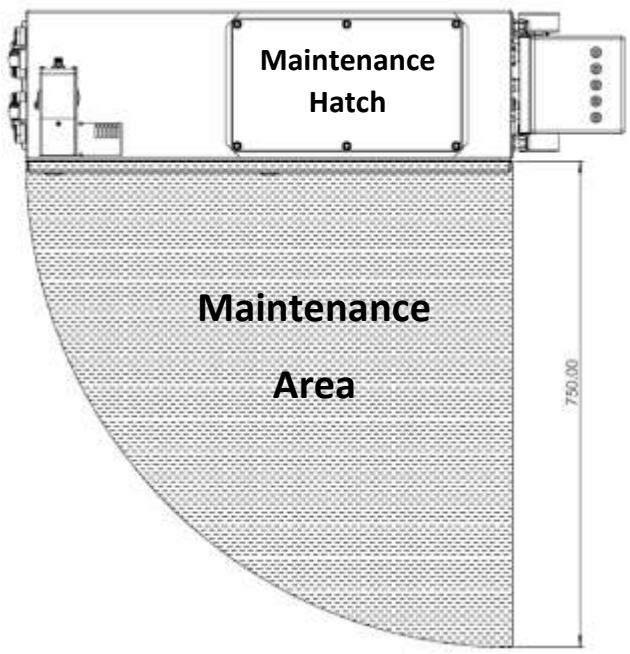
Description	Voltage	Amps	Frequency
Power Cord	100-240 V	1.25 A @ 230 V ac, 2.5 A @ 115 V ac	50-60 Hz

4.5 Location and Space Requirements

Dimensions of the acquisition unit of Asuryan are 400 mm (length) x 350 mm (width) x 215 mm (height).



For a correct installation, you must allot different areas for maintenance. The following drawing provides the minimum space requirements around the UV-VIS analyzer.



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4.6 Pneumatic Requirements

Gaz Inlet	Value
Tubing size	8 mm diameter (other sizes available on request)
Pressure	4 – 6 bars
Flow rate	≥ 25 Nm^3/h

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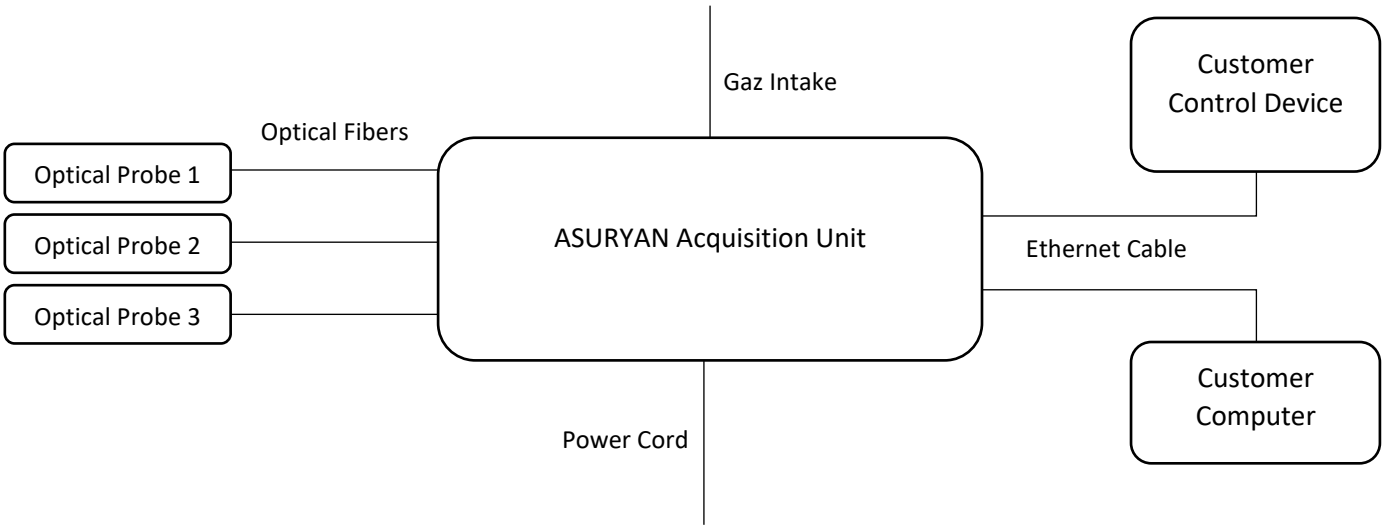
5 HARDWARE ARCHITECTURE

5.1 Equipment overview

Asuryan is designed as a robust stainless-steel unit compatible with production environment. One or multiple sampling interfaces (probes, cuvette holders or flow cells) can be connected to the measurement unit. An external computer module is needed to pilot the Asuryan instrument, acquire, save, and exchange data. The measurement unit is made of a spectrophotometer(s), light source, data processing unit (computer) and communication features presented below.



Hardware equipment

5.1.1 Lamp

The light source module is composed of a deuterium lamp, a tungsten lamp, and an internal shutter. The spectral distribution is 185 to 1100 nm. Typical lifetime in continuous mode is 1000 h as shown on the curve below:

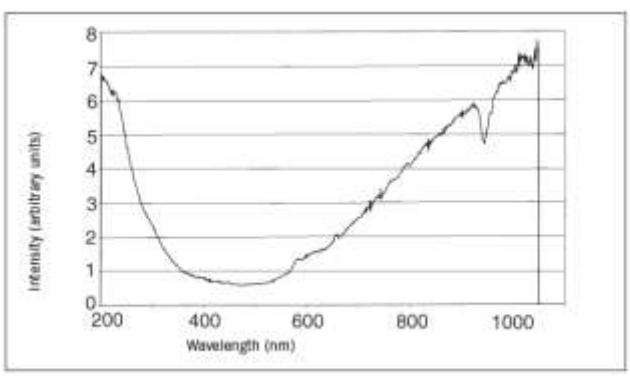
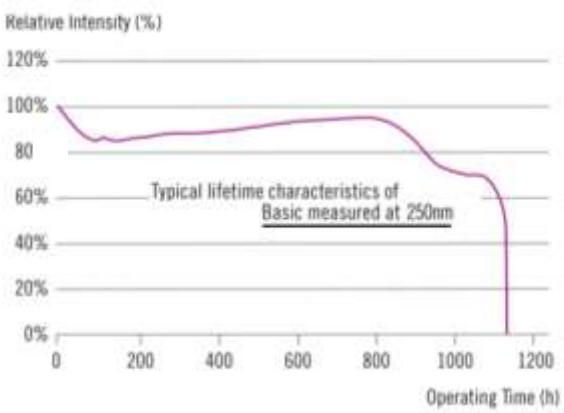


Fig. 8 Spectrum (measured with optical fibre 1 m long, Ø 400 µm)



5.1.2 Spectrometers

The spectrometer module is based on a high sensitivity sensor.

Typical spectra of different kind of light sources are given in the figure below:

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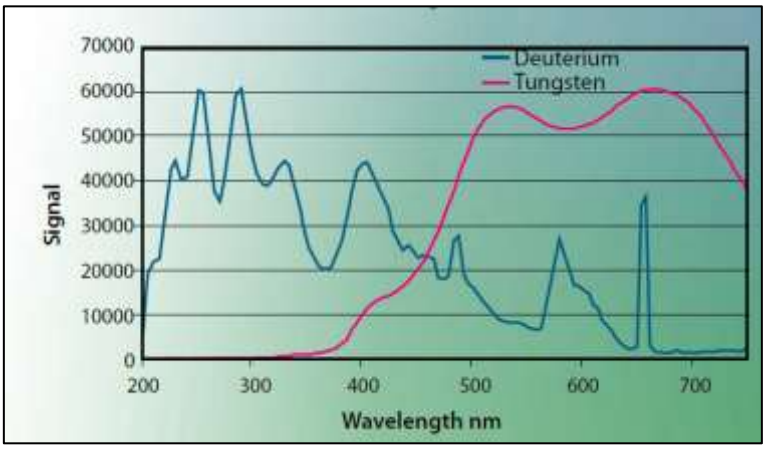
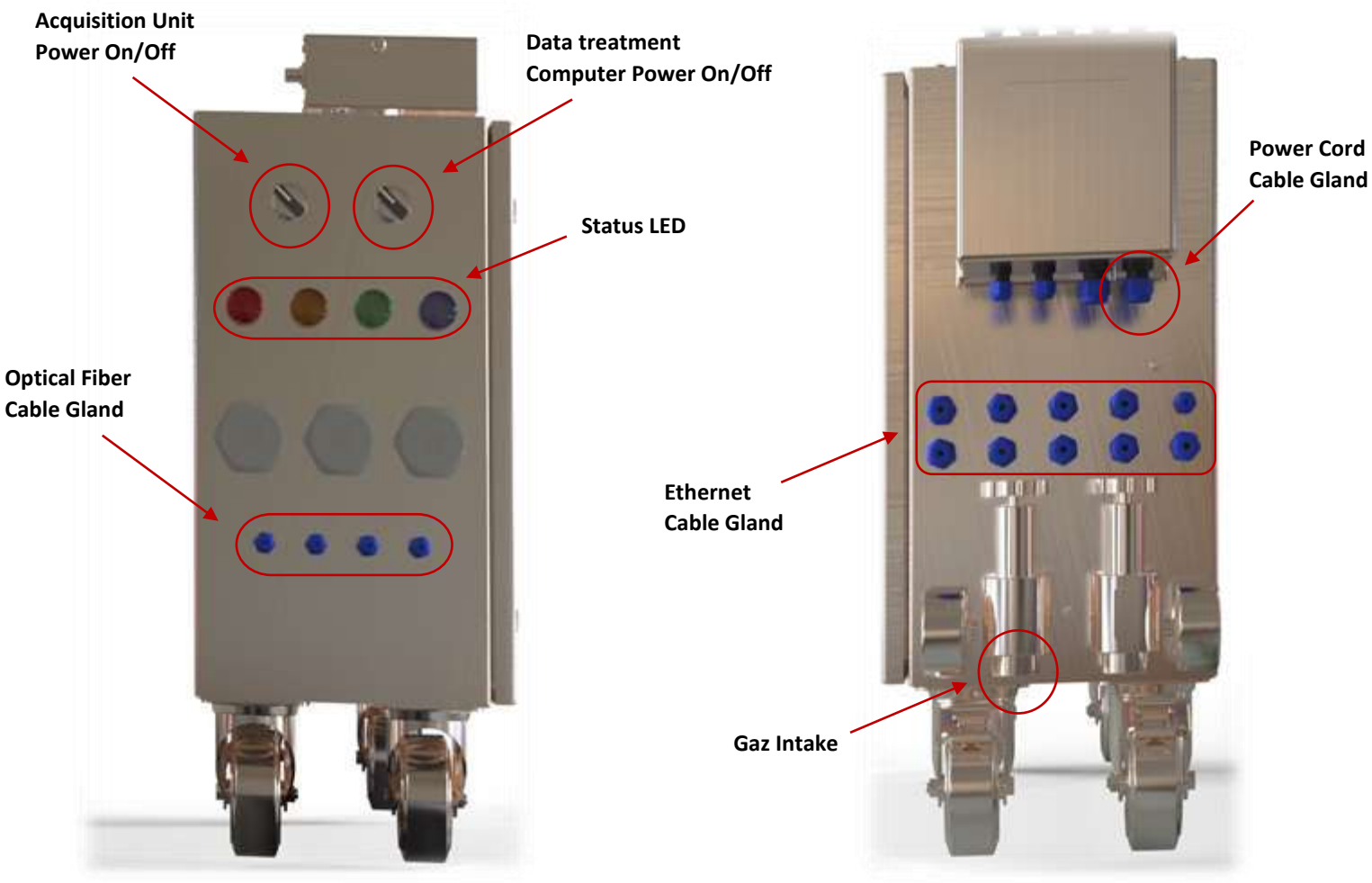


Some specifications of the spectrometer and its performance are given in the table below.

Parameter	Value
Spectral range	200-800 nm
Slit width	50 µm
Stray light	<0.25%
Resolution	6.5 nm

5.2 Acquisition module



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5.3 Sampling interface

The sampling interface depends on the application and the requirements of the user, the matrix and the final setup. Any type of UV probe or flow cell with SMA connectors on the market can be coupled to the Asuryan system. Indatech's multi-angle probe and/or flow cells multi or single path can be connected to the Asuryan unit to perform physico-chemical characterisation of the inspected samples, as well as various commercially available probes, such as optical multipath, ATR attenuation, etc.





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6 OPERATING MANUAL

6.1 Starting the unit

Before starting up the equipment, ensure that the power cord and the pneumatic tubing are connected. Verify that the ethernet cable between the acquisition module and PC is well connected. All you have to do is turn the 2 on/off button on the front of the Asuryan system.

The device will then be switched on and the green LED will light up to indicate 'system ready'.

The PC and the measurement system are independent and must be switched on separately, preferably starting with the acquisition unit then with the computer.

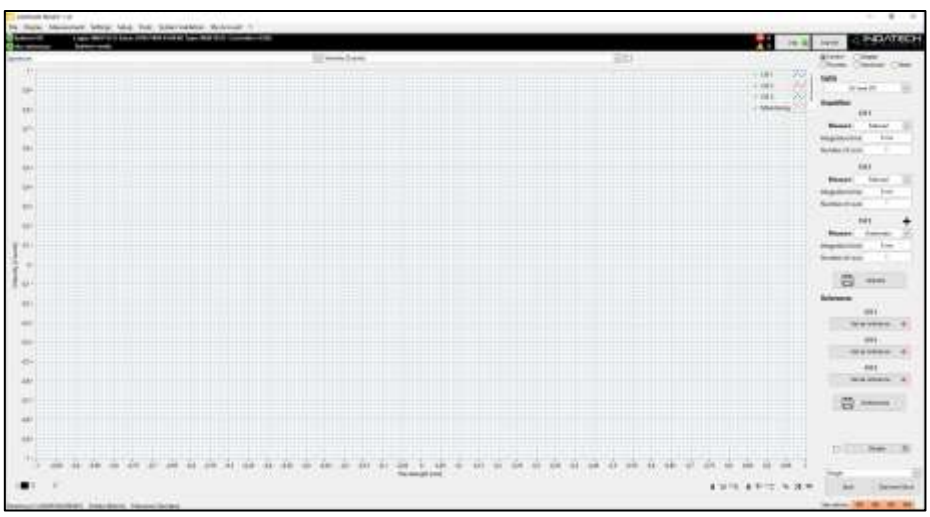
6.2 Logging into the data acquisition software

Log in to the PC by using the associated login/password.

Launch the Asuryan Ready software from the shortcut on the desktop:



The following screen appears:



6.3 Asuryan Ready

INDATECH's in-house developed Asuryan Ready® software provides all the important capabilities and requirements for use in both development and production situations:

- Definition of lamp use (UV only, Vis only, UV+Vis combined)
- Definition of acquisition parameters (integration time, number of scans, etc.)
- Definition of batch acquisition scenarios (periodic measurement, waiting time, etc.)
- Password access. Definition of different access levels (Operator, Administrator…)
- Creation and application of univariate regression models
- Import of chemometric models (PLS,PCA, SVM, ANN) from the PLS_Toolbox® (Eigenvector)
- Communication via OPC-UA

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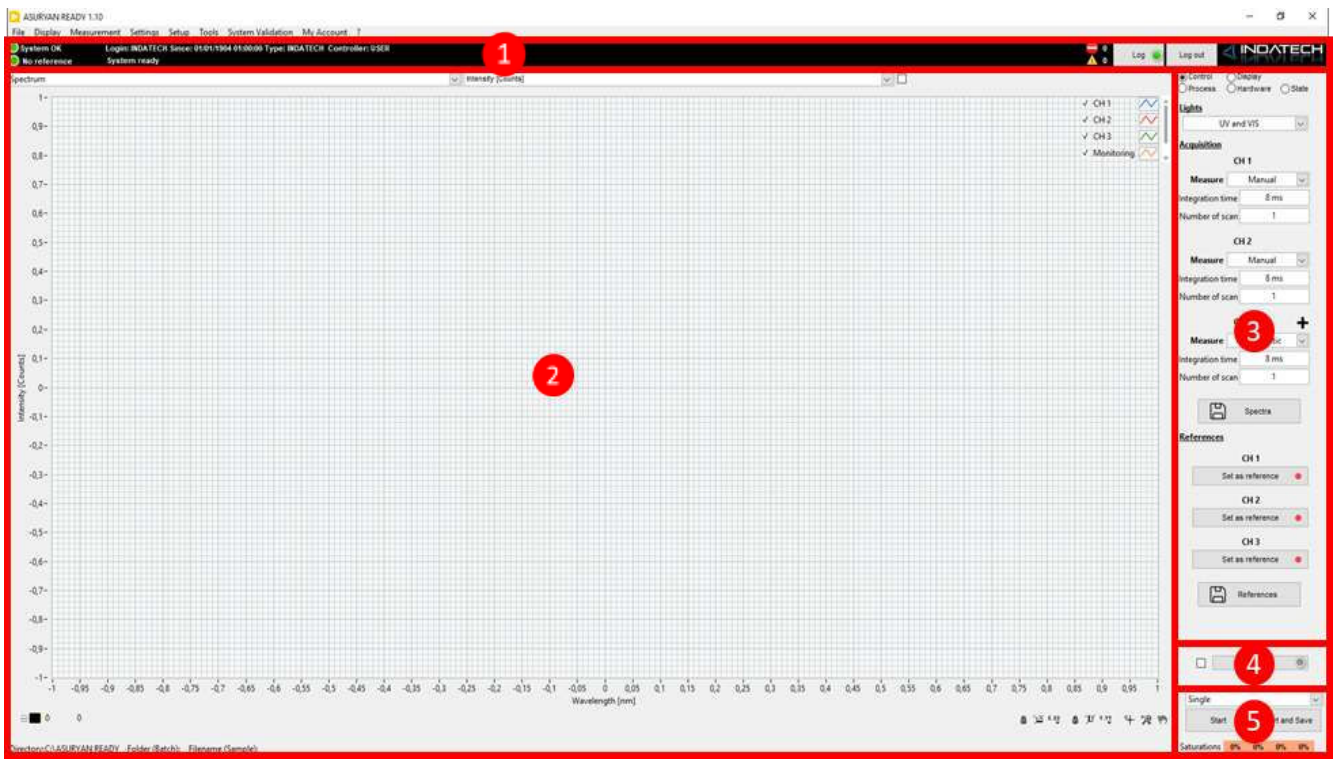
The software manual, documented as U-018, instructs users on utilizing the Asuryan Ready software. This includes a detailed explanation of setting system parameters, acquiring spectral data, visualizing and inspecting spectra, as well as developing and applying calibration models. Certain aspects of the manual will also be covered in section 6.4 of this user manual. For an in-depth understanding, users are strongly encouraged to read the complete Asuryan Ready software manual.

6.3.1 User interface

The Asuryan Ready Software interface is divided into 5 zones:

1: Equipment Status
2: Graphical interface
3: Configuration Area and Process Information
4: Processes Management
5: Acquisition Management



6.3.1.1 Equipment Status Area

- System General Status (System OK or System Fault)
- Login Name, Login time and Access Level
- Alarm and Warning counters
- Log In and Log Out button
- System Detailed State
    1. **System Ready** when the system is Ready To measure
    2. **Measuring** when Measurement is In Progress - with display of:
        - Measurement Number
        - In case of Periodic Acquisition Type, Remaining time before next measurement
    3. **Alarm** when the system is in Alarm mode
        - The cause of the alarm is displayed
    4. **No Login** when no login informed

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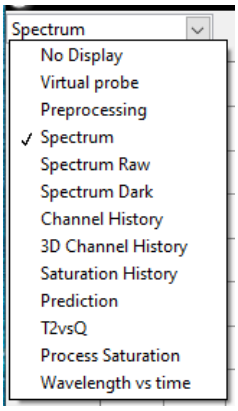
6.3.1.2 Graphical interface

Display zone is a configurable area where multiple screens can be set (up to 12 graphs simultaneously) in order to visualize the information of interest in function of your use.

Each graph can display available data, depending on the acquisition parameters and analysis parameters set prior to measurement. Available data are accessible through the selection lists above each graph.



- No Display: hides the graph
- Spectrum: Last acquired spectrum of each channel with different form
  - Intensity [Counts]
  - Absorbance: only available when system has a reference
  - Transmittance: only available when system has a reference
- 3D Spectrum: Spectrum view in a 3D strip view
- Channel History: Up to last 200 spectra for one channel, selected from the channel display list
- 3D Channel History: Channel History in a 3D strip view
- Saturation History: Up to last 200 loads on each channel
- Process: Process values over measurement number. Displayed process selection is with the channel list.
- T^2vsQ: Plot of the Q Residual Reduced over the Hotelling's T^2 Reduced for a process selected with the channel list
- Process Saturation: Maximum load, on all utilised channels for a process, over the measurement number. Displayed process selection is with the channel list.

The display lists update automatically when their data are available.

6.3.1.3 Configuration Area and Process Information

This area functions as a user-selectable visualization of controls and data, consisting of six viewable panels that allow users to set parameters or visualize system information. The available views include Control, File, Hardware, Process, Display, and State. The visible panel changes upon selection of a view using the top radio button. The figures below show the six different panels. For more information, see the U-018_ASURYAN READY User Manual.

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6.3.1.4 Processes management

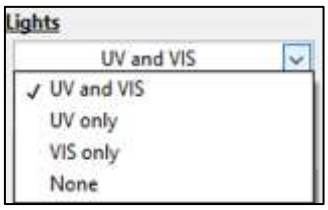
The 'Models' button provides the option to define or load a multi-model configuration allowing for real-time predictions directly inside the Asuryan Ready software. Both univariate and multivariate models can be used. For more details, please refer to the Asuryan Ready software manual.

6.3.1.5 Acquisition management

The acquisition management area allows users to perform and save data acquisitions, displaying the saturation of each measurement channel.

6.3.2 Getting started

6.3.2.1 Lamps to use



Click on the drop-down menu in the Lights section to select the light bulbs to be used. One can choose to either use both the UV and VIS light bulb, only the UV, only the visible or none (both bulbs switched off).

6.3.2.2 Spectrometers configuration

The measurements are carried out by one or more spectrometers.
To realize an acquisition, it is necessary to configure them in the CONTROL tab by selecting the type of acquisition: Manual (integration time defined by user), Automatic (automatic optimization of the integration time based on parameters defined by user), Not active (channel deactivated).
On a manual acquisition set 'Integration Time' corresponding to the time of acquisition and 'Number of scan' corresponding to the number of repetition of each acquisition.

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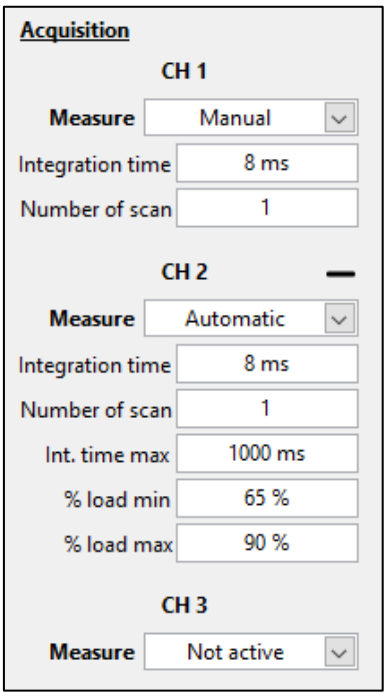
On an automatic acquisition set 'Integration time' which is the starting integration time of the automatic measure, 'Number of scan', 'Integration time maximum' corresponding to the maximum integration time to not overpass, '% load min' corresponding to the saturation level percentage minimum to reach, '% load max' corresponding to the saturation level percentage maximum to reach.

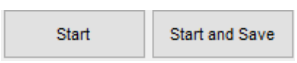


If the monitoring channel is activated, its parameters are accessible in the menu Settings→Monitoring Channel.

6.3.2.3 Acquisition Mode

Select in the dropdown menu	If…
Single	you are using the Asuryan as a benchtop unit and manually want to perform one single acquisition at a time
Periodic	you are using the Asuryan in an in-line configuration or simply want to perform multiple spectral acquisitions automatically over time

6.3.2.4 Save or not save



Click on	If…
Start	you want to perform a simple acquisition
Start and Save	you want to save all spectra in file (.IDM) on the computer. The software will ask the location (folder and filename later)

6.3.2.5 Periodic Acquisition parameters

In case of periodic acquisition, the time interval between consecutive measurements can be defined. Depending on the system configuration, the minimum acquisition period is automatically calculated. The value displayed (in seconds) corresponds to the period between the start of two measurement sequences. The user can modify it to any time interval superior to the automatically calculated value if he wishes. Click on the OK button to continue.

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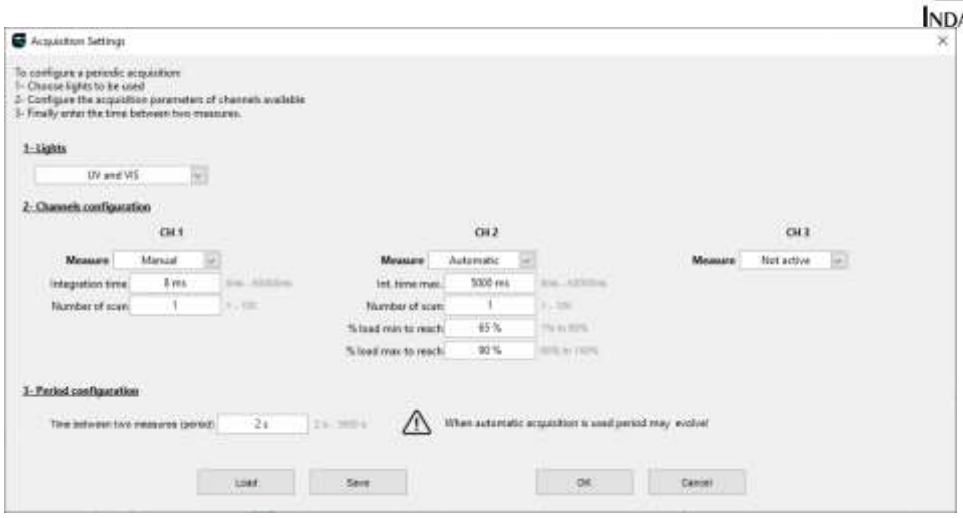


Then, the stop conditions of the periodic acquisition can be defined (duration of acquisition and/or number of measurement sequences to perform). If no stop conditions are defined, the periodic measurement will continue until a user presses the “stop” button. If two stop conditions (Duration and #Measurement) are activated, the measurement sequence will stop once the first stop condition is met.



6.3.2.6 *Status of acquisition and Stop*

The acquisition information is displayed in the status bar.

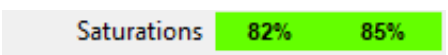
After each sequence of measurement, spectra are displayed in the graphical interface area.

In the ‘Acquisition management area’, the ‘Stop’ button allows to stop acquisition before its end.

6.3.2.7 *Display of Saturation Level of the detector*

In order to ensure a good spectrum quality, it is recommended to adjust integration time to reach a saturation level between 80 and 95%. Low saturation value implies a suboptimal SNR (Signal to Noise Ratio). 100% saturation means saturation of the detector, which is strongly discouraged.

Depending on the Asuryan UV/VIS unit (1 or 3 channels, with monitoring or not), several saturation levels are shown (leftmost channel 1, then channel 2, …..).



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7 MAINTENANCE

WARNING:

ASURYAN MAINTENANCE MUST BE DONE

ONLY BY PERSONAL TRAINED BY INDATECH

INDATECH's EQUIPMENT WARRANTY WOULD BE CANCELLED IF ANOTHER WORKER (NOT INDATECH CERTIFIED WORKER) USES THESE PROCEDURES

7.1 Maintenance calendar

The table below lists the most important actions of maintenance, together with the time interval on which they should be performed. The responsible person and the estimated working hours for the intervention are included as well.

Period	Maintenance	Who	Working Hours
After 1000 h of lamp ON	Replacement of lamp bulbs and check signal	Customer	1 h

7.2 Replacement of the Light Source

The complete lamp unit must be replaced when the lamp fails or one of the bulb has finished its lifetime.

For lamp replacement, proceed as follows:

1. Turn off the unit.
2. Unplug the power supply cable from the unit.
3. Open the maintenance panel from the Asuryan UV-Vis Unit by removing the 6 screws:



4. Disconnect the black plug from the tungsten lamp.
5. Unscrew the Allen screw (1.5 mm).

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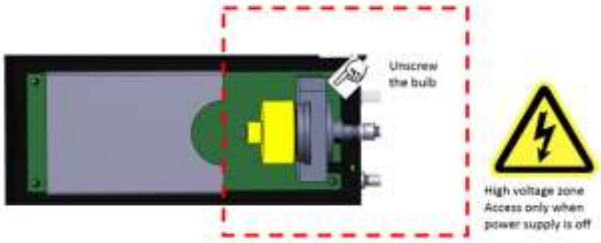

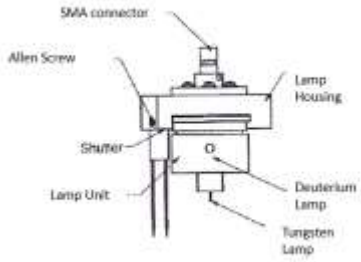

6. Pull the ceramic housing upwards (do not tilt the housing as it has an exact fit!).
7. Insert the new lamp unit from the top into the lamp housing. Ensure that the pins are inserted vertically on the bottom of the ceramic body and that they slip into the socket of the circuit board.
8. Tighten the Allen screw again.
9. Place the black plug on top of the pins of the tungsten lamp.
10. Close the side panel.
11. Plug the power supply cable back in and turn on the system.
12. Check that both the UV and VIS light source are working correctly by acquiring a spectrum.
13. Reset the counter in the Asuryan Ready software by clicking on *Reset Lamp Hours* in the *Settings* Tab.

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8 WARRANTY

Unless stated otherwise, our warranty is valid for **12 months**, starting on the date when the equipment is made available. An extract from our General Conditions of Sale will be provided on request.

The warranty does not apply in the following cases:

- Inappropriate use of the equipment or use with incompatible equipment
- Modifications made to the equipment without the explicit permission of INDATECH
- Work done on the device by a person not approved by the manufacturer
- Adaptation to a particular application not anticipated in the definition of the equipment or not indicated in the user's manual
- Damage caused by shocks, falls, or floods

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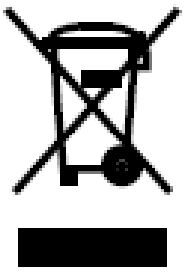
9 DISMANTLE / DICOMMISSIONING

If the user decides to decommission the equipment, it must be done according to local rules.
Contact can be taken with the INDATECH office for details.



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10 CERTIFICATIONS AND COMPLIANCES

The Asuryan fulfills the requirements of the following Applicable Standards:

- 2014/35/UE – Low Voltage Directive
- EMC 2004/108/EC – Electromagnetic Compatibility Directive
- IEC EN 61010-1: 2011 + Amdt 2016 – Safety of Measuring, Control and Laboratory Equipment
- 2011/65/EU – RoHS Directive

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CA INDATECH
Chauvin Arnoux Group
1900, Boulevard de la Lironde
34980 Montferrier-sur-Lez
FRANCE
Tel : +33 (0)4 80 78 01 40
contact@indatech.eu
www.indatech.eu
www.chauvin-arnoux.com

Measure up

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