Arc Module Incyte SU

Operating Instructions

HAMILTON

Hamilton Warranty

Please refer to the General Terms of Sales (GTS).

Important Note

Contents of this manual can be modified without previous announcement. Technical modifications reserved. Greatest possible care was used on the correctness of the information in this manual. If errors should be discovered nevertheless, Hamilton Bonaduz AG is pleased to be informed about it. Regardless of this, Hamilton Bonaduz AG cannot assume liability for any errors in this manual or for their consequences.

1 General Information

1.1 Intended Use

The Arc Module Incyte-P SU is intended to be used with dedicated sensor element «Incyte-P SU» for the measurement of permittivity in liquid medium in Single-Use (SU) stirred bag applications. This Module provides a digital Modbus signal, when connected to Incyte-P SU. Additional equipement such as an amplifier or transmitter is not required. The Arc Module Incyte SU is not gamma irradiable or steam sterilizeable. The Arc Module Incyte-W SU is intended to be used with the same sensor element «Incyte-P SU» for the measurement of permittivity in liquid medium in Single-Use (SU) wave bag applications. Both Arc Modules are designated as «Arc Module Incyte SU» and are designed to work with the same SU sensor element «Incyte-P SU». These measurements may be used for the control of bioprocesses within the defined specifications (see specifications sheets www.hamiltoncompany.com). The permittivity measurement may be correlated to the viable cell density. In addition to permittivity Incyte Arc also measures conductivity and temperature.

⚠ ATTENTION! The Arc Module Incyte SU is not gamma irradiable or steam sterilizeable.

⚠ ATTENTION! The Incyte-P SU has a built-in temperature sensor (NTC 22kOhm). This temperature sensor is to be used only for monitoring the sensor conditions, not for controlling the process temperature.

⚠ ATTENTION! The measurement values transmitted over wireless communication (with optional Arc Wi Adapter BT) are not intended to be used for process control.

NOTE: The Arc Module Incyte SU is not intended for hazardous atmospheres and has no Ex approval.

1.2 About this Operating Instruction

These Operating Instructions will help users to operate Arc Module Incyte SU correctly and safely. To achieve that goal, this document describes the different components and functions. The Operating Instructions describe both the hardware and software of Arc Module Incyte SU in depth enabling the user to operate the system. After introducing the various parts, it is shown step by step how to operate the system. After reading the Operating Instructions, users should be capable of installing and operating the Arc Module Incyte SU. Following information are highlighted within this document:

⚠ ATTENTION! Essential information for avoiding personal injury or damage to the equipment.

NOTE: Important instructions or interesting information.

2 Liability

The liability of Hamilton Bonaduz AG is detailed in the document «General Terms and Conditions of Sale and Delivery (GTS)».

Hamilton expressly shall not be liable for direct or indirect losses arising out of the utilization of the Arc Module Incyte SU or Incyte-P SU. It must in particular be ensured in this conjunction that malfunctions can occur on account of the inherently limited useful life of Arc Module Incyte SU or Incyte-P SU contingent upon their relevant applications. The user is responsible for the calibration, maintenance and punctual replacement of the Arc Module Incyte SU or Incyte-P SU. In the case of critical Arc Module Incyte SU applications, Hamilton recommends using redundant measurement points in order to avoid consequential damages. The user shall be responsible for taking suitable precautions in the event of a failure of the Arc Module Incyte SU.

3 Safety Precautions and Hazards

⚠ ATTENTION! Read the following safety instructions carefully before installing and operating Arc Module Incyte SU.

3.1 General Precautions

For safe and correct use of Arc Module Incyte SU, it is essential that both operating and service personnel follow generally accepted safety procedures as well as the safety instructions given in this document, the Arc Module Incyte SU Operating Instructions.

The specification given in the «Specification Sheet» as regards temperature, pressure etc. may under no circumstances be exceeded. Inappropriate use or misuse can be dangerous.

Cleaning, assembly and maintenance should be performed by trained personnel. Do not remove the Incyte SU-P to avoid leaking of process medium. When removing and cleaning the Arc Module Incyte SU, it is recommended to wear safety goggles and protective gloves. The Arc Module Incyte SU cannot be repaired by the operator and has to be sent back to Hamilton for inspection. Necessary precautions should be taken when transporting the Arc Module Incyte SU. For repair or shipment the Arc Module Incyte SU should be sent back in the original reusable packaging box. Every Arc Module Incyte SU sent back for repair must be decontaminated. If the conditions described in these operating instructions are not adhered to or if there is any inappropriate interference with the equipment, all of our manufacturers' warranties become obsolete.

3.2 Operation Precautions of Arc Module Incyte SU

The Arc Module Incyte SU must be used for the Intended Use (chapter 1.1 «Intended Use»), and in optimum safety and operational conditions. Potential hazards exist if the Arc Module Incyte SU is not operated correctly. Strictly follow the instructions given to connect (chapter 6.1 «Connecting the Arc Module Incyte SU to a Incyte-P SU») and disconnect (chapter 6.7 «Disconnecting the Arc Module Incyte SU from an Incyte-P SU») the Arc Module Incyte SU from an Incyte-P SU.

NOTE: Make sure that no air or gas bubbles sticks to the sensitive part of the sensor.

⚠ ATTENTION! Do not apply excessive forces while connecting, use or disconnecting the Arc Module to avoid damage.

3.3 Electrical Safety Precautions

Do not connect the Arc Module Incyte SU to a power source of any voltage beyond the power rating stated in the Specification Sheet (www.hamiltoncompany.com). Always use Hamilton VP cables for safe connection. Cables are available in a broad range of lengths (see chapter 9.3 «Parts and Accessories»). Make sure the cable is intact and properly plugged in to avoid any short circuit.

Keep the Arc Module Incyte SU away from other equipment that emits an electromagnetic radiofrequency field, and minimize static electricity in the immediate environment of Arc Module Incyte SU and Incyte SU. Carefully follow all the instructions in chapter 5 «Installation» to avoid electrical damage to the Arc Module Incyte-P SU. The contacts must be clean and dry before the Arc Module Incyte SU is connected to the cable.

⚠ ATTENTION! If the power supply (24 V +/- 10%) is switched off or disconnected, the reading on the process control system is wrong.

⚠ ATTENTION! Switch off the power supply and unplug the connector before dismounting the Arc Module Incyte SU.

Earthing

It is recommended to assign the VP8 cable shield to ground or earth especially in electromagnetically noisy environments. This significantly improves noise immunity and signal quality. The VP8 thread is connected to the metallic housing of the Arc Module Incyte SU.

NOTE: Avoid earth loops (see Figure 1), and damage of the sensor due to electrostatic discharge while mounting and dismounting of the sensor or the cable. Do not touch contacts of the connector.

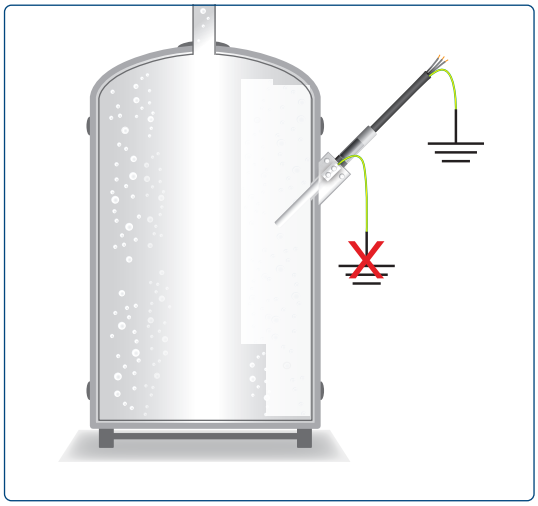


Figure 1: Single-use container with no earth connection: Connect cable shield to earth.

3.4 Chemical, Radioactive or Biological Hazard Precautions

Selection of the appropriate biological safety level and implementation of the required biosafety measures for working with Arc Module Incyte SU is the sole responsibility of the user. If working with hazardous liquids observe and carry out the maintenance procedures, paying attention to cleaning and decontamination. If Arc Module Incyte SU becomes contaminated with biohazardous, radioactive or chemical material, it should be cleaned. Failure to observe and carry out the maintenance procedures may impair the reliability and correction functioning of the system.

4 Product Description

4.1 General Description

Continuous monitoring of bioprocesses is required for both process control and optimization. The control of the environmental conditions including pH or dissolved oxygen is well established but does not provide information on the cell physiology. Parameters relating to cell physiology are usually monitored off-line after periodic sampling of the culture. This method is time-consuming and provides only discrete information on the bioprocess. The Arc Module Incyte SU together with the Incyte-P SU offer an alternative for continuous monitoring of viable cell density in real time.

The Arc Module Incyte SU in combination with the Incyte-P SU enables real-time, and on-line measurement of permittivity, which correlates with the viable cell density. The measurement is not influenced by changes in the media, or by the presence of microcarriers, dead cells, and cellular debris. The Arc Module Incyte SU together with the Incyte-P SU has been especially designed for monitoring the culture of mammalian and insect cells. Online monitoring of permittivity with Incyte enables the early detection of process deviations, may reduce sampling effort and supports timely process adjustment.

Wireless communication directly from the sensor may be used for monitoring, configuration and calibration, and saves time without compromising the quality of the wired connection.

The Arc Module Incyte SU together with the Incyte-P SU is compatible with all other components of the Hamilton Arc family, including a complete family of intelligent sensors (pH, ORP, dissolved oxygen and conductivity) and accessories. Reusable and single-use sensors can work on the same system. Additional wireless sensor

diagnostics functionality is enabled by the ArcAir™ App running on mobile devices (e.g. Hamilton's Arc View Mobile) and computers.

Key benefits include:

- Stable real-time, and online measurment of permittivity
- Simple maintenance with robust industrial design
- Reusable electronic, detachable from the Incyte SU
- No separate transmitter needed
- Direct digital Modbus communication to the PCS system
- Full online wireless option via Bluetooth for easy monitoring, configuration and calibration

4.2 Hardware Description

Always check the Arc Module Incyte SU for defects after unpacking. In the unlikely event of a damaged Arc Module Incyte SU, return it immediately in original packing to your Hamilton representative (see chapter 7.3 «Return Back for Repair»).

The Arc Module Incyte is available in two versions:

Sensor	Description
Arc Module Incyte-P SU	Arc Module for stirred tank application (mounting at a right angle to the bag respectively Incyte-P SU surface)
Arc Module Incyte-W SU	Arc Module for wave bag application (mounting parallel to the bag respectively Incyte-P SU surface)

Figure 2: Arc Module Incyte-P SU.

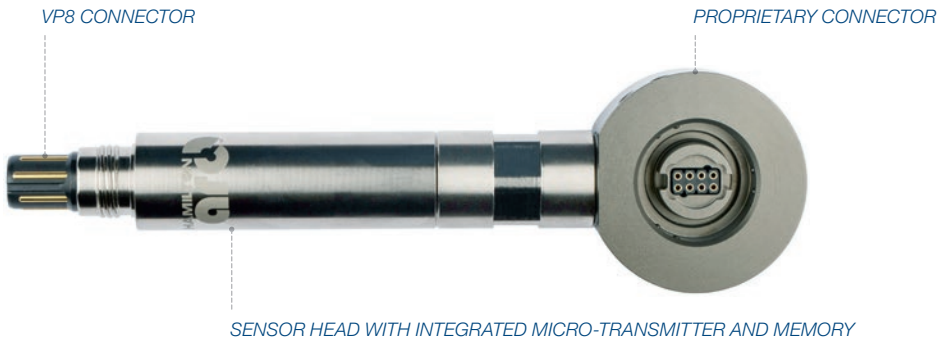


Figure 3: Arc Module Incyte-W SU.

Both Arc Modules provides the full functionality including the fitting of Cole-Cole and export of the scan data to ArcAir™. This is required to build an ArcAir Data Model.

The Arc Module Incyte SU is delivered directly from the factory, pre-configured. The integrated RS485 digital interface (Modbus RTU) is configured according to factory defaults. Full details, including serial number and the most important specifications can be found on the Incyte-P SU tag provided with each sensor element. To be sure to avoid electrical damage to the Arc Module Incyte SU, carefully follow all the instructions in the section entitled «Electrical Connection». Before using the Arc Module Incyte SU for measurement, monitoring or regulation, be sure to first check its configuration with an operational test.

The Arc Module Incyte SU provides the possibility to record 3 weeks of data in the Arc Module Incyte SU, with a recording interval of 12 minutes of dual frequency measurement and scan. This corresponds to 7191 measurement points.

4.3 The Theory of Permittivity Measurement

4.3.1 The Dual-Frequency Measurement Mode

In an alternating electrical field viable cells behave like small capacitors, but not dead cells or cellular debris (Figure 4). The charge of these small capacitors is measured by the Arc Module Incyte SU together with Incyte-P SU and reported as permittivity in pF/cm.

The permittivity of viable cells is measured at a frequency specific to the cell type (measurement frequency): usually 1 MHz for mammalian cells (Figure 5). It is continuously and automatically corrected for the background permittivity measured at high frequency (background frequency) This is the standard Dual-Frequency Measurement Mode. The permittivity measured by Arc Module Incyte SU can be correlated to the viable cell density, especially during the exponential growth phase.

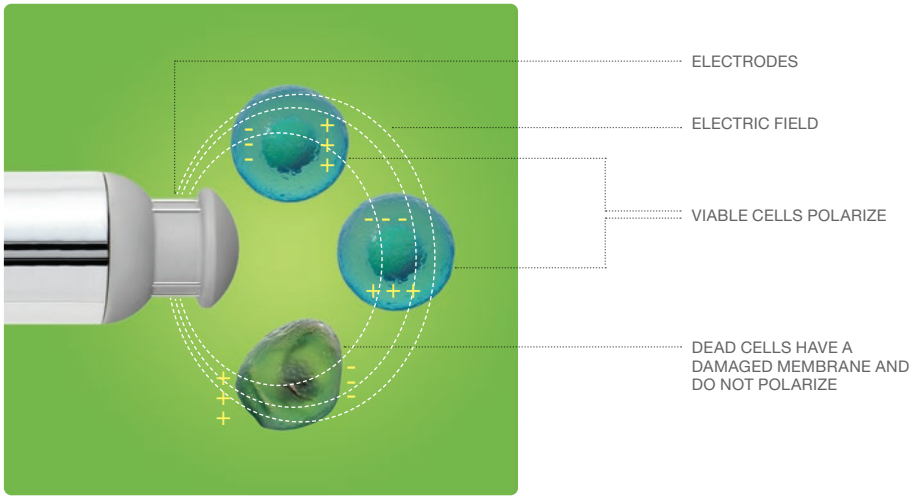


Figure 4: Incyte measurement principle. Viable but not dead cells exhibit a permittivity signal.

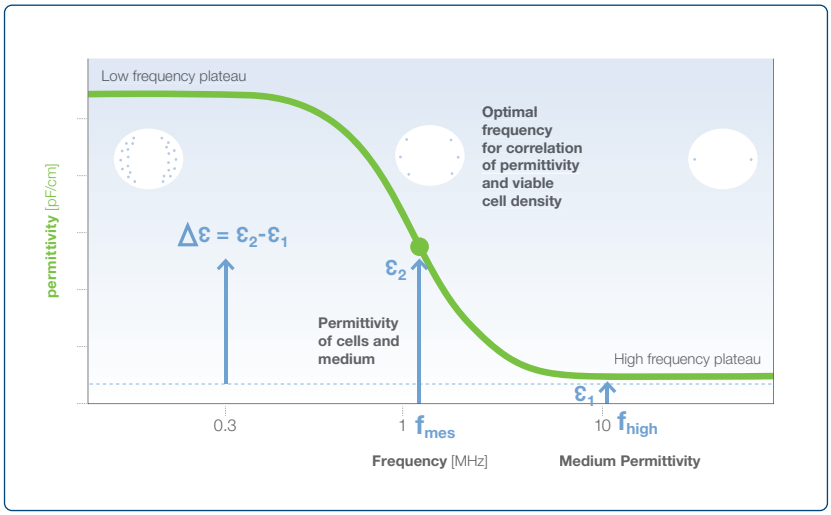


Figure 5: In the dual measurement mode the permittivity of viable cells is measured at a frequency specific to the cell type (measurement frequency) and corrected by the background permittivity measured at high frequency (background frequency).

4.3.2 Advanced Correlation and the Frequency Scan Mode

NOTE: Please contact you local representative for further details.

Theory of Data Modeling for Advanced Off-line/On-line-Correlation

The signal from the Arc Module Incyte SU indicates the bio volume in the process by measuring the permittivity. When measuring in Dual-Frequency Measurement Mode (using selected frequencies) a linear correlation of permittivity with the viable cell density can be generated. During exponential growth, the biovolume and the viable cell density are proportional. The permittivity measurement can be easily and reliably transformed into the unit of cell density via a linear correlation. This can change when the cells enter the stationary growth phase. The number of viable cells remains the same while the cells swell towards the end of their life cycle (initiation of apoptosis), this can be detected with the measuring principle of the Arc Module Incyte SU and leads to an increase in permittivity. An improvement of the correlation can be achieved by using multiple frequencies and multivariate data tools. ArcAir Data Modeling is Hamilton's tool to achieve exactly this improvement. This software is available free of charge on the website (www.hamiltoncompany.com) for customers with the Arc Module Incyte SU. For more information (e.g. usage in GMP Environment), refer to the ArcAir Data Modeling (Ref 111003989).

Theory of the Scan and Cole-Cole Fitting

The polarization behavior of cells varies strongly at different frequencies, as shown in Figure 6. Cells fully polarize at low frequency whereas they hardly polarize at high frequency. This behavior can be described by the mechanistic Cole-Cole equation. The Incyte Scan measures the permittivity signal at 17 different frequencies between 0.3 and 10 MHz (see Figure 6).

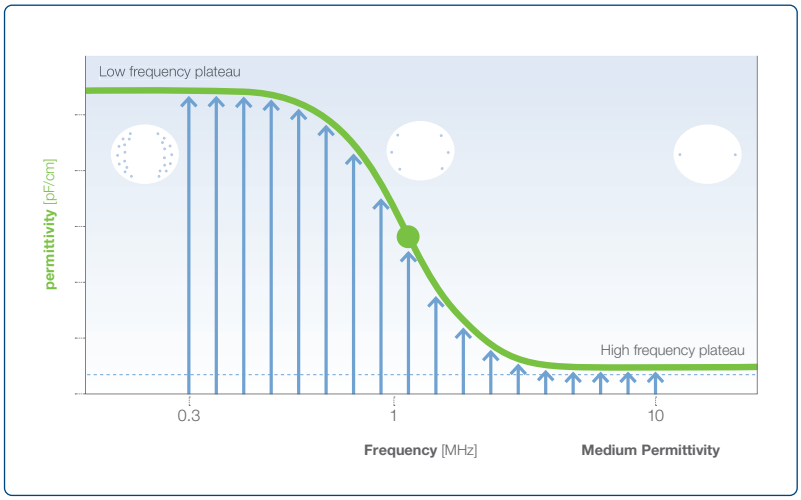


Figure 6: The ideal frequency spectrum of mammalian cells, called beta-dispersion.

The analysis of the Incyte Scan may provide additional information on the cell physiology. During the Incyte Scan the most relevant parameters of the Cole-Cole equation – Δε, f_c, and α (Figure 7) – are automatically fitted and displayed in ArcAir™. The characteristic frequency, f_c, may offer an indication of the average cell diameter. A decrease of f_c, may show that the cell diameter increases during the culture. On the contrary, a shift of f_c towards the higher frequency range may indicate that the cell size reduces. The height of the fitted low frequency plateau, Δε, can correlate with the viable cell density. It increases as the cells grow. The slope (α) of the beta-dispersion at the characteristic frequency f_c may provide an indication of the distribution of the cell diameter. A steep slope, i.e. a large α may correlate to a homogenous culture. The scan parameters are provided with a confidence rating, called fitting quality («Cole fit R2»), as not all cultivations may support a good calculation of these parameters. The indicator shows a value between 100 and 0 %, whereas 100 % relates to an ideal fit and 0 % refers to none fitting data. In addition the Model Error («Cole fit RMSE») is provided in the culture file and Modbus output for further offline data analysis. Whereas a model error as close as possible to 0 indicates a very good fit, the higher it counts to infinite, the worse is the fit.

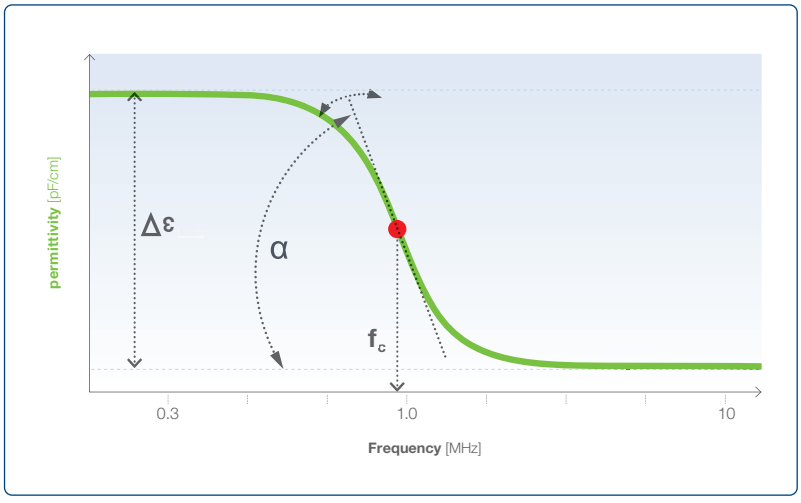


Figure 7: Data Interpretation of the beta-dispersion, gained from an Incyte Scan.

NOTE: At Arc Module Incyte SU Cole-Cole Fit is optimized to run on the sensor and may lead to different values of alpha, f_c and Δε compared to Incyte preamp-version.

5 Installation

5.1 Unpacking and cleaning

1) Carefully unpack the Arc Module Incyte SU. Enclosed you will find the Arc Module Incyte SU, the Arc Module Incyte SU Quick Guide and Declaration of Conformity (DoQ).
2) Inspect the sensor for shipping damages or missing parts.
3) For cleaning purposes of the Arc Module, soak a paper towel with Isopropanol 70 – 80 % or Ethanol 70 – 80 % and wipe down the module. After cleaning the module, air dry to connecting with the Incyte-P SU . Make sure that all contacts of module and sensor are completely dry to prevent electrical damage (short circuit).

⚠ **ATTENTION! The Arc Module Incyte SU is not designed for gamma or steam sterilization.**

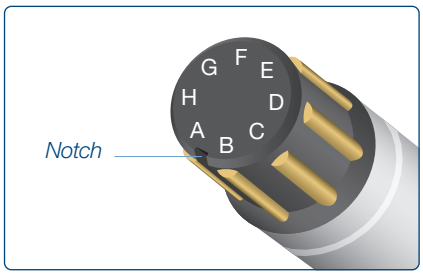
⚠ **ATTENTION! The Arc Module Incyte SU can measure and communicate over a digital RS485 interface up to a temperature of 60°.**

NOTE: The performance of the Incyte-P SU maybe altered by damage of the electrodes in aggressive media, high temperature, or by contamination of the electrodes during the sensor's lifetime. The quality indicator of the Arc Module Incyte SU shows a deviation of the zero point when performing a validation in conductivity standard 12.88 mS/cm. The quality indicator status is updated automatically after each verification.

⚠ **ATTENTION! The Arc Module Incyte SU is not compatible with the Cell Density Monitoring System. It is not possible to connect Arc Module Incyte SU to the Arc View Controller, ComBox or PC Box.**

5.2 Electrical Connection

The Arc Module Incyte SU is fitted with a VP8 socket head. The eight golden contacts are denoted as pin A to pin H. For easy identification of each pin, the head has a notch between pin A and pin B (see Figure 8). For the easiest and safest connection of Arc Module Incyte SU, always use Hamilton VP8 cables, available in a range of different lengths.



VP Pin	Function
C	Power supply: +24 VDC (7 to 30 VDC)
D	Power supply: Ground
G	RS485 (A)
H	RS485 (B)

Figure 8: Pin configuration of the Arc Module Incyte SU.

5.3 Connection to PCS or Controller

5.3.1 Layout and Overview

The Arc Module Incyte SU can be connected to the PCS or controller by a wired connection (for reference numbers see chapter 9.3 «Parts and Accessories»):

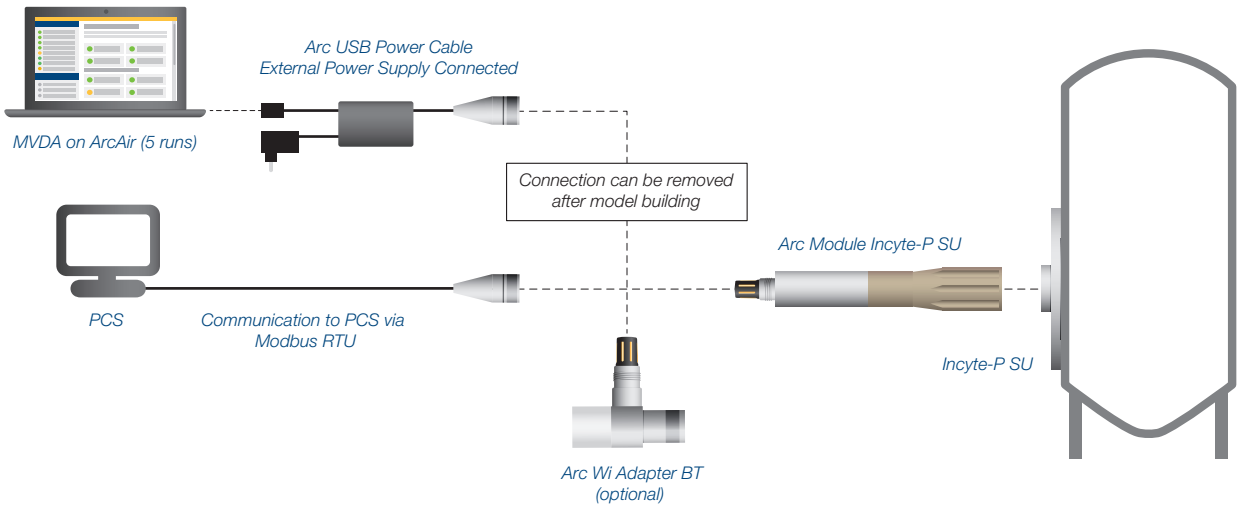


Figure 9: Wired connection to PCS with digital signal.

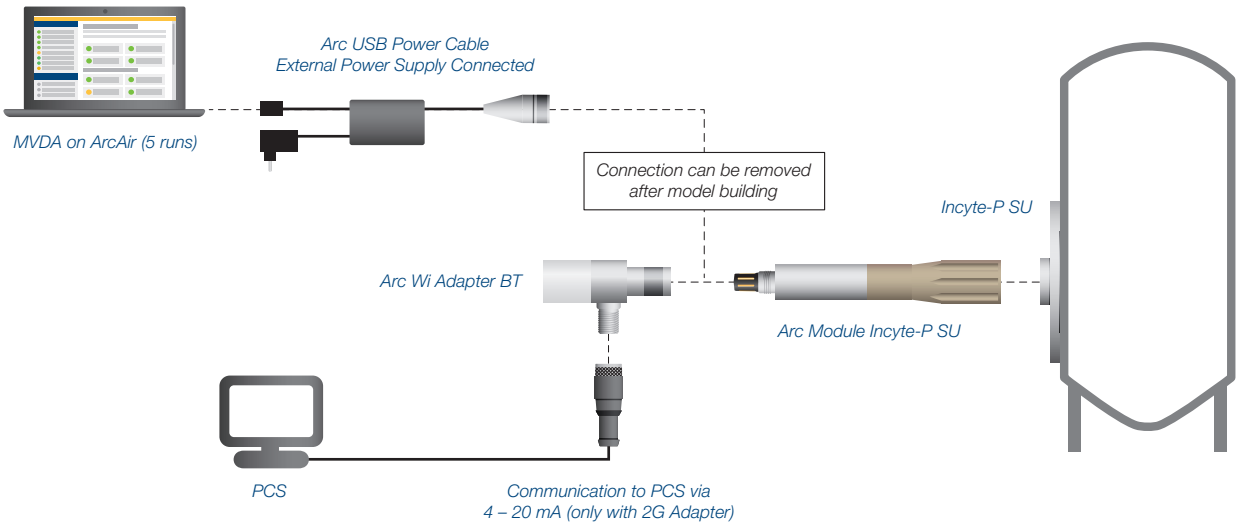


Figure 10: Wired connection to PCS with 4–20 mA signal.

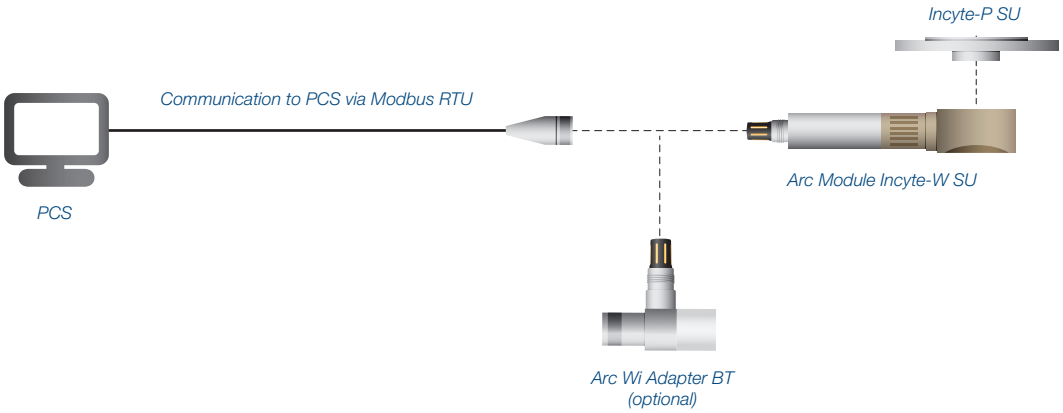


Figure 11: Wired connection to PCS with digital signal in wave bag application.

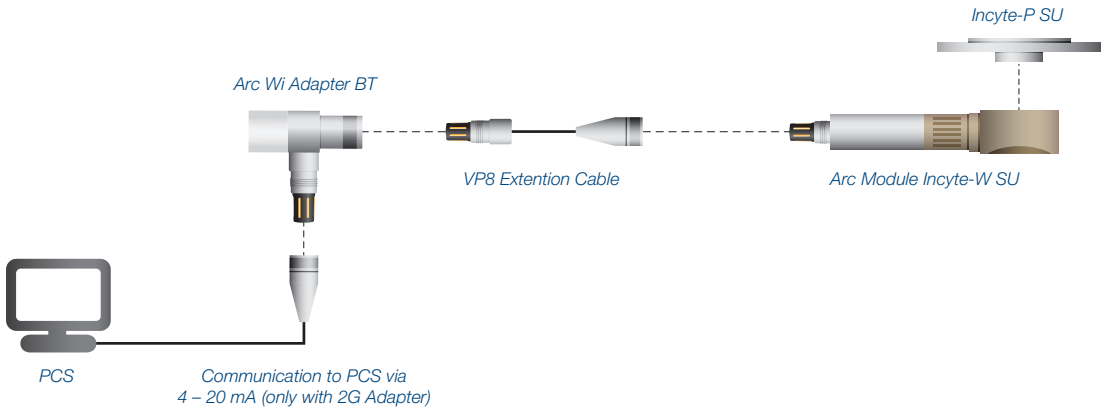


Figure 12: Wired connection to PCS with 4–20 mA signal in wave bag application.

NOTE: The MVDA is not applicable for Arc Module Incyte-W SU as the scan function is needed. In the wave application the scan function is not feasible.

The digital RS485 interface of the Arc Module Incyte SU can be accessed by operators when integrated by the OEM system supplier. The three-tier operator levels and factory default passwords are shown in the table below.

Operator Status	Operator Level	Password	Read	Calibrate	Configure
User	U	–	✓	–	–
Administrator	A	18111978	✓	✓	
Specialist	S	16021966	✓	✓	✓

⚠ ATTENTION! For automatic sensor login a unique and global Operator Level S password for all intelligent sensors is required. Please make sure you have added the same Operator Level S Password for all Arc sensors in the ArcAir application under Backstage/Settings/Operator Level S Password.

5.3.2 Electrical connection of the 4-20 mA current interface

The 4–20 mA interface enables indirect connection of the Arc Module Incyte SU (only in combination with the Arc Wi Adapter 2G, REF 243470) to a data recorder, indicator, control unit or PCS with analog I/O. With the Arc Wi Adapter the Arc Module Incyte SU works as a current sink and is passive. Connect the Arc Module Incyte SU according to the pin designations (see Quick Guide «Arc Wi 2G Adapter BT» on www.hamiltoncompany.com). The 4–20 mA interface of the combination between Arc Wi Adapter and Arc Module is pre-configured with default values for the 4–20 mA range, and measurement unit. Configure the 4–20 mA interface according to your requirements for proper measurement (see chapter 5.4.5 «Configuring the Analog Interface for Your Process Control System»).

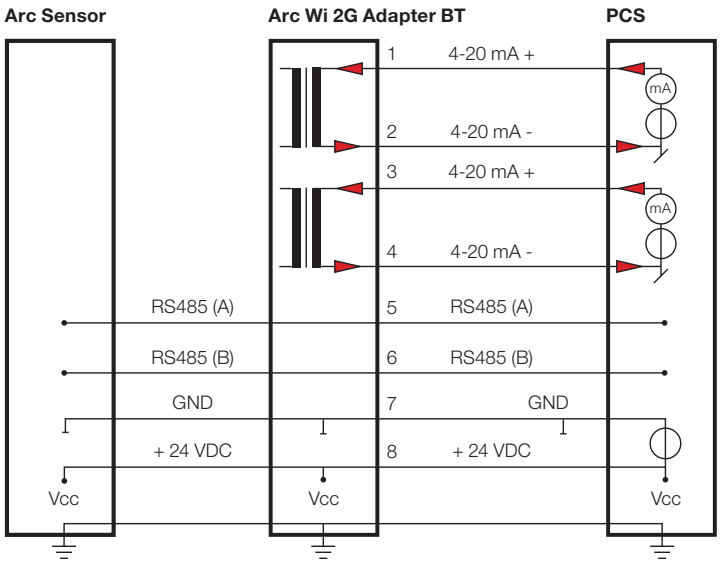


Figure 13: Typical connection to PCS using the Arc Wi 2G Adapter BT. This is the safest form of wiring an Arc sensor. The Arc Wi 2G Adapter BT provides internal galvanic isolators for enhanced analog signal quality. Connection to the PCS is simplified. Connection to the process control system is simplified.

5.3.3 Connection by Modbus

The digital RS485 interface enables communication with Arc Module Incyte SU for the Incyte-P SU to perform measurements, calibrate the sensor and change the sensor's configuration parameters. Arc Modules are always connected to digital controlling devices as a Modbus slave. To function, they require a power supply using VP8 pins C and D (see Figure 8). The section entitled «Operation» (see chapter 6 «Operation») describes the operation in digital mode.

By using the correct access password the system operator can adapt the Arc Module to many tasks by:

- Selecting the measured parameter:
  - Permittivity: PCV, g/ml, e6cells/mL, pF/cm, OD
  - Conductivity: mS/cm
  - Temperature T: °C; K, °F

In addition, operators can read sensor information from the RS485 interface such as:

- The sensor's serial number (SN), reference number (Ref) and manufacturing number (Lot)
- The Arc Module Incyte SU firmware version
- The Arc Module Incyte SU status (e.g., operation hours, warnings and errors)

Additional information:

The Modbus RTU communication protocol corresponds to the Modbus-IDA standard (see www.modbus.org). Arc Module Incyte SU for Incyte-P SU use an open register set developed by Hamilton. Additional information about the Modbus RTU communication protocol can be found in the «Arc Module Incyte SU Programmers Manual» at www.hamiltoncompany.com.

⚠ ATTENTION! Because all Arc Module Incyte SU are delivered with factory-default settings, each Arc Module Incyte SU must be configured for its specific application before first use the Arc Module Incyte SU Paratmeters (see chapter 5.4.4 «Configuring the Arc Module Incyte SU Parameters»).

NOTE: In an electromagnetically noisy environment, it is advisable to connect the VP cable shield to the earth. This significantly improves noise immunity and signal quality

Examples of the circuit arrangement

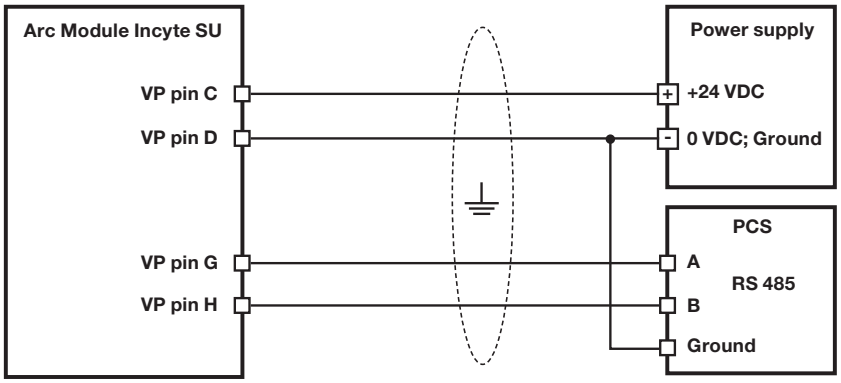


Figure 14: Wiring diagram for the RS485 interface.

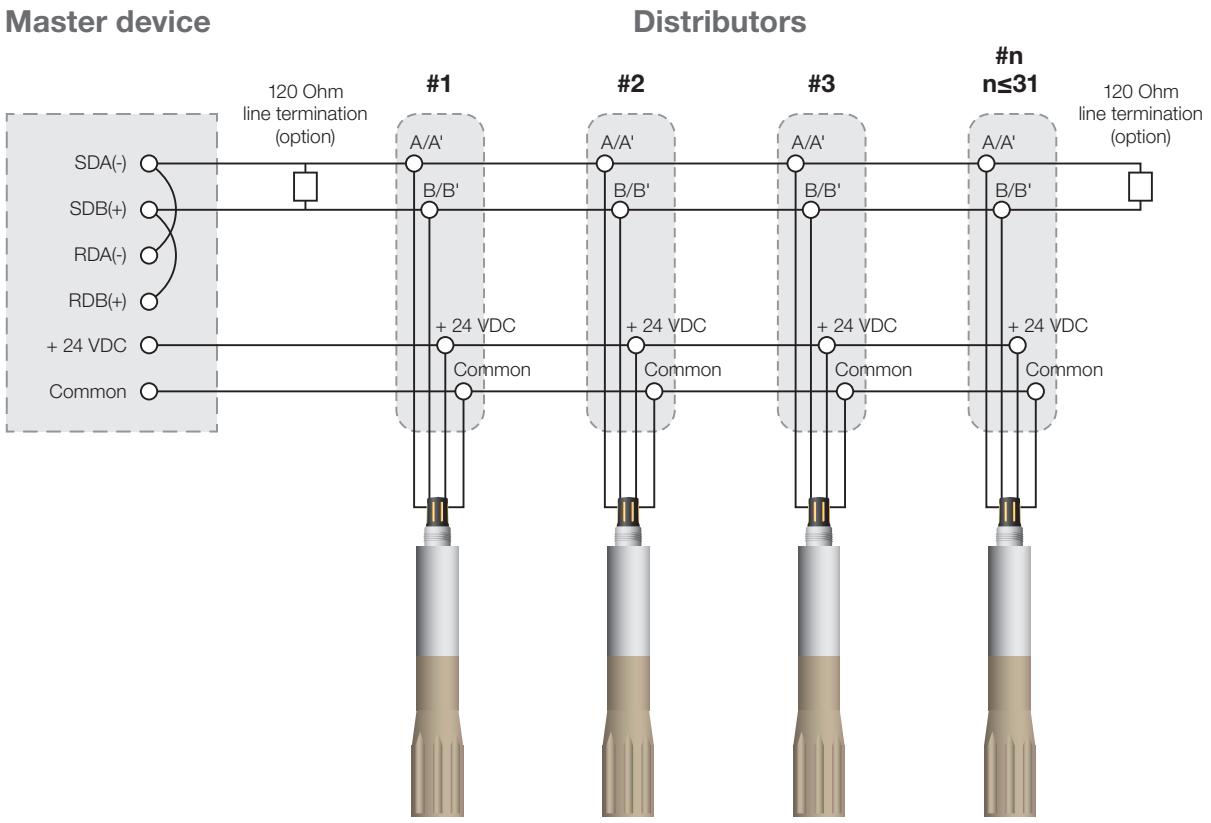


Figure 15: Multi-drop bus wiring for the Modbus two-wire mode. Each sensor functions as a Modbus slave.

NOTE: In the connection scheme shown above (see Figure 15), each Arc Module Incyte SU must have the unique Modbus device address for proper communication.

The serial Modbus connection between the RS485 port of the master and the corresponding interfaces of the sensors has to be ensured according to the EIA/TIA RS485 standard. Only one sensor can communicate with the master at any time.

5.4 Connection to PC or Mobile

5.4.1 Layout and Overview

With the Arc Sensor family, Hamilton supplies intelligent sensors for process monitoring. With their integrated micro-transmitter, the Arc Module Incyte SU enable direct communication to the process control system using digital Modbus communication, and optionally via 4-20 mA interface, using the Arc Wi Adapter 2G BT (Ref 243470). Bluetooth wireless communication with the Arc Wireless Adapter may be used for configuration, troubleshooting and saves time without compromising the quality of the wired connection (see Figure 18). It enables wireless communication with smartphones, tablets or computers. A wired connection can be realized using an Arc USB Power Cable (Ref 243490) and a computer (see Figure 19). With the integrated micro-transmitter, the Arc Module Incyte SU provide more reliable measurement directly to the process control system or to the ArcAir software.

Key benefits include:

- No separate transmitter needed
- Simple maintenance
- Easy to install
- Optional digital Modbus or analog communication via Arc Wi 2G Adapter BT (Ref 243470)
- Full on-line wireless option via Bluetooth 4.0 for easy configuration
- Recording functionality (in ArcAir, or the on sensor) with data export
- Advanced measurement correlation and multivariate data modeling by using the ArcAir Data Modeling (Ref 111003989)
- Reporting and central data management of users and validation reports for verification, configuration and communication within the GMP guidelines, including FDA CFR21 Part 11 and Eudralex Volume 4 Annex 11.

NOTE: For the Arc Module Incyte-W SU in combination with the Arc Wi Adapter BT, an extention cable (available on request) is needed as the Bloetouth signal is shielded by the tray respectively the liquid in the bag.

NOTE: Wireless communication is not intended to be used for process control.

A wired connection to the PC is possible using the USB port. For connection to the PC, an Arc USB Power Cable (Ref 243490-01; Version 01) is needed. The Version 01 is required as it offers a connector for the optional external power supply.

5.4.2 ArcAir™

The ArcAir application offers efficient and safe communication for monitoring, validating, management and recording of sensors. It also offers a user management. Combining the reliability of Arc Module Incyte SU with the power, convenience and portability of mobile devices, users benefit from configuration in the laboratory, along with product calibrations (Mark and Clear Zero) in the process environment, as well as Sensor Verification. The additional reporting functionality offers management of reports for validation, verification, configuration, communication and user profiles within the GMP regulatory requirements for all Arc sensors. ArcAir offers an overview of all the Arc sensors in the operating environment, through computer, tablet and mobile phone. The mobile version only supports the most important workflows - data recording and display of the Experiment is not available.

A detailed explanation can be found in the ArcAir System Manual (Ref 10071115).

1. Download the Zip file «ArcAir» from www.hamiltoncompany.com (search for ArcAir).
2. Unpack the ZIP file.
3. Do not plug in the Wireless Converter before the installation of ArcAir™ is completed.
4. Install ArcAir™ by double clicking «ArcAir.exe» and follow the instructions on the screen.

To upgrade your PC version from Basic to Advanced version, you must connect your PC using the Arc Wireless Converter BT Advanced with your mobile device or by using Arc View Mobile Advanced. For this

purpose, the mobile device must run on the correct ArcAir™ version (Advanced) to activate the upgrade on your PC (for more details, see also «Arc System Operating Instructions» on www.hamiltoncompany.com).

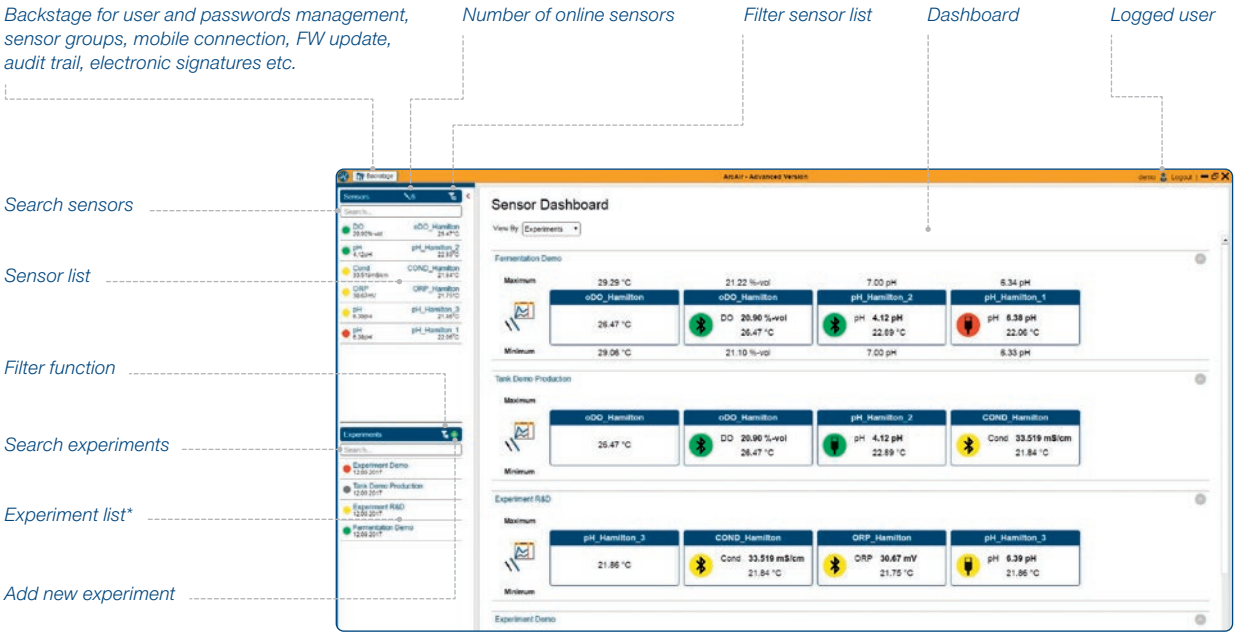


Figure 16: ArcAir™ Software application on computer.

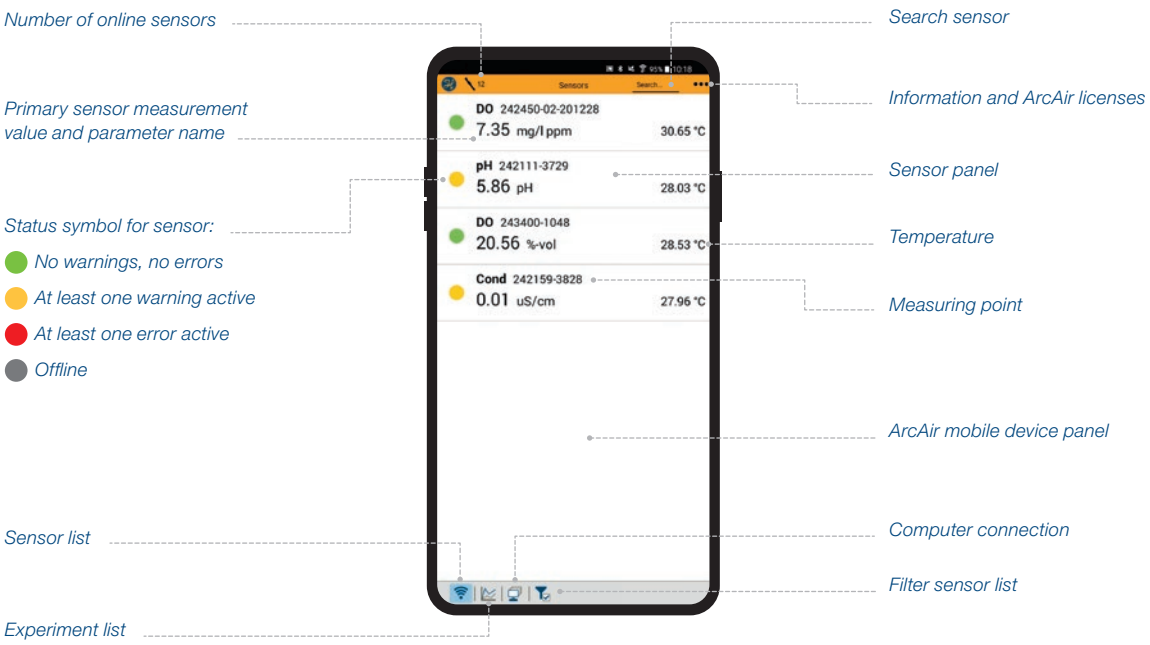


Figure 17: The ArcAir™ application on mobile.

	ArcAir Basic	ArcAir Advanced
Availability	Free download from Hamilton website or App Store	Update from Basic version via in-App purchase in the App Store or through the PC via Arc Wireless Converter BT (Ref 242333)
Intended for	PC/Mobile	PC/Mobile
Functions	Measuring, Sensor Status, Experiment function, Configuration, Firmware update	Full incl. Verification, Communication Validation, User Management, Audit Trail, Report functionality

NOTE: For more detail information and configuration see Hamilton Arc System Operating Instructions on www.hamiltoncompany.com.

5.4.3 Connecting Arc Module Incyte SU to ArcAir™

The Arc USB Power Cable (Ref 243490) is required to connect the Arc Module Incyte SU. A wireless connection is possible with an Arc Wi Adapter BT (see chapter 9.3 «Parts and Accessories»).

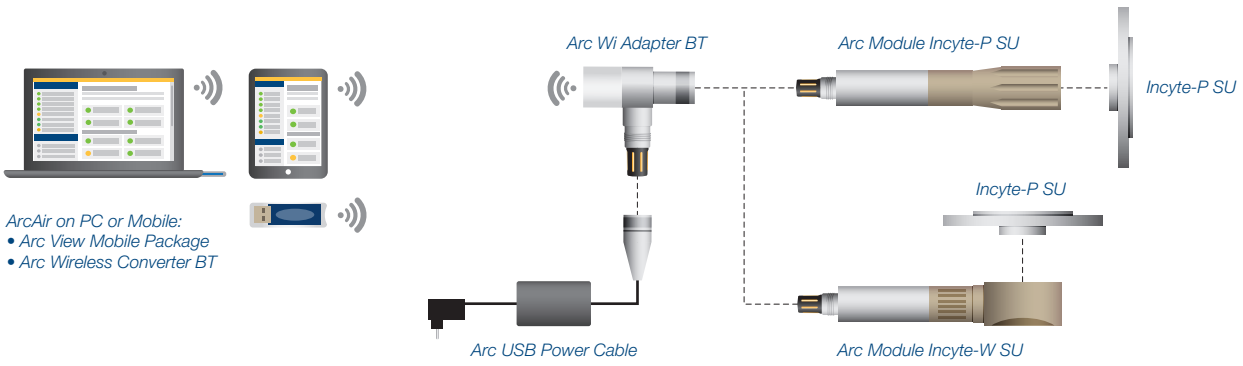


Figure 18: Layout for wireless connection.

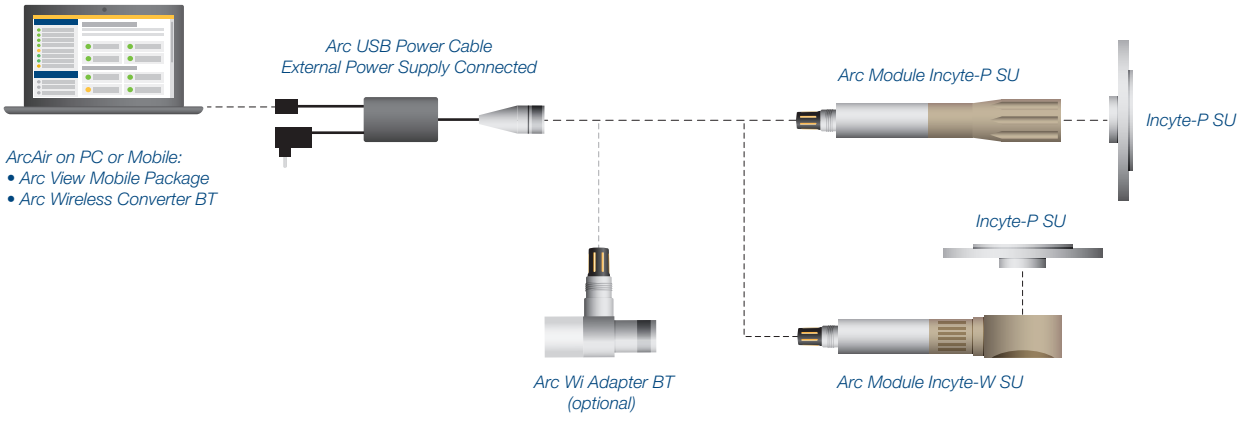


Figure 19: Layout wired connection to PC or notebook.

1) Connect the Arc Module Incyte SU with the power supply, e.g. Arc USB Power Cable (see Figure 18) or connect the optional Arc Wi Adapter BT (see Figure 19)
2) Switch on the mobile's Bluetooth connection or connect a Wireless Converter BT to USB Port of your PC (only for wireless connection)
3) The ArcAir™ application recognizes and displays the connected sensors automatically

⚠ ATTENTION! For automatic sensor login a unique and global Operator Level S password for all intelligent sensors is required. Please make sure you have added the same Operator Level S Password for all Arc sensors in the ArcAir application under Backstage/Settings/Operator Level S Password.

5.4.4 Configuring the Arc Module Incyte SU Parameters

1) Start the ArcAir™
2) Select the desired Arc Module
3) Open the tab «Settings» (make sure you have the «Sensor Settings» user right)
4) Configure the sensor

A description of the available settings is given below:

Parameter Name	Description	Default Setting	Range	Configuration	Location
Measuring Point	User can define a sensor name (must be unique) for better identification of the measuring point	10076676-1234	not empty	Recommended default parameter	Info / Measurement Point or Settings / Measurement Settings
Measurement Unit VCD	These are the measurement physical units	pF/cm	PCV, g/ml, e6 cells/ml, pF/cm, OD	Required	Measurement Settings
Measurement Unit Conductivity	These are the measurement physical units	mS/cm	mS/cm	Required	Measurement Settings
Temperature Unit	These are the temperature physical units	°C	°C, K, °F	Required	Measurement Settings
Min. Custom Measurement Temperature	Minimal value, where the electronic switches on	0	0 - 60	Required	Measurement Settings
Max. Custom Measurement Temperature	Minimal value, where the electronic switches off	60°C	0 - 60	Required	Measurement Settings

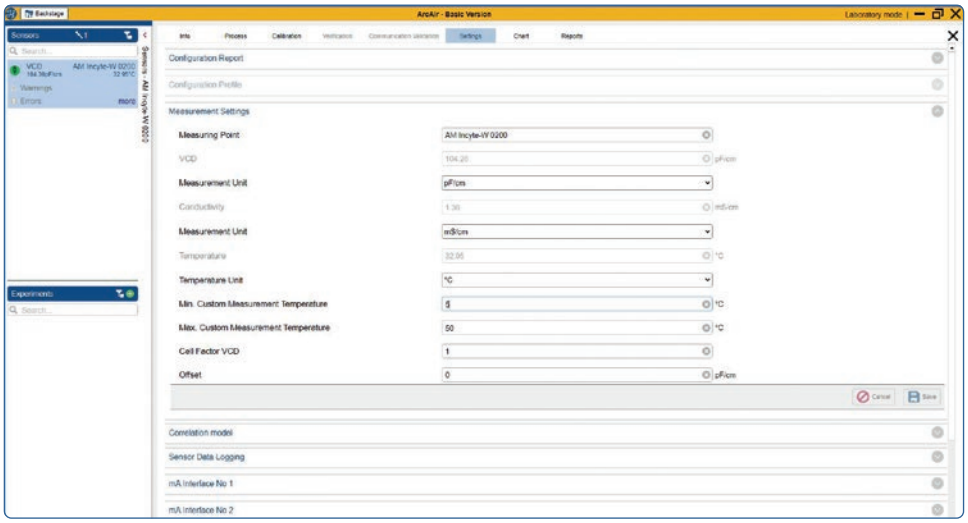


Figure 20: Measurement Settings.

5.4.5 Configuring the Analog Interface for Your Process Control System

Parameter Name	Description	Default Setting	Range	Configuration	Location
Mode	The output of the 4 to 20 mA can be configured linear, bilinear or with a fix value	4 to 20 mA linear	Off 4 to 20 mA fixed / linear / bilinear	Recommended default parameter	mA Interface
Assigned Measurement Channel	Defined measurement for this mA Interface	VCD	VCD, Conductivity, Temperature	Recommended default parameter	mA Interface
Value at 4mA (VCD)	Defined measurement value for 4 mA output	0 pF/cm	field must not be empty	Recommended default parameter	mA Interface
Value at 20mA (VCD)	Defined measurement value for 20 mA output	100 pF/cm	field must not be empty	Recommended default parameter	mA Interface
Value at 4mA (Conductivity)	Defined measurement value for 4 mA output	1 mS/cm	field must not be empty	Recommended default parameter	mA Interface
Value at 20mA (Conductivity)	Defined measurement value for 20 mA output	50 mS/cm	field must not be empty	Recommended default parameter	mA Interface
Value at 4mA (Temperature)	Defined measurement value for 4 mA output	0 °C	field must not be empty	Recommended default parameter	mA Interface
Value at 20mA (Temperature)	Defined measurement value for 20 mA output	100 °C	field must not be empty	Recommended default parameter	mA Interface
Warning Mode	Current output mode in case of warnings	Off	Off Continuous Warnings	Recommended default parameter	mA Interface
Error Mode	Current output mode in case of errors	Continuous errors	Off Continuous Errors	Recommended default parameter	mA Interface
Warning Value	Current output mode in case of warnings	3.6 mA	field must not be empty	Recommended default parameter	mA Interface
Error Value	Current output mode in case of errors	3.6 mA	field must not be empty	Recommended default parameter	mA Interface
Temperature out of range value	Current output mode in case of temperature out of limit	3.6 mA	field must not be empty	Recommended default parameter	mA Interface

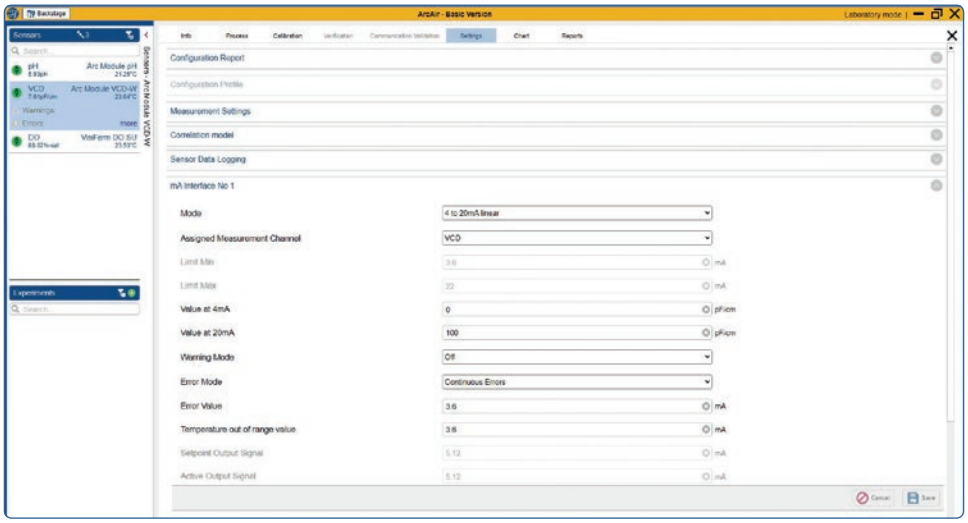


Figure 21: Measurement Settings for Analog Interface.

5.4.6 Defining a Measuring Point Name for Identification of the Process

Parameter Name	Description	Default Setting	Range	Configuration	Location
Measuring point	User can define a sensor name (must be unique) for better identification of the measuring point	10076676-1234	not empty	Recommended default parameter	Info / Measurement Point or Settings / Measurement Settings

5.4.7 Definition of the Modbus Communication in ArcAir™

1) Go to the «Measurement Settings» (Figure 20)
2) Open «Modbus»
3) Adjust, Device Address, Baudrate, Parity and Stopbits according to the needs
4) Press «Save»

NOTE: Following values are the standard settings: Device Address: 1; Baudrate: 19200, Parity: None, Stopbit:2

5.4.8 Reset the Sensor

1) Go to the «Measurement Settings» (Figure 20)
2) Open «System»
3) Activate «Restore of Factory Settings» and press «Save»

6 Operation

NOTE: This operation description refers to ArcAir™. For operation with PCS refer to operating instructions from the OEM system supplier.

⚠ ATTENTION! Only use the Arc Module Incyte SU according to the «Specification Sheet» on www.hamiltoncompany.com. Failure to do so may lead to damages or measurement failure.

6.1 Connecting the Arc Module Incyte SU to a Incyte-P SU

⚠ ATTENTION! Do not apply excessive forces while connecting the Arc Module Incyte SU to avoid any damage.

Prepare the sensor for measurement as follows:

1) Connect the Arc Module Incyte SU to the Incyte-P SU (see chapter 5.2 «Electrical Connection»).
   For Arc Module Incyte-P SU:
   - Hold the Arc Module Incyte SU housing and screw in the coupling nut
   For Arc Module Incyte-W SU:
   - Push the Arc Module Incyte-W SU gently on the Incyte-P SU
   The Connectors of the Incyte-P SU as well as the Arc Module Incyte SU is keyed. Please make sure to align the Arc Module Incyte SU to the alignment of the Incyte SU before fixing the Arc Module Incyte SU. This avoids unnecessary damage to the Incyte-P SU.
3) Make sure that the Arc Module Incyte SU is configured as required. If in doubt, test as described in chapter 5.4 «Connection to PC or Mobile»

The Arc Module Incyte SU is programmed with default calibration values. To achieve the best accuracy, execute calibration of the sensor (see chapter 6.2 «Calibration»).

NOTE: The status of the Arc Module Incyte SU (see Figure 60) maybe red initially, as the Arc Module Incyte SU cannot measure correctly in air. Upon insertion in conductivity solution or medium the Arc Module Incyte SU stay in yellow warning-state, as the Arc Module Incyte SU data are not applied for no scan fitting, or correlation-calculation can be done without cells/microorganisms.

NOTE: To create Communication Report go to the Communication Validation Tab in ArcAir™ and follow the instructions on the screen.

NOTE: The Arc Module Incyte SU is configured to Baudrate 19'200. In case the Baudrate is changed, the Arc Module may not be recognised by ArcAir. In this case go to the Backstage area >> «Settings» >> «Wired connection» and select the Baudrate, Parity and Stopbit according to your settings of the Arc Module Incyte SU. Press «Save».

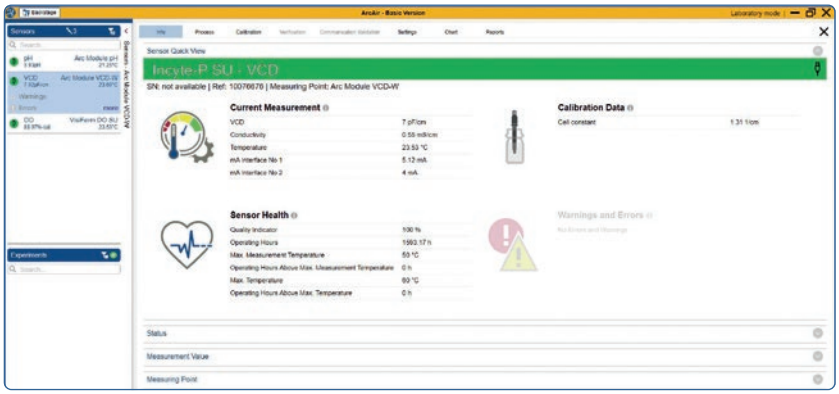


Figure 22: Overview Sensor Info Quick View.

NOTE: It is possible to connect up to 6 Arc Module Incyte SU via Arc USB Power Cable to one computer, using ArcAir. Data can then be recorded using the experiment feature in one or separate experiments. If connected via Bluetooth, only 1 Arc Module Incyte SU can be added to an experiment.

6.2 Calibration

The Incyte-P SU has been pre-calibrated; hence calibration prior to the process is not necessary. The calibration values for the cell constant can be found on the label attached to the Incyte-P SU.

Figure 23: Example of sensor label with calibration data.

1) Read the cell constant written on the Incyte-P SU label (Figure 23).
2) Enter the calibration and sensor data into the Arc Module Incyte SU:

   Calibration data (mandatory):
   Cell constant

   Incyte-P SU data (enter data for traceability):
   - Ref-number
   - Name
   - Lot-number
   - Lot date
   - SN-number
   - Sensor ID

   Push the save button to save the data.

3) If required, perform a product calibration step to increase accuracy for the conductivity value
4) Save the data to the Arc Module Incyte SU

NOTE: ArcAir™ on Mobile or Tablet supports automatic calibration for pre-defined calibration values by scanning the 2D-code. Use ArcAir™ to perform manual input of the calibration data. The concept behind Hamilton single-use Arc System enables calibration based on the pre-calibrated values.

Product calibration

The product calibration is an in-process calibration procedure in order to adjust the measurement to specific process conditions. Product calibration is an additional calibration procedure to a standard calibration. In order to restore the original standard calibration curve, the product calibration can be deleted at any time by selecting «Discard Existing Product Calibration». A new standard calibration deletes a product calibration as well.

1) Connect the Arc Module Incyte SU to ArcAir™
2) Select the desired sensor from the sensor list
3) Go to «Process Settings»
4) Click «Start» to start the product calibration wizard of the ArcAir™ App
5) Follow the instruction on the screen

NOTE: The product calibration is not the same as a «Mark Zero» in the process. It only calibrates the conductivity value to the process conditions.

6.3 Presetting of the Arc Module Incyte SU

6.3.1 Prepare the Sensor and Choose the Cell Type Mode

Measurement Settings

All important settings that are based on the measurement of the Arc Module Incyte SU can be found in this section. To activate the changes, click the save button at the bottom.

Setting	Description
Measuring Point	Name of the *Measuring Point*
VCD	According to the *Measurement Unit* below
Measurement Unit	pF/cm (Standard) and user defined correlated to the off-line measurement
Conductivity	Measurement of the conductivity in mS/cm
Measurement Unit	Set to mS/cm
Temperature	Temperature of the medium
Measurement Unit	°C as Standard, may be adjusted to K or °F
Min. Custom Measurement Temperature	Minimal temperature value, defined by the customer, where the electronic switches on

Setting	Description
Max. Custom Measurement Temperature	Maximum temperature value, defined by the customer
Cell factor	Cell factor value from 0.01 to 1 000 000, standard value is 1
Offset	Offset Value with two decimals. Will be overwritten if the Mark Zero Button is pressed in the Experiment.
Measurement Unit	pF/cm (Standard) and user defined correlated to the off-line measurement

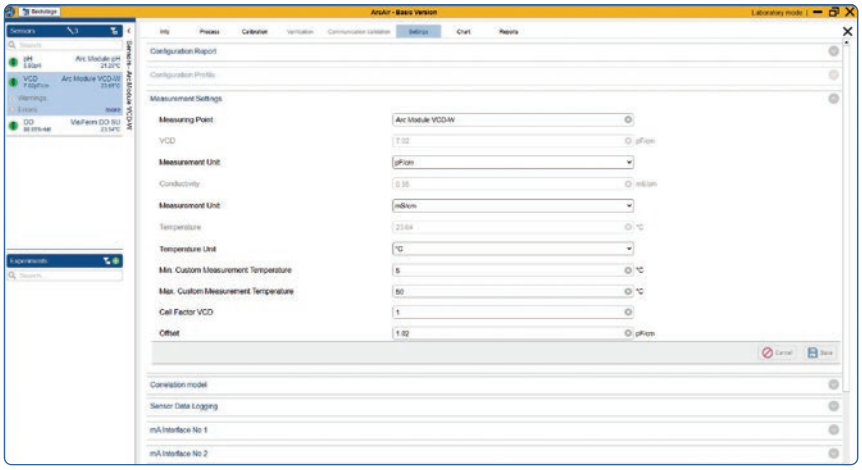


Figure 24: Example of the Setting section – Configuration Profile.

NOTE: For the whole range of Measurement Settings please refer to the ArcAir System Manual (Ref 1007115).

NOTE: A change of the measurement unit is not possible, when an AADM model is set active.

Available units for permittivity:

Unit	Description
PCV	Packed cell volume
g/l	gram per liter
e6 cells/ml	10^6 cells per milliliter
pF/cm	pico farad per centimeter
OD	Optical density

Available units for conductivity:

Unit	Description
mS/cm	Millisiemens per centimeter

Available units for temperature:

Unit	Description
°C	Degree Celsius
K	Kelvin
°F	Degree Fahrenheit

Cell Type Mode

It is possible to filter the signal. There are three different default settings based on the experience collected from different organism types. To activate the changes, click the save button at the bottom.

To create a customized cell type mode see «Cell Type Mode Configuration».

Cell Type Mode	Measurement frequency	Background frequency	Moving Average / Signal integration
Animal	1,000kHz	10MHz	Middle
Yeast	2,000kHz	10MHz	High
Bacteria	1,000kHz	10MHz	High
User 1	User defined	User defined	User defined
User 2	User defined	User defined	User defined
User 2	User defined	User defined	User defined

Find some further explanations on the Moving Average/Signal integration in the table below.

Moving Average/ Signal integration	Count of Measurements	Time needed for moving average calculation in Dual Scan Mode	Time needed for moving average calculation Scan Mode
None	1	3 s	3 s
Low	32	32 s	96 s
Middle	64	64 s	192 s
High	128	128 s	384 s

NOTE: The wave algorithm overwrites the integration time. The averaging time is adjusted automatically between 64 s up to 512 s depending on the rocking motion settings.

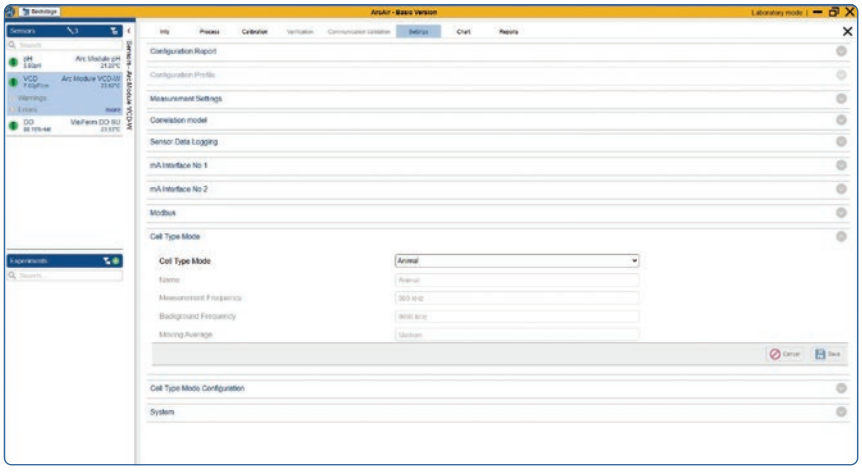


Figure 25: Example of the Setting section – Cell Type Mode.

Cell Type Mode Configuration

The filter option via the Cell Type Mode can be individualized using this menu item. The frequencies for the dual measurement can be defined and the values for the averaging can be set. The settings can be saved in three locations and provided with their own name (User 1-3).

NOTE: If Cole-Cole fittings are used for data analysis a high moving average time is strongly recommended.

1) Select User 1, 2 or 3 were the settings would be saved on.
2) If needed, define a dedicated name
   - Choose the measurement frequency from the drop down list
   - Press «Save»
   - Choose the background frequency from the drop down list
   - Press «Save»
   - Choose a moving average, between low, middle and high The moving average is a mean value over a defined amount of measurements:
     Low: 32 measurements (refers to dual 32 sec scan 96 sec)
     Middle: 64 measurements (refers to dual 64 sec, scan 192 sec)
     High: 128 measurements (refers to dual 128 sec, scan 384 sec)
3) Press «Save».

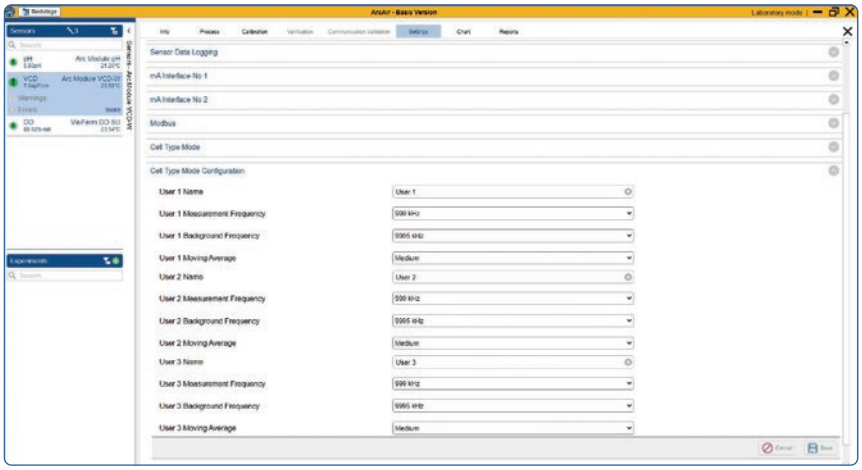


Figure 26: Example of the Setting section – Cell Type Mode Configuration.

6.3.2 Correlation to offline data

Correlation of the Dual Frequency Measurement

The Arc Module Incyte SU signal indicates the bio volume in the process by measuring the permittivity. When measuring in Dual-Frequency Measurement Mode (using selected frequencies) a linear correlation of permittivity with the viable cell density can be generated. During exponential growth, the biovolume and the viable cell density are proportional. The permittivity measurement can be easily and reliably transformed into the unit of cell density via a linear correlation. This can change when the cells enter the stationary growth phase. The number of viable cells remains the same while the cells swell towards the end of their life cycle (initiation of apoptosis). This can be detected with the measuring principle of the Arc Module Incyte SU and leads to an increase in permittivity. An improvement of the correlation can be achieved by using multiple frequencies and multivariate data tools. ArcAir Data Modeling is Hamilton's tool to achieve exactly this improvement (only available for Arc Module Incyte-P SU).

This software is available free of charge on the website (www.hamiltoncompany.com) for customers with Arc Module Incyte-P SU. For more information (e.g. usage in GMP Environment), refer to the ArcAir Data Modeling (Ref 111003989).

The measured permittivity may be correlated to off-line measurements in a simple linear calculation, by defining a cell factor on the dual frequency measurement.

1) Go to the «Process Settings» and select the «Process Settings»
2) Select the correlated Measurement Unit between PCV (packed cell volume), g/l, e6cells/ml or OD. PF/cm is the standard set up, as this refers to the measurement itself
3) Insert the calculated Cell Factor in the section «Cell Factor VCD»
4) Press «Save», the cell factor is copied to the process and measurement settings in the settings area

Cell Density Correlation on the Scan Data (only for Arc Module Incyte-P SU)

Using the frequency scan of Arc Module Incyte-P SU it is possible to improve the off-line/on-line correlation for reproducible processes (e.g. production), on the overall process, especially during the plateau and death-phase. The model is created offline in the ArcAir Data Modeling Software. The model can be transferred and run on the sensor to provide a real-time prediction of the viable cell density.

NOTE: The model is identified by a checksum and creation date and time to ensure data integrity between model building and import to ArcAir™. This information cannot be changed.

1) Go to the «Settings» and select the «Correlation Model»
2) Go to the «Import model» and select the correlation file (.incal)
3) Press «Import»

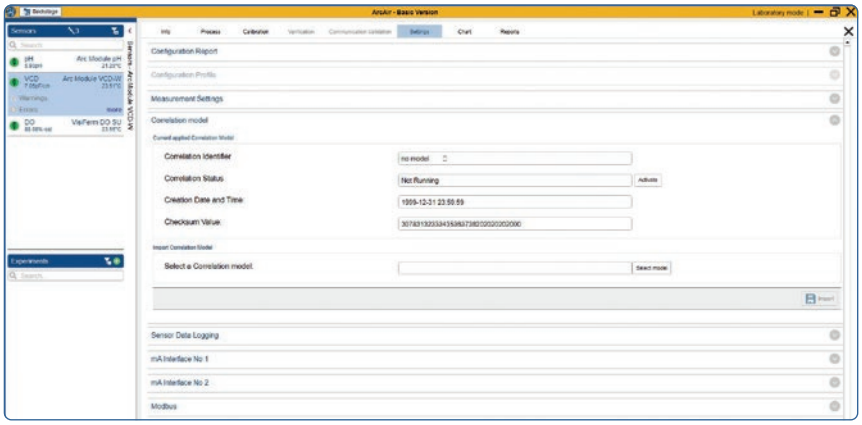


Figure 27: Arc Data Model Import.

1) Go to the «Current applied model»
2) Check that «Creation Date and Time» as well as «Checksum Value» are the same like in the selected model
3) Press «Activate»

NOTE: For the whole range of functionality of the ArcAir Data Modeling (AADM) please refer to the AADM Operating Instruction Manual (Ref 111003989).

6.3.3 Sensor Data Logging

In addition to ArcAir recording by cultivation data with the Experiment (chapter 6.4 «Run Culture») the data can also be stored independently from ArcAir directly on the sensor head. This function is available via Sensor Data Logging. The internal memory allows the storage of 8191 measurements. The record rate setting defines the length of time that the data can be recorded. With a record rate of 5 min (= 300 s) a recording over 28 days is possible.

When the Sensor Data Logging is restarted, the old data will be overwritten. Make sure the file is downloaded before a new recording is started. Once the storage is full, a warning will be provided and recording is stopped, until the memory is freed up. This can be done by starting a new recording. Please make sure that the old data is saved before it is deleted. To activate the changes, click the save button at the bottom.

NOTE: It is recommended to use the external power supply in addition to ensure sensor power supply independently from the PC USB connection.

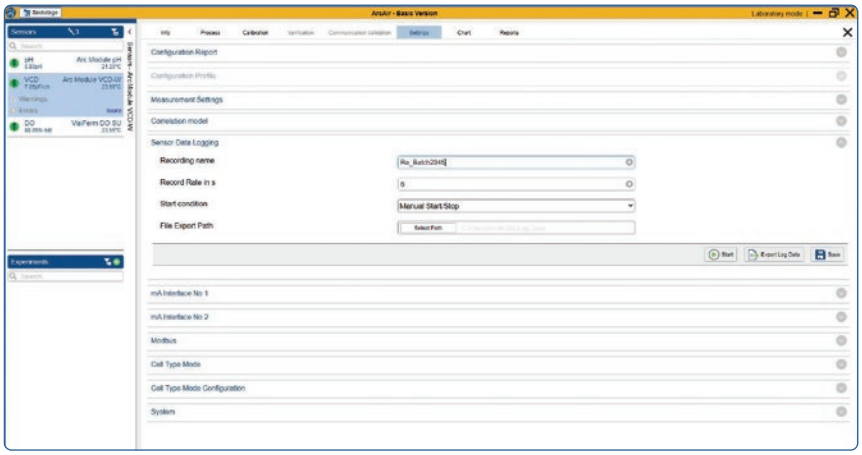


Figure 28: Example of the Setting section – Sensor Data Logging.

1) Insert a Recording name. This name will appear in the header of the CSV-file as Batch Name
2) Define the recording rate in seconds. The table below this section can be used to estimate the recording rate.
3) Define the start condition for recording:
   a. Manual Start/Stop > used in ArcAir with the Computer Software, or via mobile version (see Figure 29). A pop up window will appear asking about reset inoculation. Please select yes, if no inoculation has been done for this run (Figure 30). Be aware that the inoculation button in the Experiment is enabled when «no» is selected.
   b. Start recording with Inoculation, will start the recording once the culture is inoculated (inoculation button is pressed in ArcAir Computer Software, or via mobile version > Experiment chapter 6.4.11 «Inoculate» or Figure 29).
   c. Start Recording with next Power up > upon powering up the sensor, recording automatically starts once and has to be configured again for the next power up.
4) Press «Save».
5) The configuration is confirmed with a pop up message (Figure 31).

Depending on the settings of point 3. The Sensor Data Logging will be started or stopped (see Figure 31 and Figure 32). Once the Sensor Data Logging has been started, a red «LOG» will indicate the data logging for the sensor in the Sensor List (see Figure 31).

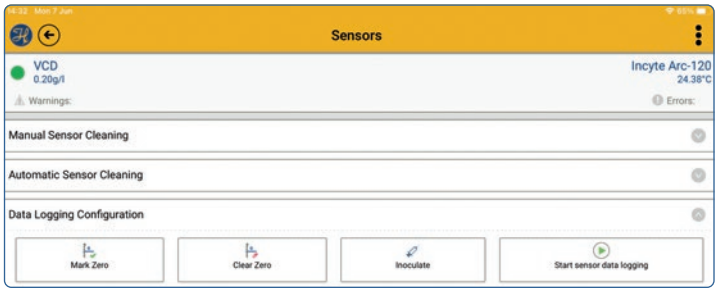


Figure 29: Sensor Data Logging on mobil ArcAir Version.

NOTE: Recording a new file will automatically overwrite on previous file.

NOTE: To store the data of the Sensor Data Logging on a computer the Arc Wi Adapter BT has to be removed and a direct connection over the Arc USB Power Cable (Ref 243490) has to be used.

To export the logged data select an Excel Export Path and click the button Export Log Data. The data can be found under the specified storage path. The name of the file is composed of the date and time of the export and the addition Log Data.

Planned Record Rate	Record Rate for ArcAir (S)	Resulting in max. Record Time
6 seconds	6	13.65 hours
10 seconds	10	22.75 hours
15 seconds	15	34.13 hours
30 seconds	30	68.25 hours
1 minute	60	5.69 days
5 minutes	300	28.44 days
10 minutes	600	56.88 days
12 minutes	720	68.25 days
15 minutes	900	85.21 days
30 minutes	1800	170.63 days

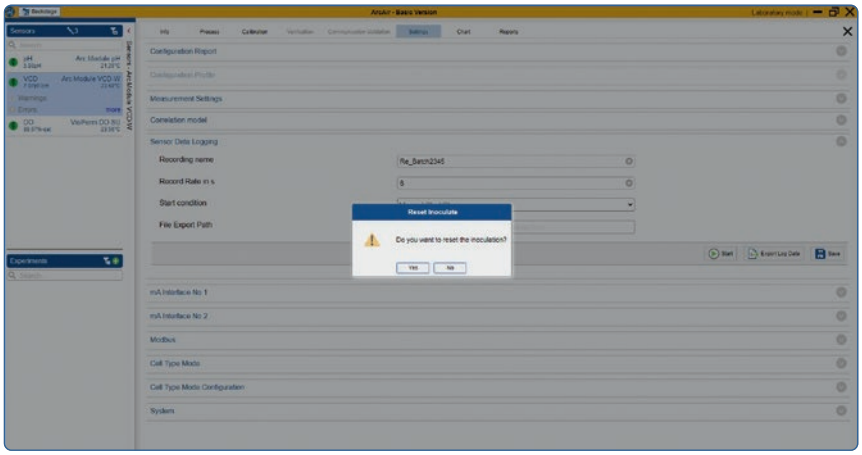


Figure 30: Example Screen of Sensor Data Logging using a Manual Start Option.

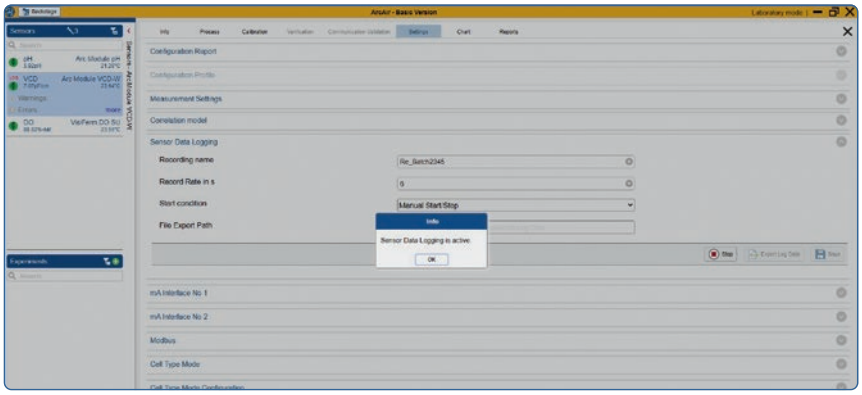


Figure 31: Example Screen of activated Sensor Data Logging.

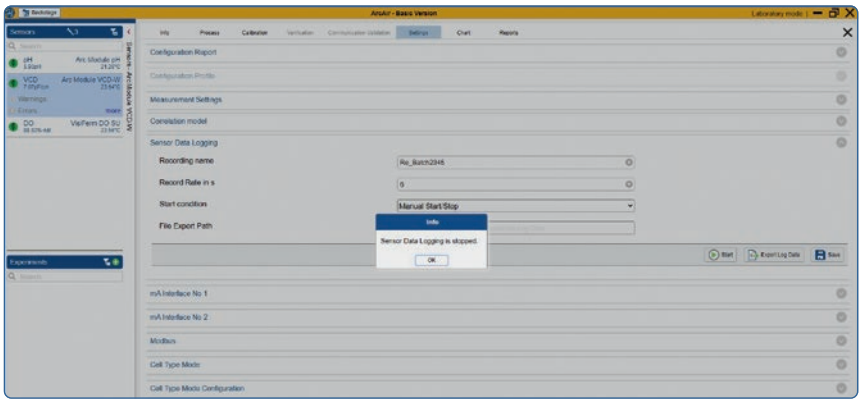


Figure 32: Example Screen of inactivated Sensor Data Logging.

6.4 Run Culture

6.4.1 Chart functionality

NOTE: The “Chart” function is not anymore available in ArcAir.

In this menu area, the measurement of the Arc Module Incyte SU was managed until ArcAir version 3.5. With the latest ArcAir version 3.6. this area has moved to the Experiment function. With this move, the Arc Module Incyte SU can be combined with other sensors in an Experiment.

Important for the understanding of this function is the overview of the difference between a peer-to-peer connection and the use of advertiser data. In peer-to-peer mode, the Arc sensor is in an active Bluetooth or wired connection to ArcAir and all functions and information of that specific Arc sensor are available. No further connection to other Arc sensors is possible. Advertiser mode is a wireless broadcast mode in which multiple sensors send information wireless to PC or mobile device. Every three seconds, the following information can be read from a PC or mobile device without any active peer to peer connection to the Arc sensor:

- Measured value and unit
- Temperature value and unit
- Sensor status

The experiments use advertiser mode to record multiple sensors.

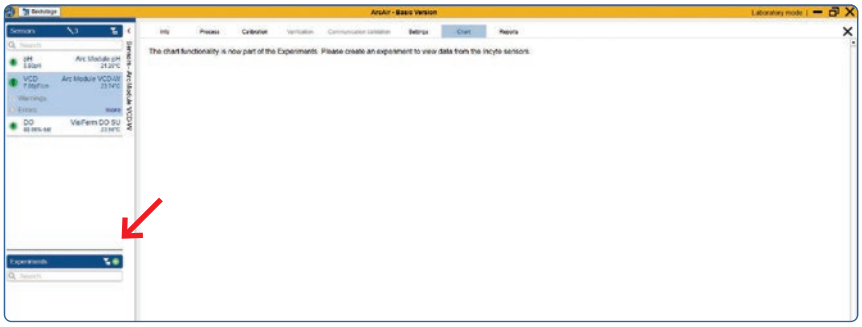


Figure 33: Example Screen of Chart section – This Functionality has been moved to the Experiment Section.

6.4.2 Set up an Experiment

Sampling time							
3 s	6 s	30 s	1 min	5 min	12 min	30 min	1h

To start an *Experiment*, click + on *Experiment* under the *Sensors List*. Select all sensors that should be listed together in one *Experiment*. Assign a *Batch name* (will be found in the header of the Excel Sheet) and an *Experiment name* (under Name, defines the Name of the Excel-file). The sampling time can be assigned to an interval between 3 s and 1 h or to a self-defined time interval. All Hamilton Arc sensors have a temperature sensor. For the *Experiment*, it is sufficient to display one of them in the graph. This can be selected under *Temperature Sensor*.

Make sure that all sensors planned for the *Experiment* have the right unit. It is not possible to change the units within a running *Experiment*.

Select the storage path, where the *Experiment* data will be saved. Click *Save* to store the *Adjust Settings* and to start with the recording of the *Experiment*.

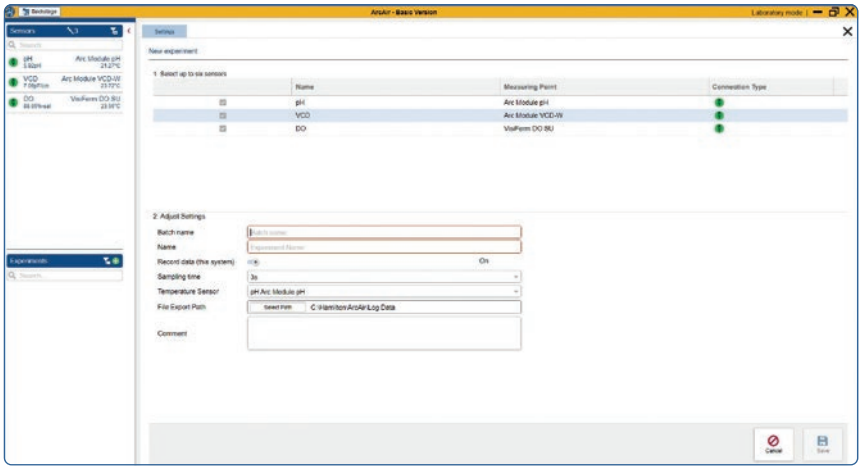


Figure 34: Example Screen – New Experiment.

6.4.3 Introduction into Experiment Functionality

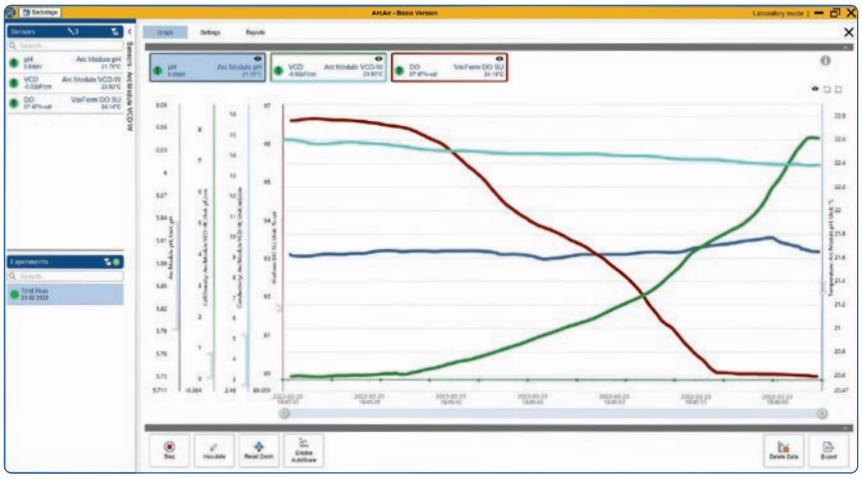


Figure 35: Example Screen of Experiment.

There are a few points to consider when using the Arc Module Incyte SU in combination with other Arc sensors in an *Experiment*. An Arc Module Incyte SU connected via Bluetooth can only be used alone in an *Experiment*. This is due to the peer-to-peer connection, which allows the use of *Mark Zero* and *Clear Zero*. In a peer-to-peer connection other Bluetooth sensors are ignored. The use of an Arc Module Incyte SU with other Arc sensors without restrictions is possible via connection with an Arc USB Power Cable (Ref 243490).

The *Experiment* function gives the possibility to graphically display the trend of six sensors side by side. Each sensor is displayed with a different color, which can be identified by the frame around the sensor name (Example: Figure 36 Name: Incyte Arc-120 is displayed in orange). Individual sensors can be hidden: Push on the little eye icon next to the sensor name to hide or show the measurement (see Figure 36).

Figure 36: Example of Sensor listed in Experiment – displaying or hiding the same sensor.

The buttons below the graph apply to all sensors. Thus, starting and stopping, as well as inoculation, is an action that affects all sensors. The buttons on the right side are only valid for the sensor selected in the *Sensor List above*. This is highlighted by a blue background. The affected functions are *Mark Zero*, *Clear Zero* and *Scan on/off*, they are framed with the same color as the selected sensor (example Figure 37 – Selected sensor: Arc Module Incyte-P SU, frame: orange). In addition, the displayed conductivity, offset, cell factor and cell density is applying to the selected sensor as well.

The sliders on the sides of the axes allow zooming in a certain interval range (see Figure 37), they do not define the range of values of the scale. The value range of the y- axes can be set under *Configure Y-Axes*. The results can be exported not only at the end of the *Experiment*, but also at any time during an *Experiment* (Export button). Events like Inoculate or *Mark Zero/Clear Zero* as well as comments are tracked and will be available later via an Excel file.

As soon as the *Experiment* contains more than 5000 data points, a new graph is created. The «Previous» and «Next» buttons can be used to switch back and forth between the graphs to view old and new data.

Use the button «Restore axes» to set the y-axes configuration back to the setting stored on the sensor. Use the button «Reset Zoom» to reset the zoom, initiated by the slider on the axes.

NOTE: The Experiment function is not available on mobile devices.

Figure 37: Example of two Sensors in an Experiment.

6.4.4 Settings of the Arc Module Incyte SU for an Experiment

To prepare the Arc Module Incyte SU for use in an *Experiment*, the following checkup is recommended:

Checklist	Subject	Short description	See Chapter for further information:
☐	Cell Type Mode	Set a filter adapt the sensor to Experiment conditions.	6.3.1 «Prepare the Sensor and Choose the Cell Type Mode» > Cell Type Mode > Cell Type Mode Configuration
☐	Off-line Correlation	The permittivity signal of the Arc Module Incyte SU can be transferred to the viable cell number via different correlation attempts. Check if a cell factor or a AADM model is required	6.3.2 «Correlation to offline data» > Linear Correlation to Dual Frequency Measurement > Cell Density Correlation on the Scan Data (only for Arc Module Incyte-P SU)
☐	Sensor Data Logging	It is possible to store Experiment data directly on the sensor and independent from ArcAir. Check if Sensor data logging is required.	6.3.3 «Sensor Data Logging»

6.4.5 Getting Started with an Experiment (Arc Module Incyte-P SU)

Once the Experiment has been started, the following workflow is recommended:

Checklist	Subject	Short description	Where to click	Additional Information
☐	Scan Functionality (for Arc Module Incyte-P SU only)	Switch the Scan on or off, if needing during the Experiment	Scan On or Scan Off	6.4.10 «Scan Functionality»

Checklist	Subject	Short description	Where to click	Additional Information
☐	Mark Zero	It is normal to start an Experiment at point (0|0). To start with 0 pF/cm or 0 g/l use Mark Zero. To switch off the offset use Clear Zero. These events will be displayed in the graph.	 or 	6.4.9 «Mark Zero, Clear Zero and Offset»
☐	Inoculate	When the cells are injected or pumped into the bioreactor click inoculate. These events will be displayed in the graph. This event can only be done once in an Experiment.		6.4.11 «Inoculate»
☐	Add a comment	Click on a measurement point to add a comment when needed.		6.4.12 «Add a Comment»
☐	Set the y-Axes Scale	Click on the respective axes to set expected minimum and maximum value. Recommendation: Min = -10 pF/cm, Max = 100 pF/cm (or the respective equivalent in e6/mL or g/l) and click on save		See also ArcAir system manual

⚠ ATTENTION! If using an ArcAir Data Modeling, the event «Inoculation» starts the calculation of the Model in the sensor and is highly important to be marked.

6.4.6 Getting Started with an Experiment (Arc Module Incyte-W SU)

Once the Experiment has been started, the following workflow is recommended:

Checklist	Subject	Short description	Where to click	Additional Information
☐	Start Experiment	Define the experiment data and start recording. The data recording is required to execute the following steps.	Experiments	Fix the bag on the rocker and fill the bag with the desired medium (please check the minimum volume from the system supplier for the respective bag size). To start the experiment, press the «+» button.
☐	Initialization	Initialize «Patch Conditioning» and wait until the conditivity and permittivity values have been stabilized.		For initialization bring the rocker into the largest tilt position (static position). NOTE: Ensure that the sensor is properly covered with liquid.
☐	Product Calibration	If needed, a product calibration of the conductivity can be executed.	Process	The product calibration of the conductivity improves the accuracy for the conductivity measurment. The VCD measurement is unimpaired. 6.2 «Calibration»
☐	Wave Algorithm (for Arc Module Incyte-W SU only)	Start «Wave Algorithm», wait for 120 s and start the rocking motion to the needed set-points (rocking angle and speed).		The setpoints for the rocking motion process needs to be set in the control system of the rocker platform.
☐	Mark Zero	Press «Mark Zero» just before inoculation.	 or 	The VCD displayed should be Zero. If the value is unstable, this can be repeated until inoculation. See also 6.4.9 «Mark Zero, Clear Zero and Offset»

Checklist	Subject	Short description	Where to click	Additional Information
☐	Inoculation	For inoculation, there are two possibilities; a) stop the rocker, add cells and wait two minutes and set the rocker in motion again b) add sells, stop the rocker for two minutes, then set the rocker in motion.	Inoculate	Ensure that the sensor is properly covered with liquid. If the current tilt angle does not allow this, increase it to the largest possible value and decrease it later while the platform is rocking. See also 6.4.11 «Inoculate»
☐	Feeding or take a probe (for Arc Module Incyte-W SU only)	For feeding or taking a probe, there are two possibilities; a) stop the rocker, feed/take a probe and wait two minutes and set the rocker in motion again b) feed/take a probe, stop the rocker for two minutes, then set the rocker in motion.	See control system of the rocker	Ensure that the sensor is properly covered with liquid. If the current tilt angle does not allow this, increase it to the largest possible value and decrease it later while the platform is rocking. See also 6.4.12 «Add a Comment»

In case any technical problems occur, or if the warning for the wave algorithm appears, stop the rocker in the tilt position, such that sufficient liquid is in contact with the sensor, for 120 s and allows restarting the algorithm.

NOTE: No other user intervention needed. The algorithm will reinitialize by itself.

6.4.7 Patch Conditioning

The Sensor Conditioning is recommended per default to allow most accurate measurement and low drift. Use the Sensor Conditioning with caution and only previous to inoculation. The Sensor Conditioning has a fixed preset of 400 s and cannot be changed.

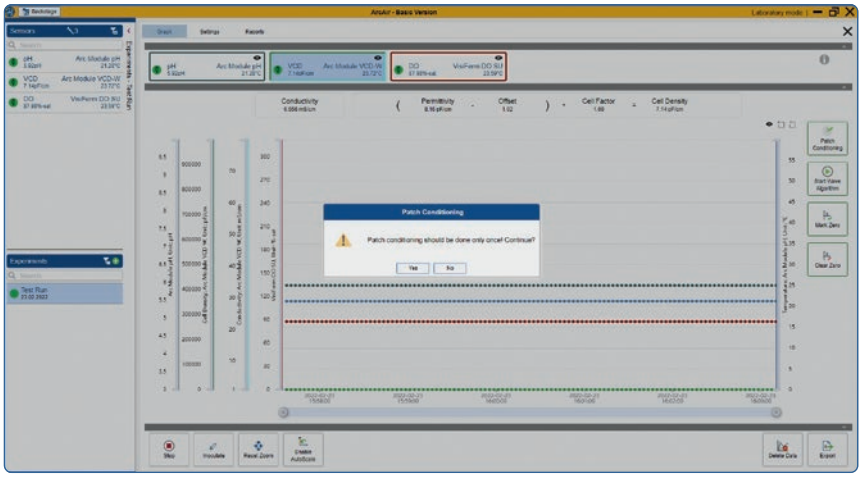


Figure 38: Example screen with message for sensor conditioning to be executed only once.

NOTE: The signal may be unstable up to two hours after Sensor Conditioning. Sensor Conditioning should be executed only once with a Incyte-P SU.

NOTE: No measurements available during the Sensor Conditioning.

NOTE: The Sensor Conditioning in serum (FBS) containing media is not recommended. Culture media containing proteins, i.e. fetal bovine serum should be avoided when using the Sensor Conditioning.

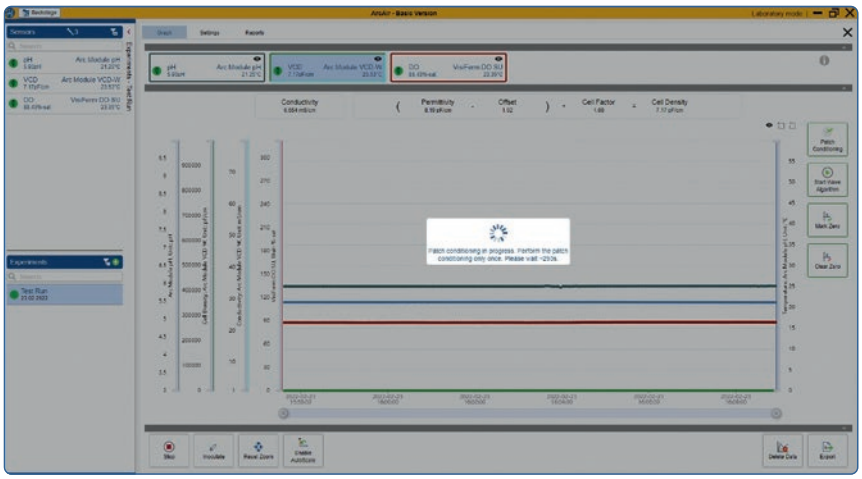


Figure 39: Example Screen if Sensor Conditioning was activated.

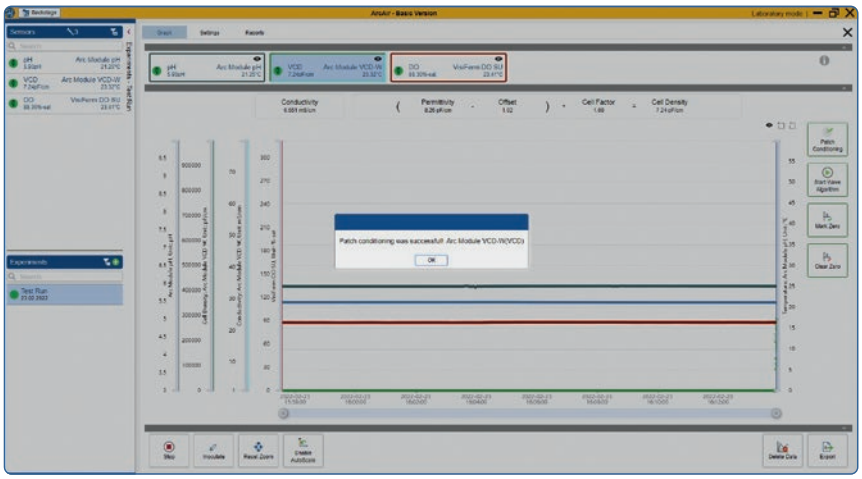


Figure 40: Example Screen if Sensor Conditioning was successful.

6.4.8 Wave Algorithm

The Wave Algorithm is recommended per default to allow most accurate measurement also in the wave bioreactor. The Wave Algorithm determines the physical behavior in the rocking motion where the Incyte-P SU is not covered with liquid all the time.

NOTE: The functionality «Wave Algorithm» is only available for the Arc Module Incyte-W SU.

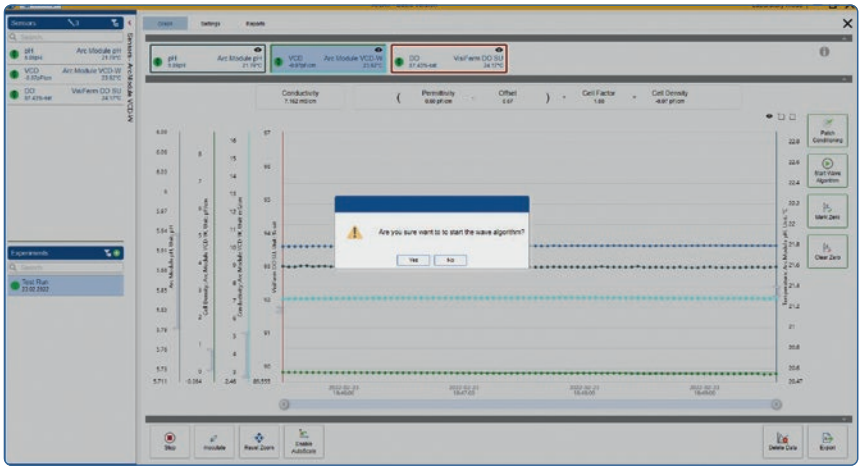


Figure 41: Example Screen if Wave Algorithm was activated.

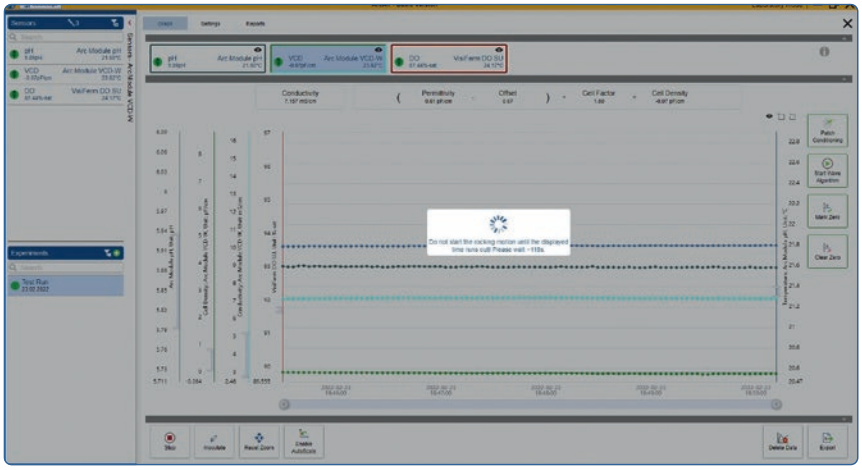


Figure 42: Example Screen if Wave Algorithm is in activation phase.

NOTE: Do not start the rocking motion until the displayed time runs out. The time needed to establish the basic values of the algorithm will take 120 s.

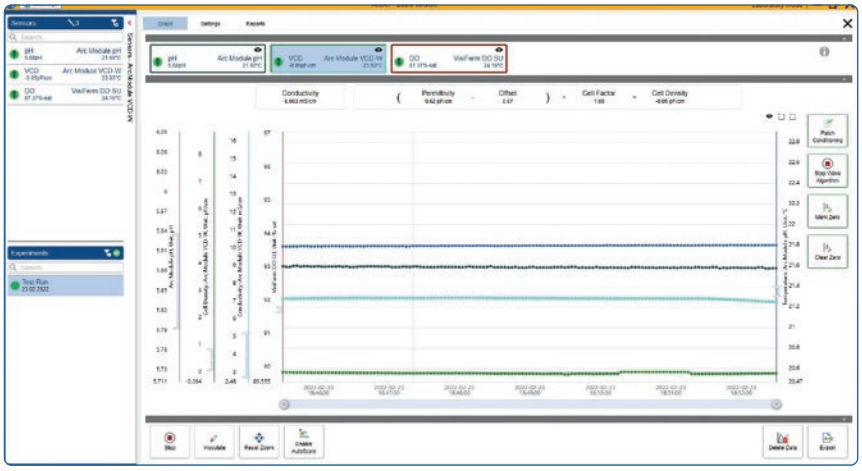


Figure 43: Example Screen if Wave Algorithm is active.

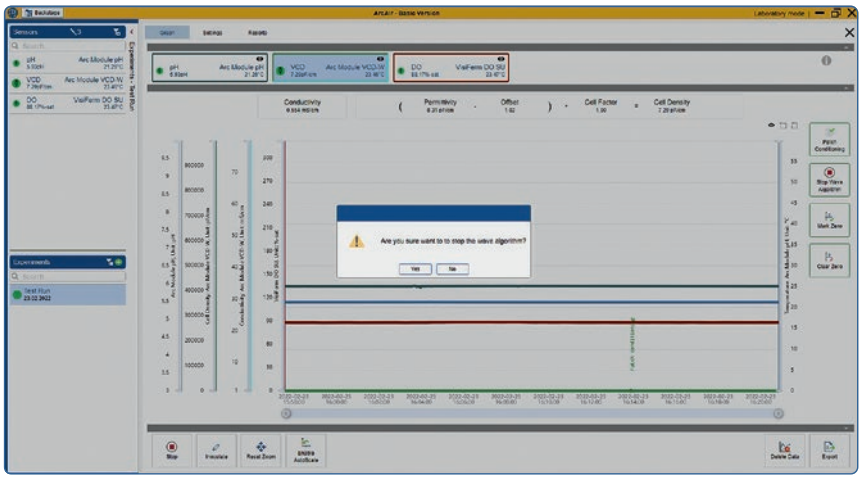


Figure 44: Example Screen if the Wave Algorithm was stopped.

6.4.9 Mark Zero, Clear Zero and Offset

Even though the Dual Frequency Measurement Mode reduces the influence of medium and medium changes on the measurement, it is usual to do an in-process adjustment i.e. a zero-adjustment before inoculation. The in-process adjustment is done by pressing the *Mark Zero* button and will be applied to both permittivity and scan.

There are two ways to set the offset. Use *Measurement Settings* or click *Mark Zero* during an *Experiment*.

Once the *Experiment* is started, a message will show up, if the *Mark Zero* was successful. After «Inoculation» ArcAir will always ask if a *Mark Zero/Clear Zero* is done on purpose. Press «Yes» to continue.

NOTE: A Mark Zero is recommended before inoculation.

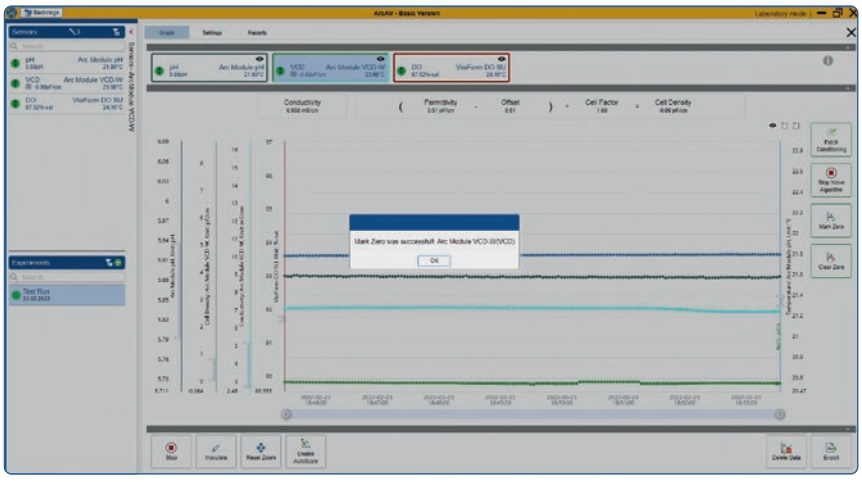


Figure 45: Example Screen if Mark Zero was clicked after Inoculation.

In addition to the Mark Zero and manual offset can be set. The value can be added in Settings/

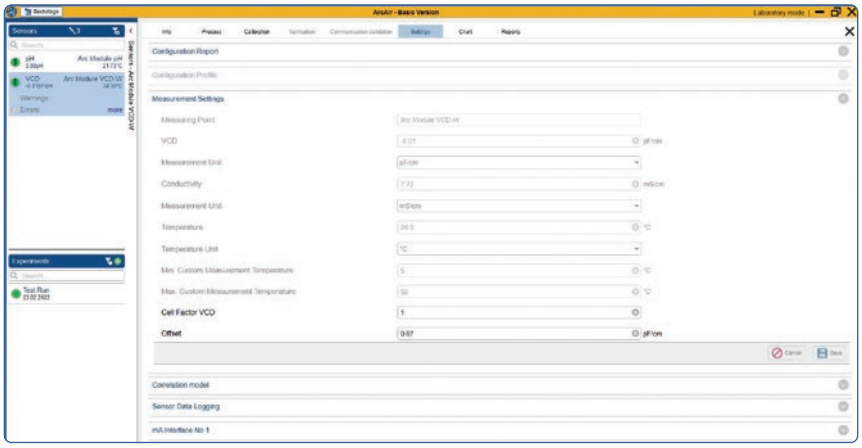


Figure 46: Add an offset to the permittivity reading.

NOTE: A «Mark Zero» will delete the manual offset.

6.4.10 Scan Functionality (for Arc Module Incyte-P SU only)

NOTE: The scan functionality is not available as the rocking motion of the media do not allow a constant measurement for all frequencies.

All frequencies of the Arc Module Incyte-P SU can be used by switching on the Scan Functionality during an *Experiment*. It should be switched on before Inoculation. For *Experiments* that use an ArcAir Data Model the scan has to be switched on.

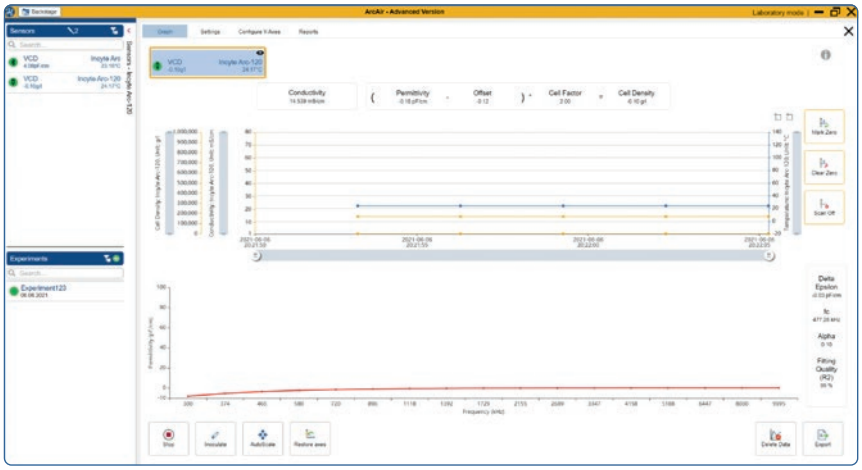


Figure 47: Example Screen with switched on Scan during an Experiment.

The «Fitting Quality R2» is a fitting indicator in ArcAir and describes how well the scan data can be fitted to the Cole-Cole equation.

An indicator between 90 and 100 % describes a good fitting, between 70 and 90 % refers to an average fit, whereas everything below 70 % is considered not to be reliable. In the *Experiment* File, the corresponding values are recorded between 0 and 1.

If the scan is switched off during an *Experiment*, only the dual frequency measurements will be available. A pop up message with prevent from hitting this button by accident (see Figure 48).

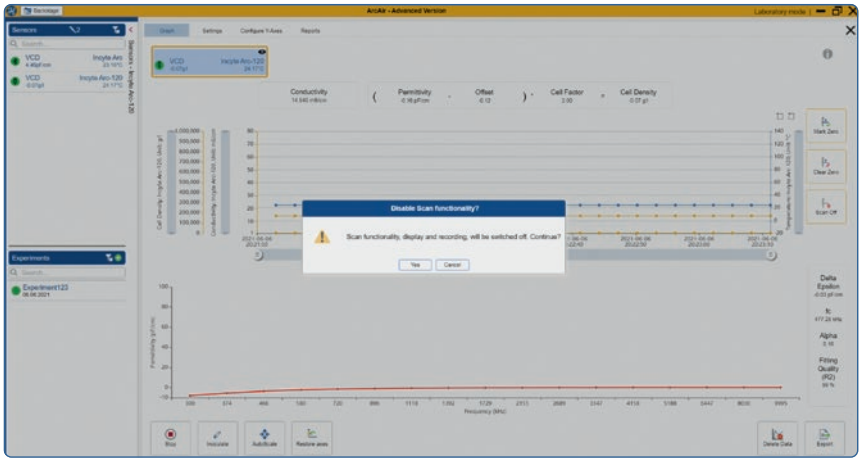


Figure 48: Example Screen when Scan is switched off during an experiment.

6.4.11 Inoculate

The Inoculation button enables marking of the time point when the cells have entered the cultivation system. The inoculation is available in the *Experiment* Function in ArcAir. This event is unique and occurs once in a process cycle. It is highlighted in the *Experiment* graph (Figure 50). ArcAir is reporting if the inoculation was successful after clicking the inoculation button (see Figure 49).

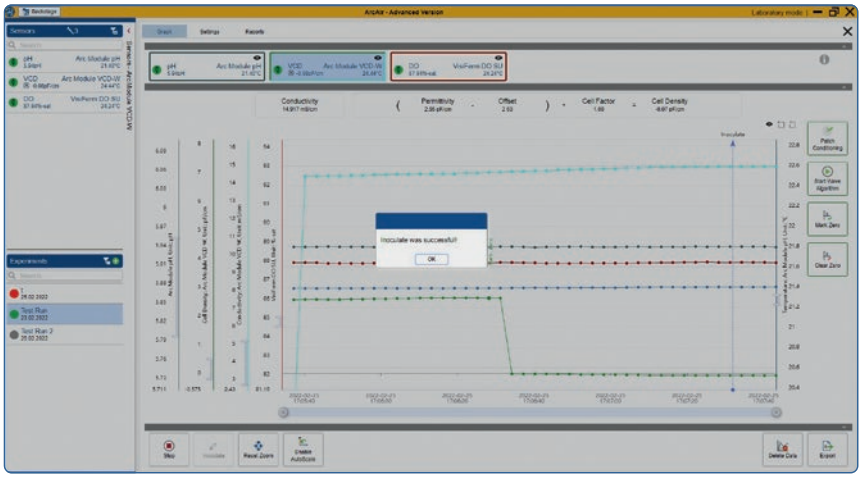


Figure 49: Example Screen when Inoculation was successful.

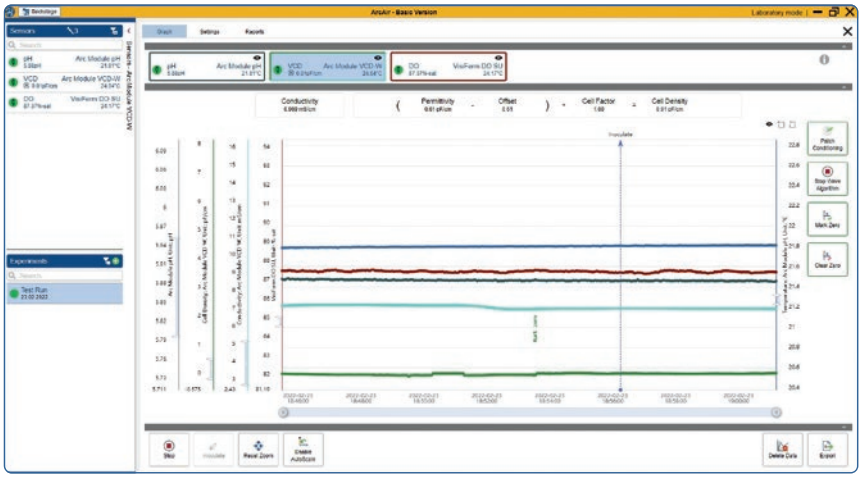
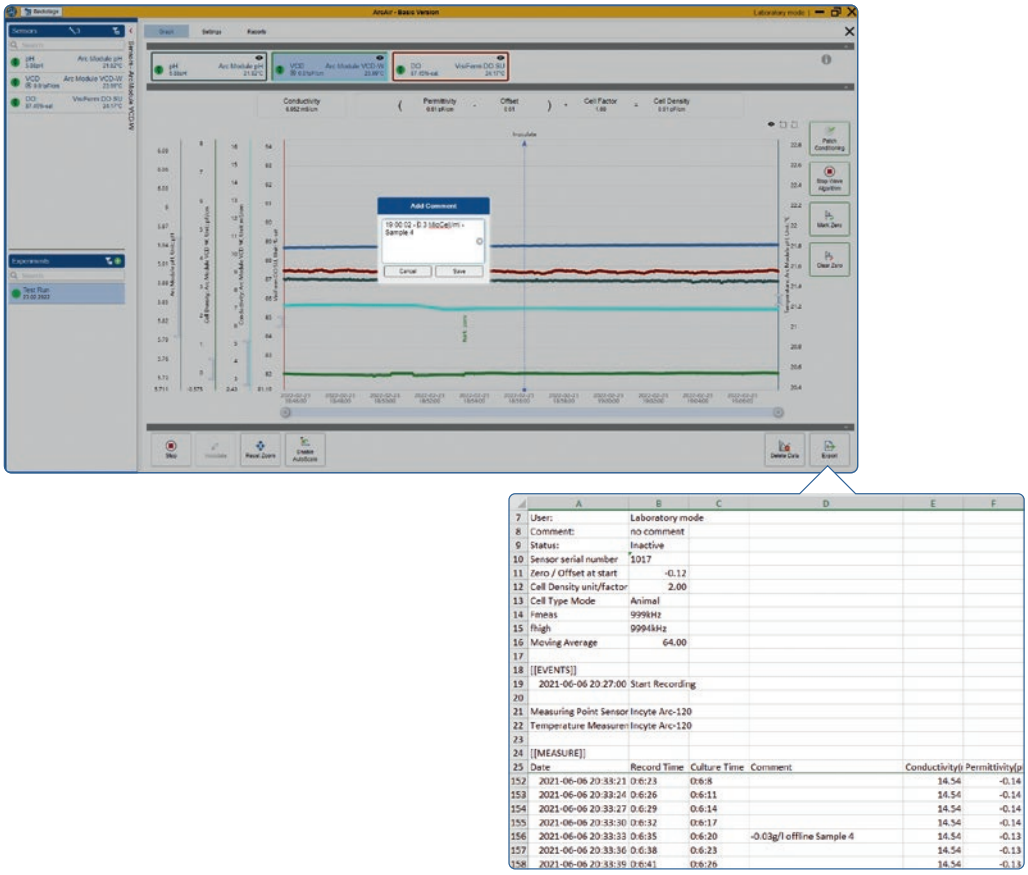


Figure 50: Example Screen with marked time point after Inoculation in the Experiment, Inoculation button is now grey and not clickable.

6.4.12 Add a Comment

During recording, a comment can be added at any time to the Export file of the Experiment. This functionality may be used to track off-line samples.

Figure 51: How to add a comment during Experiment.



	A	B	C	D	E	F
7	User:	Laboratory mode				
8	Comment:	no comment				
9	Status:	Inactive				
10	Sensor serial number	1017				
11	Zero / Offset at start	-0.12				
12	Cell Density unit/factor	2.00				
13	Cell Type Mode	Animal				
14	Fmeas	999kHz				
15	fhigh	9994kHz				
16	Moving Average	64.00				
17						
18	[[EVENTS]]					
19	2021-06-06 20:27:00	Start Recording				
20						
21	Measuring Point Sensor	Incyte Arc-120				
22	Temperature Measurem	Incyte Arc-120				
23						
24	[[MEASURE]]					
25	Date	Record Time	Culture Time	Comment	Conductivity(	Permittivity(p
152	2021-06-06 20:33:21	0:6:23	0:6:8		14.54	-0.14
153	2021-06-06 20:33:24	0:6:26	0:6:11		14.54	-0.14
154	2021-06-06 20:33:27	0:6:29	0:6:14		14.54	-0.14
155	2021-06-06 20:33:30	0:6:32	0:6:17		14.54	-0.14
156	2021-06-06 20:33:33	0:6:35	0:6:20	-0.03g/l offline Sample 4	14.54	-0.13
157	2021-06-06 20:33:36	0:6:38	0:6:23		14.54	-0.13
158	2021-06-06 20:33:39	0:6:41	0:6:26		14.54	-0.13

Figure 52: Example Screen of a comment added during an Experiment.

A comment can be added by clicking on a sample point on the graph. The point will be highlighted after the comment has been saved. The comment will appear in the Excel file after exporting (see Figure 52).

6.4.13 Stop an Experiment

Once the Experiment is over the recording is stopped by clicking the stop button. The recording can be restarted by clicking start. A gap will be found in the Excel file between click stop and restarting the Experiment.

By pressing the Export button, all data of the running experiment is stored in a xlsx-file in the designated folder. The export can be executed more than once. The existing files will not be overwritten. The new files is defined by the experiment name together with save date/time (e.g., Experiment_Test01_2022-02-02 10-30-55.xlsx where «Test01» is the name of the experiment). The «Batch name» of the experiment will appear only in the file itself.

To delete experimental data and the graph click the button «Delete Data», be aware that all data stored from the time point of starting the Experiment until now is deleted and cannot be recovered.

6.5 Use Sensor Cleaning

The Sensor Automatic Cleaning is deactivated per default. It is only required if cell adhesion at the sensor electrodes is noticed. The Cleaning function may reduce the attachment of cells and may be required in few processes, i.e. in long-term cell culture or fermentation of filamentous fungi. Use the cleaning mode with caution and only if adhesion of cells at the platinum electrodes is noticed or suspected. Start with short Cleaning Duration and a long Reception rate (Auto-Cleaning Period), at least every 12 h. Increase cleaning duration / decrease the reception rate only if no improvement is observed.

NOTE: The signal may be unstable up to two hours after cleaning.

NOTE: No measurements available during the cleaning cycle.

NOTE: The cleaning in serum (FBS) containing media is not recommended. Culture media containing proteins, i.e. fetal bovine serum should be avoided when using the in-process cleaning functionality.

Manual Sensor Cleaning

NOTE: Manual cleaning can be performed at a specific time in the culture as described here.

1) Go to the «Process Settings»
2) Select «Manual Sensor Cleaning»
3) Choose between short (10 seconds) and long (100 seconds) cleaning
4) Press «Start»

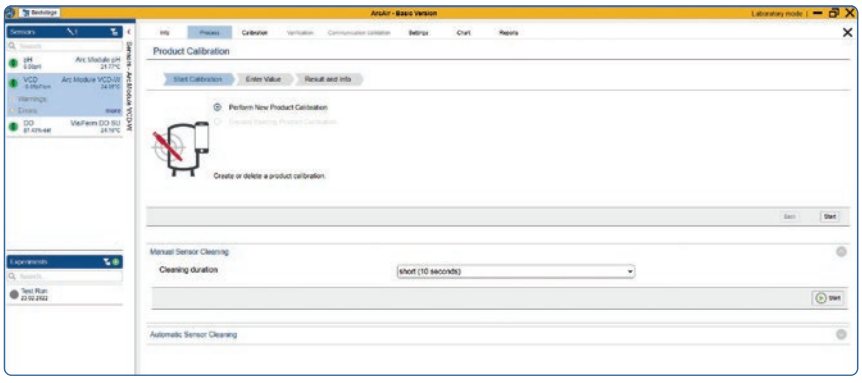


Figure 53: Manual sensor cleaning.

Automatic Sensor Cleaning

1) Go to the «Process Settings»
2) Select «Automatic Sensor Cleaning»
3) Enable automatic sensor cleaning

4) Choose between short (10 seconds) and long (100 seconds) cleaning
5) Define the repetition rate (the time where a cleaning is done) in hours. The shortest rate is 1 cleaning per hour.
6) Press «Save»

NOTE: Measurements are unavailable during the cleaning cycle.

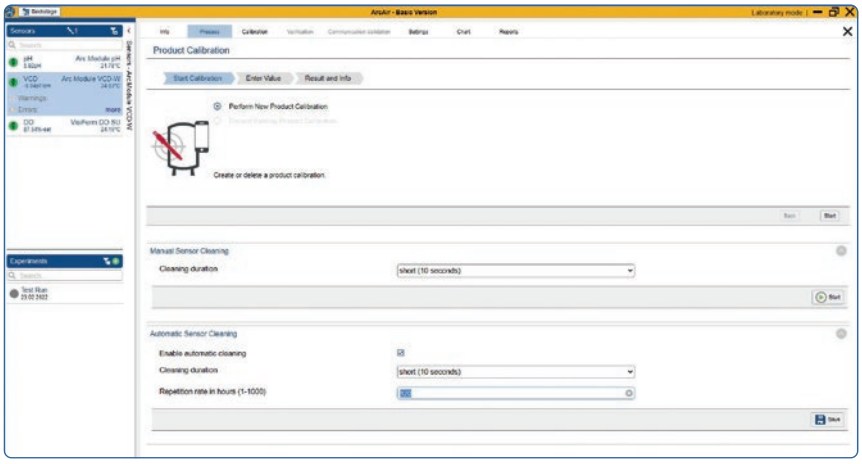


Figure 54: Automatic sensor cleaning.

6.6 Sensor Verification

In general, a sensor verification can be used to determine whether the sensor measures a specified value within a defined tolerance or not. Acceptance criteria for successful verification: $\Delta\varepsilon = 0$ pF/cm ± 5 pF/cm Measured in Hamilton's 12880 µS/cm Conductivity Standard (Ref 238988) at Dual Frequency with an fmeas at 1MHz.

When a sensor fails a verification, a recommendation can be made to readjust the sensor. In the case of an Arc Module Incyte SU Verification, a cleaning (similar to Manual Sensor Cleaning) is recommended. During the verification procedure, the dual frequency measurement as well as the scan are analyzed to check the purity and consistency of the electrodes and functional elements. At this point, it should be noted that even if the sensor verification is successful, ArcAir would check whether cleaning could still be beneficial. Follow the instruction of ArcAir during Verification procedure. The verification influences the sensor quality indicator. It is recommended to proceed to a verification for accurate quality indicator.

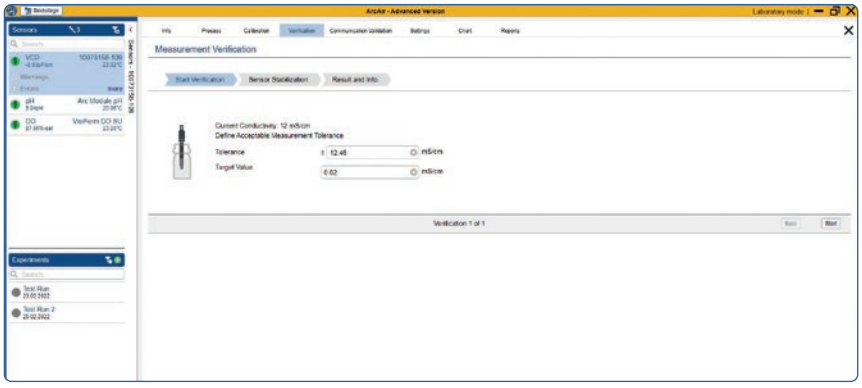


Figure 55: Sensor Verification.

NOTE: To run a Sensor verification ArcAir Advanced is required.

1) Start ArcAir™ and connect the Arc Module Incyte SU with the power supply, e.g. by using the Arc USB Power Cable on a standard USB port (see chapter 9.3 «Parts and Accessories») and equilibrate for at least 30 minutes prior to starting the Sensor Verification procedure
2) Go to the «Verification» (Figure 55)
3) Optionally add the Lot number of the buffer
4) The verification Standard is pre-defined and refers to the Hamilton Conductivity standard (REF 238988).
5) Fill your cleaned SU device with the conductivity standard. Alternatively remove the sensor element from the SU container and immerse it in a standard. Ensure sufficient space around the sensor element for comparable measurement. Try to avoid air bubbles around the tip.
6) Press «Start», the sensor will now equilibrate for 120 sec. (Figure 56)
7) In case impurities are detected on the electrodes a cleaning will be recommended and the sensor quality indicator will decrease (see chapter 6.5 «Use Sensor Cleaning»)
8) Perform a cleaning and run the verification again
9) The successful verification is shown, in case the verification was not successful press done and try again once (Figure 57)
10) Press «Save Report»

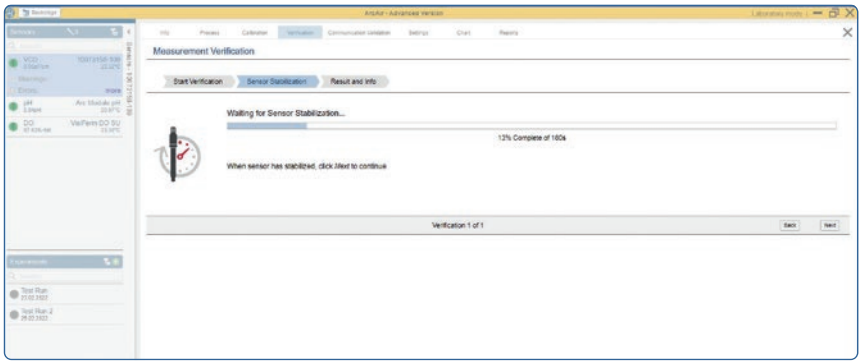


Figure 56: Sensor Stabilization.

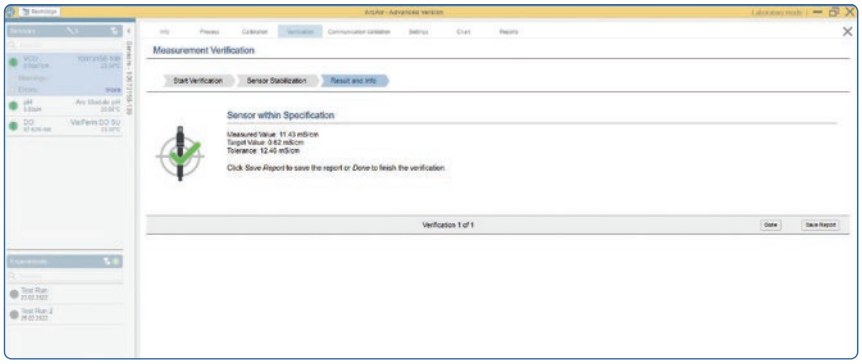


Figure 57: Succesfull Sensor Verification.

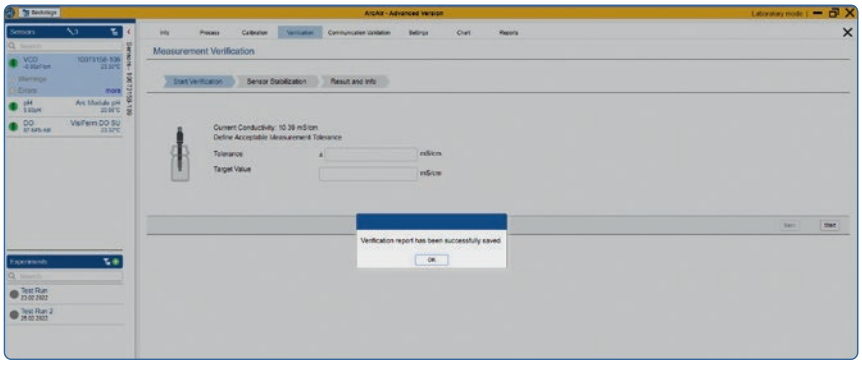


Figure 58: Succesfull Sensor Verification.

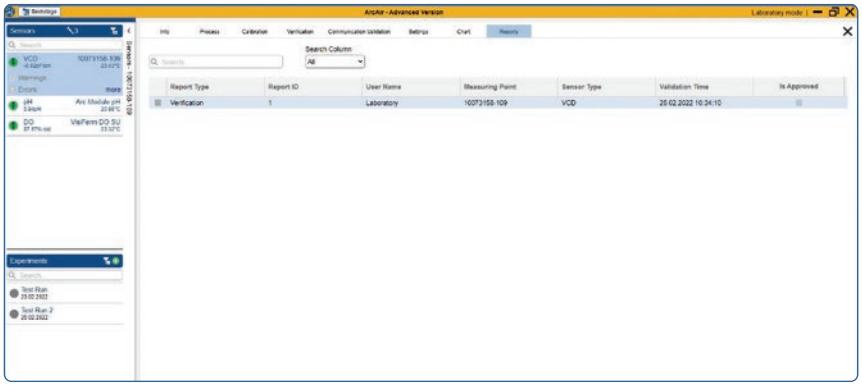


Figure 59: Approve Verification Report and Create PDF.

6.7 Disconnecting the Arc Module Incyte SU from an Incyte-P SU

⚠ ATTENTION! Do not apply excessive forces while disconnecting the Arc Module Incyte SU to avoid any damage.

1) Switch off power supply
2) Hold the Arc Module Incyte SU housing
3) Unscrew the coupling nut
4) Remove the Arc Module Incyte SU (not applicable for the Arc Module Incyte-W SU) from the Incte-P SU

NOTE: To remove the Arc Moduel Incyte-P SU from the Incyte-P SU after unscrewing the coupling nut you can push away the Incyte-P SU with the coupling nut. This avoids disconnecting forces on the bag. To remove the Arc Module Incyte-W SU from the Incyte-P SU it is recommended to squeeze of the Incyte-P SU with the finger tips. A video showing the best practice to remove the Incyte-P SU is available on www.hamiltoncompany.com.

7 Troubleshooting

7.1 Arc Module Incyte SU and Incyte-P SU Self-Diagnostics

7.1.1 Verify Status of Arc Module Incyte SU and Incyte-P SU

The Arc Module Incyte SU and Incyte-P SU provides a self-diagnosis functionality to detect and identify the most common sensor malfunctions. The communication interfaces can be used for warning and error messages. The analog 4-20 mA interface (when using Arc Wi 2G Adapter BT) can be configured according to the NAMUR recommendations to indicate an abnormal event. Use the ArcAir™ for monitoring the sensor status and for troubleshooting. The following types of messages are provided by the self-diagnosis function.

Indicator status		What does it mean?
	The Status symbol on the ArcAir™ App respectively LED on Arc Wi Adapter BT are green.	The connectivity to the sensor is OK. The sensor is operating correctly and no warnings or errors have been registered.
	The Status symbol on the ArcAir™ App respectively LED on Arc Wi Adapter BT are yellow.	The connection to the sensor is OK. However, the sensor indicates a warning. Verify the sensor warnings in «Info > Status».
	The Status symbol on the ArcAir™ App respectively LED on Arc Wi Adapter BT are red.	The connection to the sensor is OK. However, the sensor indicates an error. Verify the sensor error in «Info > Status».
	The Status symbol on the ArcAir™ App is grey respectively LED on Arc Wi Adapter BT for a sensor is flashing red.	The ArcAir™ App lost connection to the sensor due to one of the following reasons: • The wireless signal strength is low (ArcAir™ indicator grey; LED on Arc Wi Adapter BT can be green/yellow/red). • The Arc Wi Adapter BT has been removed from the sensor. • The Arc Module Incyte SU or Arc Wi Adapter BT electronic is defective.

Figure 60: Description ot the traffic lights on ArcAir™.

NOTE: Quality Indicator – The quality indicator provides infotmation about the measurement performance rated between 100 and 30 %. At every verification the integrity of the sensor is checked at the relevant frequencies and aligned to the upper and lower acceptance limit. If the quality indicator stays below 30 % after changing the Incyte-P SU please contact Hamilton Technical Support.

7.1.2 Warnings

Warning	Cause	Solution
T sensor defective	Temperature measurement not possible, please contact your Hamilton Responsible	Change sensor patch
Patch missing	No Patch connected	Please connect a Incyte SU to the Arc Module Incyte SU
Patch not valid	Wrong Patch attached	Please connect a Incyte SU to the Arc Module Incyte SU
Sensor quality low	Sensor quality low	Please connect a Incyte SU to the Arc Module Incyte SU
Wave algorithm not converging	Reading of the VCD signal not stable	Stop rocking motion and put into tilt position for

7.1.3 Errors

Error	Cause	Solution
Conductivity too low	The conductivity is below the specified range, so no measurement of the permittivity is possible.	Increase conductivity (> 1 mS/cm)
Conductivity too high	The conductivity is above the specified range, so no measurement of the permittivity is possible.	Decrease conductivity (< 80 mS/cm)
External interferences detected	The permittivity measurement is disturbed by external electrical interferences.	Please check your environment and ground the sensor as described in chapter 3.3 «Electrical Safety Precautions».
Ambient temperature too high, no measurment is possible	Electronic overheat because of high ambient and process temperature.	Please ensure temperature conditions below 50 °C.
Power too low, no measuremnt possible	The supply power not sufficient	Check power supply has sufficient power output (> 1.5 W). With USB Power Cable, please use the provided power supply (power supply from the USB connection not sufficient)
Sensor supply voltage too low	The supply voltage is too low	Check power supply is above 21.6 VDC. With USB Power Cable, please use the provided power supply (power supply from the USB connection not sufficient)
Sensor supply voltage too high	The supply voltage is too high	Check power supply is below 26.4 VDC. The electronics are regulated down to not get damaged.
Parameter fitting cannot be applied, as the input data quality is not good enough	Parameter fitting cannot be applied, as the input data quality is not good enough	The Cole-Cole parameter fitting cannot be calculated as the measured viable cell density values are too low. This may be the case if the sensor is in medium only, or at process start, as well as low density cultures.
Temperature too low, no measurement possible	The temperature is below the specified range, so no measurement of the permittivity is possible.	Please ensure at least 4 °C temperature.
Temperature too high, no measurement possible	The temperature is below the specified range, so no measurement of the permittivity is possible.	Please ensure at least 4 °C temperature.
Apply / Set Calibration Data	Arc Module Incyte SU was disconnected from power supply or from the Incyte SU	Apply calibration data (chapter 6.2 «Calibration»)
Memory full, no further recording possible	The internal memory of the sensor is full.	Please download the data and re-connect the sensor.

7.2 Getting Technical Support

If a problem persists even after you have attempted to correct it, contact Technical Support: Please refer to the contact information at the back of this operating instruction.

7.3 Return Back for Repair

Before returning an Arc Module Incyte SU to Hamilton for repair, contact our Customer Service (correct reference) and request a Returned Material Authorization (RMA) number. Do not return an Arc Module Incyte SU to Hamilton without an RMA number. This number assures proper tracking of your sensor. Arc Module Incyte SU that are returned without an RMA number will be sent back to the customer without being repaired. Decontaminate the Arc Module Incyte SU and remove health hazards, such as radiation, hazardous chemicals, infectious agents etc. Provide complete description of any hazardous materials that have been in contact with the Arc Module Incyte SU.

8 Disposal

The design of Arc sensors optimally considers environmental compatibility. In accordance with the EC guideline 2012/19/EU Hamilton sensors that are worn out or no longer required must be sent to a dedicated collection point for electrical and electronic devices, alternatively, must be sent to Hamilton for disposal. Sensors must not be sent to an unsorted waste disposal point.

有害物質表，請參閱www.hamiltoncompany.com, 章節過程分析，符合性聲明

9 Ordering Information

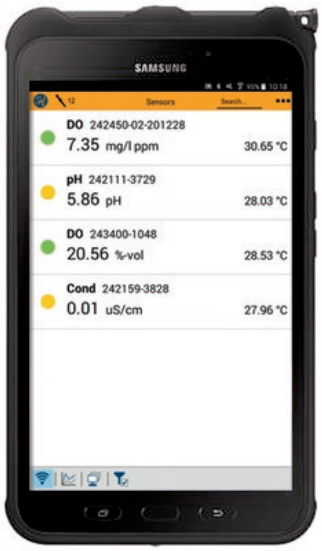
9.1 Arc Module Incyte SU

REF	Name
10073158	Arc Module Incyte-P SU
10087686	Arc Module Incyte-W SU

9.2 Incyte-P SU

REF	Name
10076676	Incyte-P SU

9.3 Parts and Accessories



REF	Name
10071111	Arc View Mobile Basic for non Ex environment

Description: The pre-configured Arc View Mobile, Hamilton's mobile solution for monitoring measurement values, calibrating Arc sensors and configuring various parameters with the unified user interface for pH, DO, Conductivity and ORP. The Arc View Mobile is based on the Samsung Galaxy Tab Active tablet and comes pre-configured with the ArcAir basic, app blocker application, power supply cable, instruction manual and Hamilton quick guide.

REF	Name
10071113	Arc View Mobile Advanced for non Ex environment

Description: The pre-configured Arc View Mobile, Hamilton`s mobile solution for monitoring measurement values, calibrating Arc sensors and configuring various parameters with the unified user interface for pH, DO, Conductivity and ORP. The Arc View Mobile is based on the Samsung Galaxy Tab Active tablet and comes pre-configured with the ArcAir advanced application, including features for CFR 21 Part 11 and Eudralex Volume 4 Annex 11 compliance, app blocker application, power supply cable, instruction manual and Hamilton quick guide.

REF	Name
243490-01	Arc USB Power Cable with VP8 connector (for the Arc Wi 1G Adapter BT)
243490-02	Arc USB Power Cable with M12 8-pole connector (for the Arc Wi 2G Adapter BT)

Description: The Arc USB Power Cable provides power supply via USB port for Arc sensors and digital communication.

REF	Name
243460	Arc Wi 1G Adapter BT
243470	Arc Wi 2G Adapter BT

Description: Designed to add Bluetooth communication to the Arc Module Incyte SU when connecting directly to the PLC via modbus. The Arc Wi 2G Adapter BT also simplifies analog connection (4-20 mA) to the PLC.

REF	Name
243499	Arc Wireless Converter BT
242333	Arc Wireless Converter BT Advanced

Description: Designed for wireless communication between ArcAir and Arc Wi Adapter BT.

ArcAir™ Application
PC version: download from www.hamiltoncompany.com
Mobile version: download from App Store oder Google Play Store

Download on the App Store

GET IT ON Google Play

NOTE: In some territories, such as China, ArcAir™ is available as well after downloading on Android devices the Amazon Appstore as described at www.amazon.cn/androidapp

REF	Name
355263	Sensor Data Cable VP8, 1m
355264	Sensor Data Cable VP8, 3m
355265	Sensor Data Cable VP8, 5m
355266	Sensor Data Cable VP8, 10m
355267	Sensor Data Cable VP8, 15m
355268	Sensor Data Cable VP8, 20m

REF	Name
10070910	Data Cable VP8/M12, 1m
10071905	Data Cable VP8/M12, 3m
10067844	Data Cable VP8/M12, 5m
10067846	Data Cable VP8/M12, 10m

9.4 Services

Hamilton service engineers provide customers with on-site services. Hamilton offers a wide range of services from technical support to initial operation, qualification and maintenance of the sensors.

Various tailored services are offered especially for OEM customers. Experienced service engineers ensure an optimal and professional service.

In order to find your local service support please visit: www.hamiltoncompany.com/process-analytics/support

Overview of service offers

NOTES

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