

# Incyte Arc Sensors

## Operating Instructions



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## Hamilton Warranty

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

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# 1 Preface

Congratulations on your purchase of a transmitter integrated Incyte Arc sensor. This Arc sensor can be combined with a computer and mobile device using Hamilton's software solution ArcAir. The combination enables the in-line monitoring and visualization of conductivity and cell density during biotechnological processes. This opens a new possibility to generate data and use it for process control. The Incyte Arc can be installed in a standard measuring loop that consists of an Arc sensor, which is connected via VP8 cables directly to the process control system (PCS). In addition, an integration into Supervisory Control and Data Acquisition (SCADA) or to Hamilton's ArcAir (standalone application) is possible.

Using an Arc Wi Bluetooth adapter, the ArcAir application allows a wireless communication of up to 31 Arc sensors at the same time and in parallel to the process control system. Within the ArcAir application, Hamilton provides a validation functionality that offers a central management of users and validation reports for calibration, verification, configuration and communication within the GMP guidelines for nearly all Arc sensors. Those functionalities are also ready for compliance with FDA CFR 21 Part 11 and Eudralex Volume 4 Annex 11.

To learn about proper care and maintenance, please take the time to read this manual. Hamilton would like to thank you for your purchase of an Incyte Arc.

## 2 General Information

### 2.1 Intended Use

Incyte Arc is designed to measure permittivity in a liquid medium. These measurements may be used to make bioprocess control decisions within the defined specifications (see specifications sheets [www.hamiltoncompany.com](http://www.hamiltoncompany.com)). The permittivity measurement may be correlated to the viable cell density. In addition to permittivity measurement, Incyte Arc is able to measure conductivity and temperature.

 **NOTE:** Incyte Arc has no Ex approval.

### 2.2 About This Operating Instructions

These Operating Instructions will help users to operate Incyte Arc in combination with ArcAir (version 3.6.) 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 Incyte Arc 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 sensor. 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.

In order to provide quick help, some of the most common problems are addressed in the Quick Tips chapter. They can be found here: chapter 9.1.

## 3 Liability

The liability of Hamilton Bonaduz AG is detailed in the document «General Terms and Conditions of Sale and Delivery (GTS)», chapter 12. Hamilton expressly shall not be liable for direct or indirect losses arising out of the utilization of the sensors. It must in particular be ensured in this conjunction that malfunctions can occur on account of the inherently limited useful life of sensors contingent upon their relevant applications. The user is responsible for the calibration, maintenance and punctual replacement of the sensors. In the case of critical sensor 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 sensor failure.



## 4 Safety Precautions and Hazards

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

### 4.1 General Precautions

For safe and correct use of Incyte Arc, 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 Operating Instructions of Incyte Arc. The specifications given 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 personnel trained in such work. Before removing the sensor from the measuring setup, always make sure that no process medium can be accidentally spilled. The vessel should have no overpressure and be cooled down. When removing and cleaning the sensor, it is recommended to wear safety goggles and protective gloves. If the sensor cannot be repaired by the operator, it has to be sent back to Hamilton for inspection. Necessary precautions should be taken when transporting the sensors. For repair or shipment the sensor should be sent back in the original reusable packaging box. Every sensor 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.

### 4.2 Operation Precautions of Incyte Arc

Incyte Arc must be used for the intended applications, and in optimum safety and operational conditions. The customer has to validate, if the sensor is qualified for the application. Make sure that the process connections and O-rings are not damaged when screwing a sensor into the process. O-rings are consumable parts, which must be exchanged regularly (at least once per year). Even when all required safety measures have been complied with, potential risks still exist with respect to leaks or mechanical damage. Wherever there are seals or screws, gases or liquids may leak out undetected. Do not put stress on the system by vibration, bending or torsion. The sensor can be connected to PCS, SCADA or computer during cleaning in place (CIP) and sterilization in place (SIP). Stand clear of sensor during CIP and SIP procedures as it may become very hot.

### 4.3 Electrical Safety Precautions

Only use the cables provided by Hamilton. Do not connect the sensor to a power source of any voltage beyond the range stated in the specifications (see [www.hamiltoncompany.com](http://www.hamiltoncompany.com)). Failure to do so may lead to malfunction or damage of the system or impair user safety. It is recommended to inspect the entire grounding (sensor / sensor with reactor) before use.

In areas having significant electronic noise, Incyte Arc sensors may require grounding. Locations having electronic noise may cause interference to permittivity readings. Grounding the sensor should alleviate the interference. If the head plate of a benchtop bioreactor is not grounded, connect an earth ground wire to it (Figure 1 A). For large metallic bioreactors it is not, necessary to ground the Incyte Arc sensor if the bioreactor is already grounded (Figure 1 C). For large bioreactors, without a ground (e.g., glass-lined reactors) connect a ground wire to the fitting the sensor is mounted to (Figure 1 B).

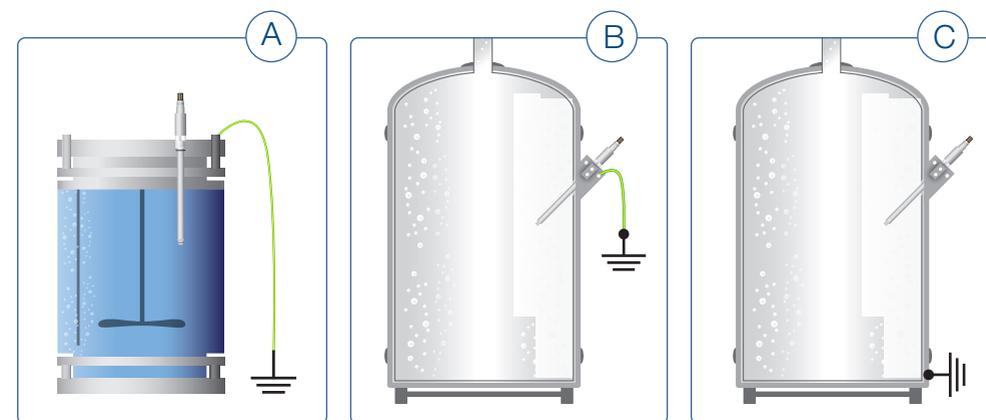


Figure 1: Incyte Arc grounding:

- A (not grounded benchtop bioreactor): Connect the head plate to the ground. The sensor will be grounded via its stainless steel PG 13.5 thread.
- B (not grounded large bioreactor): In case the tank is not grounded, connect the fitting to the ground. The sensor will be grounded via its stainless steel PG 13.5 thread.
- C (grounded large bioreactor): If the tank is grounded, the stainless steel PG 13.5 thread connect the sensor to the ground.

### 4.4 Chemical, Radioactive or Biological Hazard Precautions

Selection of the appropriate biological safety level and implementation of the required biosafety measures for working with Incyte Arc 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. Avoid any contact of the equipment with corrosive media. If Incyte

Arc 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 correct functioning of the system. Avoid damaging the power cord. Do not bend it excessively, step on it, or place heavy objects on it. A damaged cord can easily become a shock or fire hazard. Never use a damaged power cord.

## 5 Product Description

### 5.1 General Description

The Incyte Arc sensor is designed to provide continuous real-time measurement of permittivity in a bioprocess. Permittivity is directly proportional to viable cell biovolume, and is correlated to viable cell density in many applications. The measurement is not influenced by media composition or the presence of micro carriers, allowing for a robust measurement in both adherent and suspension-based bioprocesses. Additionally, dead cells and cellular debris do not contribute to the permittivity measurement, providing an independent measurement of viable cell density within a culture.

Incyte Arc will perform in many mammalian, insect, bacterial, and fungal systems, depending upon the cell concentration at inoculation.

|                           |  |
|---------------------------|--|
| <b>Permittivity</b>       | 0 - 700 pF/cm                              |
| <b>Animal</b>             | $5 \times 10^5$ - $8 \times 10^9$ cells/ml |
| <b>Bacteria and Yeast</b> | 5 - 200 g/l                                |

### 5.2 Measurement Principle

#### 5.2.1 The Dual-Frequency Measurement Mode

In the presence of an alternating electric field, viable cells behave like small capacitors and store a charge distribution within the cellular membrane (Figure 2). The charge of these small capacitors is measured by the Incyte Arc sensor 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 3). It is continuously and automatically corrected for the background permittivity measured at high frequency typically at 10 MHz (background frequency). This measurement mode is referred to as the standard Dual-Frequency Measurement Mode. The permittivity measured by Incyte Arc can be correlated to the viable cell density, especially during the exponential growth phase.

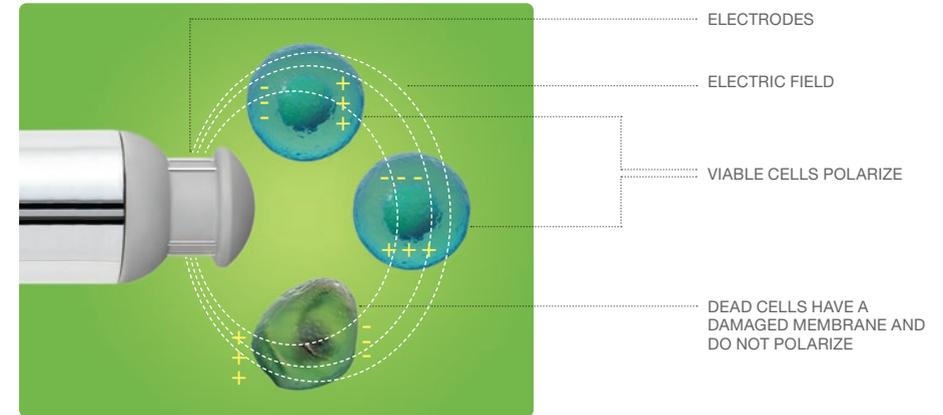


Figure 2: Incyte measurement principle. Only viable, but not dead cells, exhibit a permittivity signal

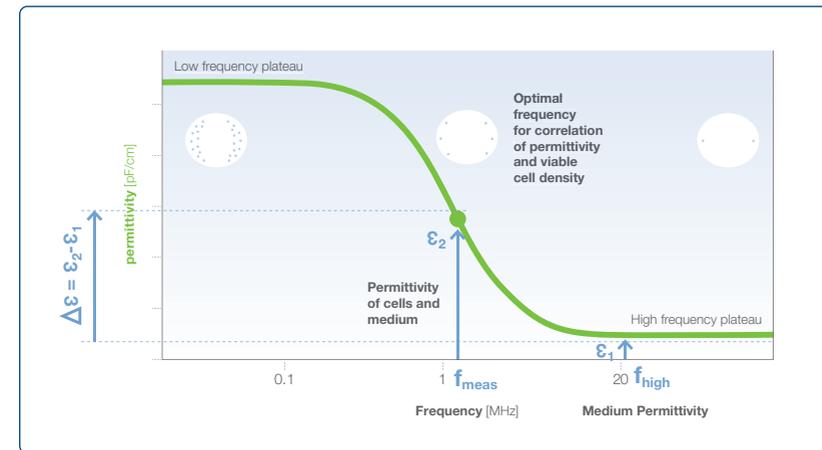


Figure 3: In the Dual-Frequency Measurement Mode the permittivity of viable cells is measured at a frequency specific to the cell type and corrected by the background permittivity measured at high frequency

#### 5.2.2 Theory of the Scan and Cole-Cole Fitting

The polarization response of cells varies strongly at different frequencies, as shown in Figure 3. Cells fully polarize and provide a measurable permittivity at lower frequencies, whereas cells do not appreciably polarize at higher frequencies. This response can be described by the Cole-Cole equation. The Incyte Frequency Scan measures the permittivity signal at 17 different frequencies between 0.3 and 10 MHz (Figure 4).

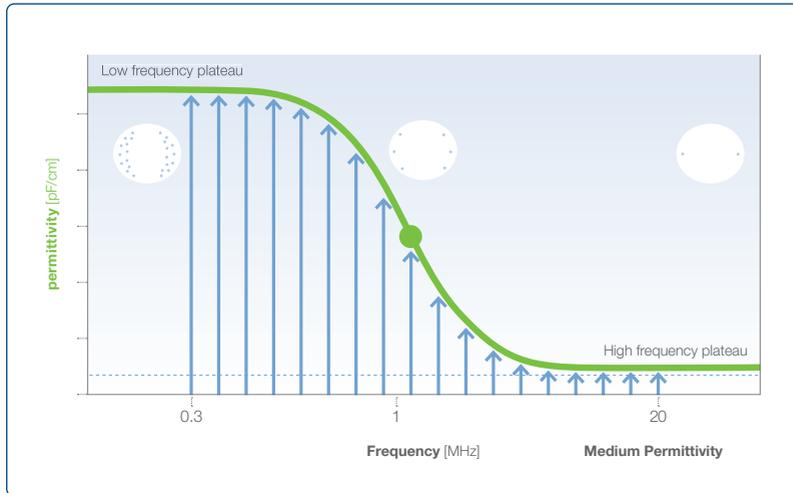


Figure 4: The ideal frequency spectrum of mammalian cells, called beta-dispersion

The analysis of the Incyte Scan may provide additional information on cell physiology response throughout the duration of the culture. To better characterize the change in Incyte Scan curve shape, and therefore, cell response within the dielectric field, empirically calculated parameters fitting the curve to the Cole-Cole equation are calculated.

The relevant parameters of the Cole-Cole equation –  $\Delta\epsilon$ ,  $f_c$ , and  $\alpha$  – are automatically fitted and displayed in ArcAir. In general, qualitative observations of changing Cole-Cole parameters can often be linked to process-specific changes in culture parameters.

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,  $\Delta\epsilon$ , can correlate with the viable cell density, and is a theoretical calculation of the maximum permittivity able to be generated in the culture at that time. The slope ( $\alpha$ ) 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  $\alpha$ , may correlate to a homogenous culture.

The Cole-Cole parameters are provided with an estimation of calculation performance, 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%, where 100% relates to an ideal fit and 0% refers to a non-converging dataset. In addition, the model error («Cole fit RMSE») is also provided as a secondary reference metric.

### 5.2.3 Theory of Data Modeling for Off-line/In-line-Correlation

Incyte Arc provides a measure of the viable cell density through the measurement of permittivity and viable cell biovolume. The measurement of permittivity is influenced by different parameters such as cell size, internal conductivity of the cells, and membrane permeability. As a result, correlation strength between permittivity and an established off-line metric may differ post exponential phase as a culture undergoes metabolic stress, cell swelling, and the start of apoptosis. To obtain a good permittivity to off-line correlation on reproducible processes, the data of Incyte Scan (please see chapter 5.2.2 for details) can be utilized by the ArcAir Data Modeling Software to create a multivariate model. The model can be uploaded into the sensor, resulting in a real-time MVDA-based VCD calculation. In order to build a correlation model using ArcAir Data Modeling software, at least three to four batches including off-line data of the same process (including relevant/possible variations) are required to build and validate in the ArcAir Data Modeling Software (see Manual of ArcAir Data Modeling (Ref 111003989) for further details).

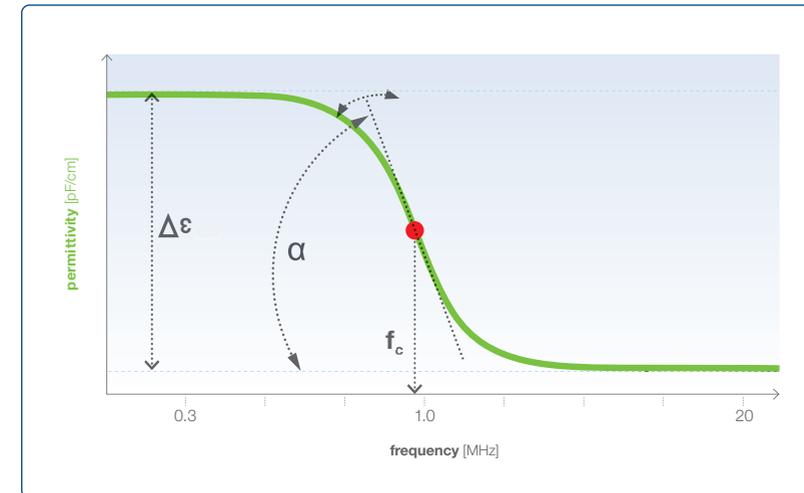


Figure 5: Data Interpretation of the beta-dispersion, gained from an Incyte Scan

**NOTE:** The Incyte Arc Cole-Cole Fit is optimized to run on the sensor and may lead to different values of  $\alpha$ ,  $f_c$  and  $\Delta\epsilon$  compared to Incyte Pre-Amp version.



### 5.3 Combination with Arc Portfolio

With the Arc Sensor family, Hamilton supplies intelligent sensors for process monitoring. With their integrated micro-transmitter, Incyte Arc sensors 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 7). 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 6). With the integrated micro-transmitter, Incyte Arc sensors 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.

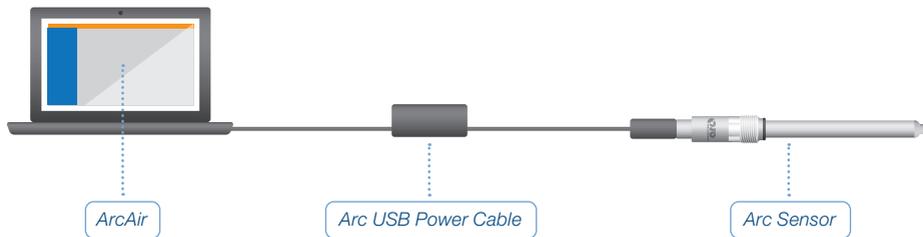


Figure 6: Arc System wired connection to ArcAir application

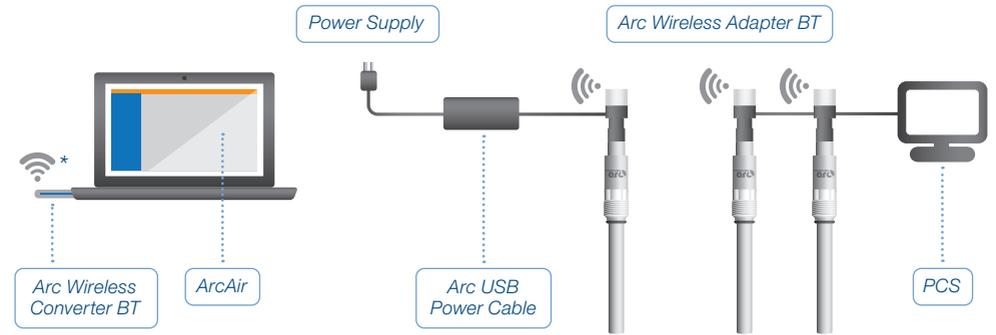


Figure 7: Arc System wireless connection to ArcAir application (\*for sensor configuration only)

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

#### 5.3.1 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 Incyte Arc sensors 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).



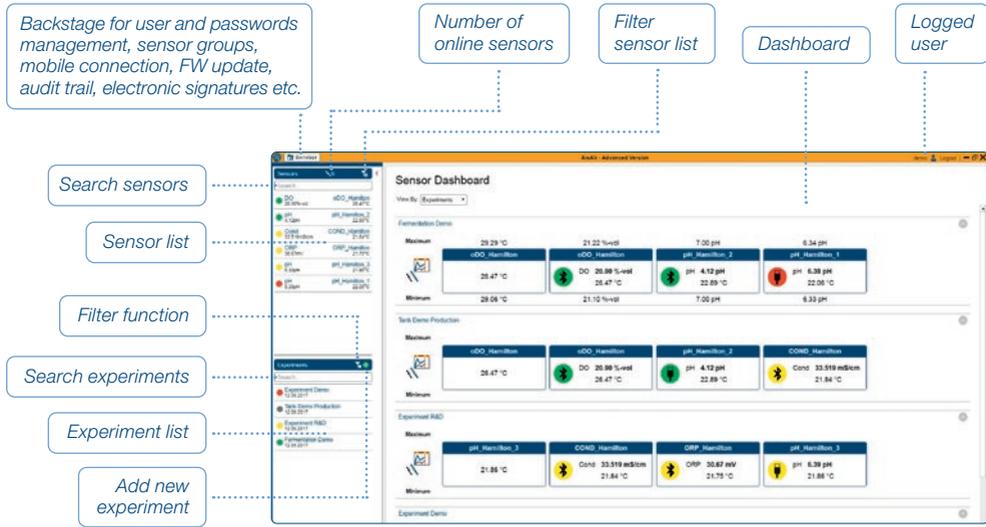


Figure 8: ArcAir Software application on computer



Figure 9: The ArcAir application on mobile

There are two different ArcAir versions:

|                     | ArcAir Basic  | ArcAir Advanced   |
|---------------------|---|---|
| <b>Availability</b> | 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) |
| <b>Intended for</b> | PC/Mobile   | PC/Mobile   |
| <b>Functions</b>    | Measuring, Sensor Status, Experiment function, Configuration, Firmware update | Full incl. Verification, Communication Validation, User Management, Audit Trail, Report functionality                       |

### 5.3.2 Accessories

The Incyte Arc Sensor can be combined with different hardware accessories from the Arc portfolio. These are related to specific applications. All listed accessories should be provided for each Incyte Arc sensor scheduled in a bioprocess. Our Hamilton team is looking forward to supporting you in finding the accessories that are needed for a complete application with the Incyte Arc Sensor.

An overview is given here.

- Wireless
  - Arc Wi 2G Adapter BT (Ref 243470) > 4-20 mA, Modbus and Bluetooth connection
  - Arc Wi 1G Adapter BT (Ref 242360) > Modbus and Bluetooth connection, recommended with Arc Modbus OPC Converter (Ref 10089359)
- Wired/Power
  - External Power supply with Arc USB Power Cable (Ref 243490-01 or -02) > Modbus

**NOTE:** When an USB extension cord is used, it is recommended to use an additional power supply of the Arc USB Power Cable (Ref 243490) that provides the Incyte Arc Sensor with enough power.



### 5.3.3 ArcAir Data Modeling

The Incyte Arc 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 Incyte Arc probe sensor 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](http://www.hamiltoncompany.com)) for customers with Incyte Arc Expert sensors.

For more information (e.g. usage in GMP Environment), refer to the ArcAir Data Modeling (Ref 111003989).

## 5.4 Hardware Description

A schematic illustration of the sensor is shown in Figure 10. The sensor has a VP8 connector at the end for connection to e.g. the PCS. In addition, the sensor is supplied with power via this connector. The sensor head contains the micro-transmitter and an internal memory for data logging (*Sensor Data Logging*). The memory is big enough to record data for 28 days at a measurement interval of 5 minutes (for more information see chapter 6.4.5.5). The PG13,5 is the standard connector for mounting the sensor into the port of different bioreactors. The reference number and the serial number of the sensor can be found on the shaft of the sensor. The sensitive platinum electrodes, which enable the measurement, are located at the tip of the sensor.

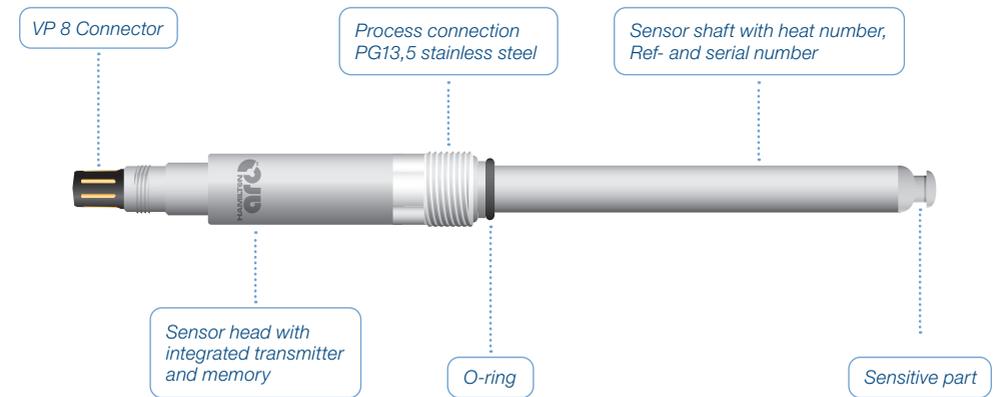


Figure 10: Incyte Arc Sensor

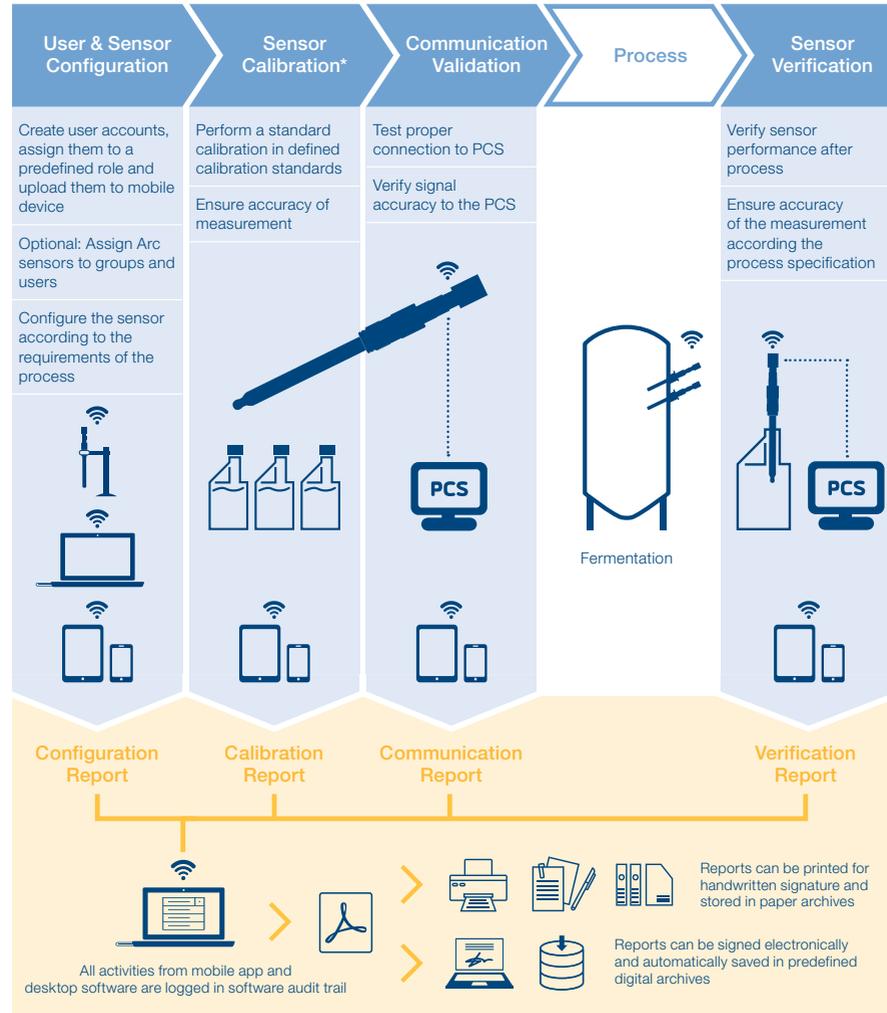
### 5.4.1 Incyte Arc with Micro-Transmitter inside

With the integrated micro-transmitter, Incyte Arc sensors offer fully compensated signal directly to the PCS. Communication protocols include digital Modbus and optional 4-20 mA, using the Arc Wi 2G Adapter BT (Ref 243470). The micro-transmitter located in the sensor head stores all relevant sensor data, including factory calibration and diagnostic information, simplifying verification and maintenance.

## 5.5 Incyte Arc in GMP

Find below the validation process of Arc sensors in GMP environments or laboratory:

### Laboratory and Production



Office

\* No customer calibration for Incyte Arc



## 6 Installation of Hardware and Software

### 6.1 Hardware Installation

#### 6.1.1 Unpacking the sensor

- Carefully unpack the Incyte Arc sensor. Find enclosed the Incyte Arc sensor, the Declaration of Quality, the Operating Instructions as well as the Material Certificates.
- Inspect the sensor for shipping damages or missing parts.



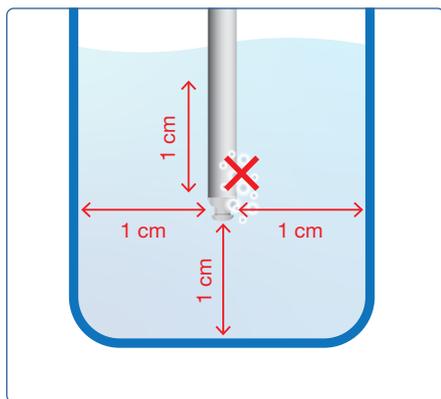
Figure 11: Incyte Arc sensor delivery package

#### 6.1.2 Mounting Sensor into the Bioreactor

Depending on the bioreactor, there are different opportunities to mount the Incyte Arc sensor into the reactor. In addition, there are various housings available to custom fit the sensor in every installation.

- Remove the yellow protective caps from the Incyte Arc sensor tip and from the VP8 sensor head.

2. Check the Incyte Arc Sensor
  - a. Check the O-ring on the sensor shaft.
  - b. Verify if the platinum electrodes are not mechanically damaged (e.g. scratches).
3. Insert the sensor in the port. Do not scratch the platinum electrodes while inserting the sensor.
4. When mounting the Incyte Arc, please note that gas bubbles will interfere the measurement. It is recommended to revalidate the positioning regularly and make adjustments if necessary. In general, the sensor should always reach deep enough into the measurement environment. A distance to a solid part (e.g. stirrer, reactor wall), in particular metal, of more than 1 cm in all directions is recommended.



5. The sensor should be installed in the PG13,5 hand tight and not be tightened to more than 2 Nm.

When the Incyte Arc is used in combination with an Arc Wi Adapter BT, the notch dictates the connection orientation of the two components. This orientation combinations should be individually adapted to the process conditions (signal quality and distance to other reactor components).

**⚠ ATTENTION! No tools should be used to install or remove the Incyte Arc. The Arc Wi Adapters BT should not be used to unscrew the sensor from the reactor.**

## 6.2 Connection to the Process Control System

Hamilton offers a broad range of options for integrating the sensors in a wide variety of process situations. In the following, these will be briefly presented and an introduction to the different connection possibilities via cable will be given. For further details please refer to the Incyte Arc Programmers Manual (Ref 695251). The mechanical design of the Incyte Arc sensor is compatible with all Hamilton process housings, including FlexiFit (Ref 237344, 237345, 237380-OP), Retractable (Ref 243240, 243275, 237730, 237735, 237740, 237745, 243200, 243255, 243220, 243265, 243210, 243260, 243230, 243270), RetractoFit (Ref 237240, 237490, 237440 and 237480) and Hygienic Sockets (Ref 242535, 542545, 242548, 242550). Before installing the armatures, check if the seal is tight and the parts are all in working order. Ensure that there is no damage to the sensor or the armature. Check whether all O-rings are in place in the appropriate grooves and are free of damage. To avoid any mechanical damage to O-rings on assembly, they should be slightly greased.

Please note that O-rings are wetted parts and greasing compounds must comply to individual FDA application needs.

### 6.2.1 VP8 or M12 Pin Designation

Always use Hamilton's VP8 or M12 sensor cables for safe connections, which are available in different lengths. For easy identification of each pin on the VP8, the head has a notch between pin A and pin B.

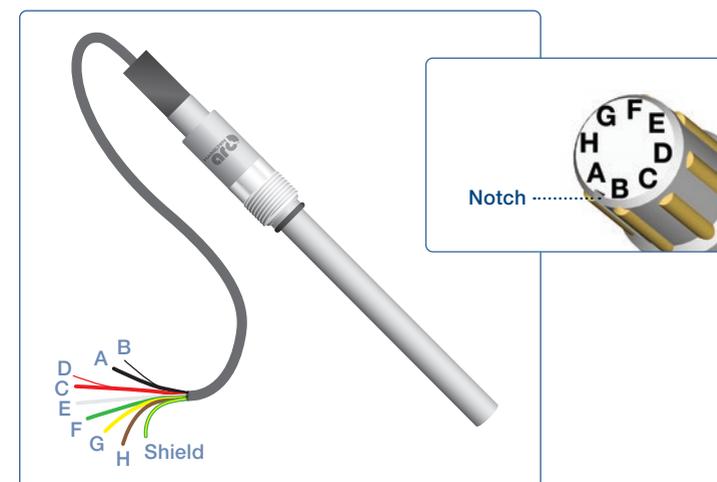


Figure 12: Arc sensor with VP8 double coaxial open-end cable

| VP Pin | Function                        | Color Double Coaxial Cable     | Color Data Cable |
|--------|---------------------------------|--------------------------------|------------------|
| A      | Not used                        | Coaxial core black transparent | Yellow           |
| B      | Not used                        | Coaxial shield black           | Green            |
| C      | Power supply: +24 V ± 10 %      | Coaxial core red transparent   | Red              |
| D      | Ground                          | Coaxial shield red             | Blue             |
| E      | Not used                        | White                          | Brown            |
| F      | Not used                        | Green                          | White            |
| G      | RS485 A                         | Yellow                         | Gray             |
| H      | RS485 B                         | Brown                          | Pink             |
| Shield | Sensor shaft connected to earth | Green/Yellow                   | Green/Yellow     |

**NOTE:** Always use Hamilton sensor cables for safe connection.

M12 (A coded) Pin Designation with Respect to Hamilton's M12 Sensor Cable Conductor Colors:

| M12 Pin | Function     | Color        | Description  |
|---------|--------------|--------------|--|
| 1       | +4-20 mA # 1 | White        | 4-20 mA two-wire interface, functions as a current sink and needs to be powered.                                     |
| 2       | -4-20 mA # 1 | Brown        | It regulates the input current according to the sensor measurements and galvanically isolated from the power supply. |
| 3       | +4-20 mA # 2 | Green        |  |
| 4       | -4-20 mA # 2 | Yellow       |  |
| 5       | RS485 (A)    | Gray         | Modbus RTU RS485   |
| 6       | RS485 (B)    | Pink         | Modbus RTU RS485   |
| 7       | GND          | Blue         | Ground   |
| 8       | + 24 VDC     | Red          | Power supply: +24 V ± 10 % (Power supply can be external; not from PCS)  |
| Housing | Shield       | Green/Yellow | Connected to the housing including the VP8 female connector.   |

## 6.2.2 Connect via 4-20 mA

A connection of the Incyte Arc sensor via a 4-20 mA interface is realized via an Arc Wi 2G Adapter BT (Ref 243470).

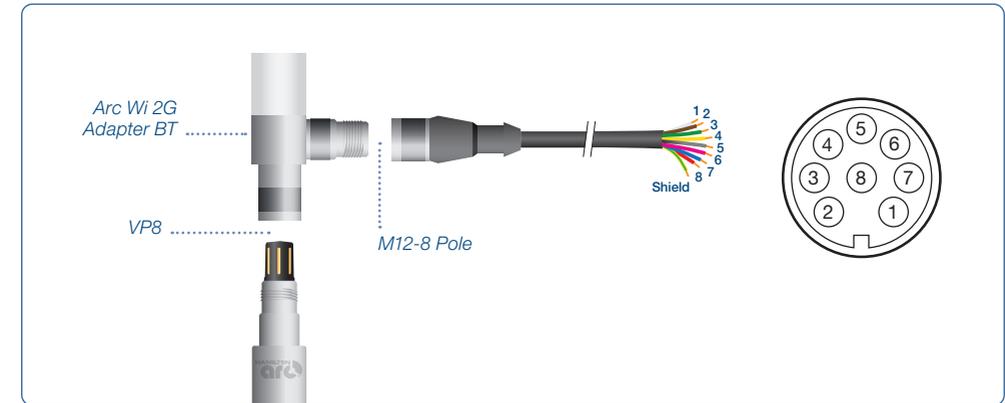


Figure 13: Arc sensor with Arc Wi 2G Adapter and M12-8 pole open-end cable

### 6.2.2.1 Electrical Connection for Analog 4-20 mA Connection

The 4–20 mA interface enables connection of the Incyte Arc sensor to a data recorder, indicator, control unit or PCS with analog I/O. Incyte Arc requires the Arc Wi 2G Adapter BT (Ref 243470) for a 4-20 mA interface connection. In combination with the Arc Wi 2G Adapter BT (Ref 243470) the sensor works as a current sink and is passive (see Figure 14). Connect the sensor according to the pin designations (see chapter 6.2.1). The 4–20 mA interface of the Arc Wi 2G Adapter BT (Ref 243470) in combination with the Arc sensor is pre-configured with default values for the 4–20 mA range and measurement unit. Configure the 4–20 mA interface according to individual requirements for a proper measurement in ArcAir (see chapter 6.4.5.6 chapter and chapter 6.4.5.7).



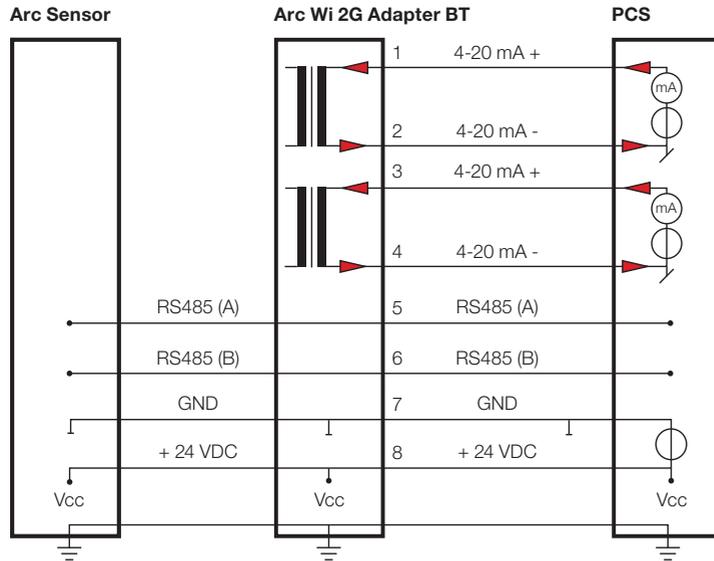


Figure 14: Typical connection to PCS using the Arc Wi 2G Adapter BT (Ref 243470). This is the safest form of wiring an Arc sensor. The Arc Wi 2G Adapter BT (Ref 243470) provides internal galvanic isolators for enhanced analog signal quality. Connection to the process control system is simplified.

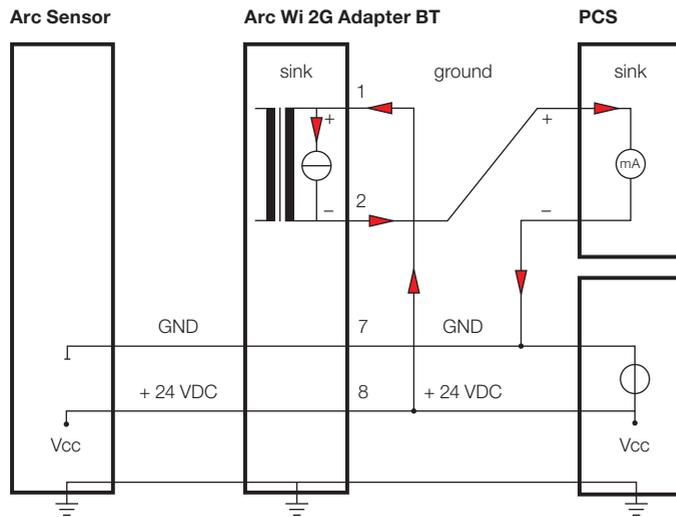


Figure 15: Typical connection to PCS using the Arc Wi 2G Adapter BT (Ref 243470)

### 6.2.3 Connection by Modbus

The digital RS485 interface enables communication with Arc sensor for performing measurements and monitoring the sensor status of the Arc sensor and for changing the sensor's configuration parameters. Arc sensors are always connected to digital controlling devices as a Modbus slave. To function, they require a power supply (VP 8 pins C and D, see above).

Additional information:

The Modbus RTU communication protocol corresponds to the Modbus-IDA standard (see [www.modbus.org](http://www.modbus.org)). The Modbus physical layer is described in detail with requirements on cabling and line termination in the «Modbus Serial line Protocol and Implementation Guide» [www.modbus.org](http://www.modbus.org) > Technical Resources / Modbus Specifications / Modbus Serial line Protocol and Implementation Guide.

**NOTE:** Because all sensors are delivered with factory-default settings, each sensor must be configured for its specific application before first use (see the section entitled «Configuring Arc Sensors»). 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

#### Example of circuit arrangement

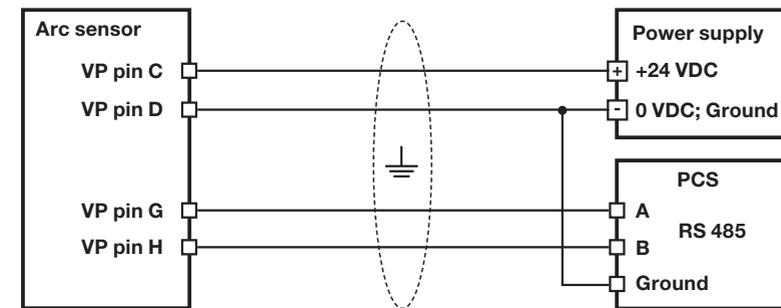


Figure 16: Wiring diagram for the RS485 interface

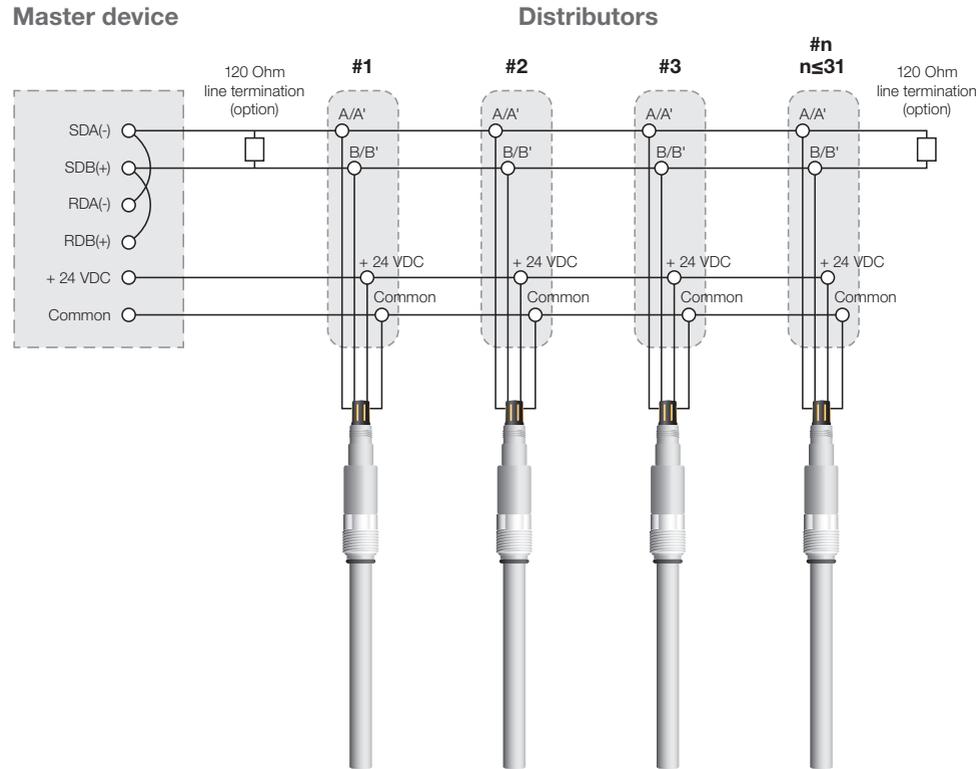


Figure 17: Multi-drop bus wiring for the Modbus two-wire mode. Each sensor functions as a Modbus slave

**NOTE:** In order to avoid signal reflection on the lines the use of line termination resistors (120 Ohm each) is recommended. The effect of signal reflections becomes more relevant with long cable length and/or high baud rates. In the connection scheme shown above, each sensor must have the unique Modbus device address for proper communication.

### 6.3 Installation of ArcAir Software

ArcAir can be installed on computer and/or mobile devices like mobile phones and tablets.

**NOTE:** Please refer to chapter 7 in the ArcAir System Manual (Ref 10071115) for the general workflow.

#### 6.3.1 Installing ArcAir on the Computer

Download the latest software version from the website [www.hamiltoncompany.com](http://www.hamiltoncompany.com).

#### 6.3.2 Installing ArcAir on Mobile or Tablet

Download the latest ArcAir Version from the App-Store.

#### 6.3.3 Software Update

**NOTE:** Please make sure that all configuration and experimental data are exported and saved before a new software version is installed.

1. Please check our website [www.hamiltoncompany.com](http://www.hamiltoncompany.com) for new updates. If an update is available: save the file on an USB or the required PC.
2. Install the software.

### 6.4 Connecting Incyte Arc with ArcAir

The Arc USB Power Cable (Ref 243490) is required to connect the Incyte Arc sensor. A wireless connection is possible with an Arc Wi Adapter BT (refer to chapter 13.2). See chapter 9.1 Quick Tips in Troubleshooting.

1. Connect one Incyte Arc sensor with the power supply and the computer, by using the Arc USB Power Cable (Ref 243490) on a standard USB port.



- The ArcAir application recognizes and displays the connected sensor automatically on the Sensor Dashboard. It is displayed via which connection type the sensors can be reached. E.g. via Bluetooth or via the USB power cable (see Figure 18).

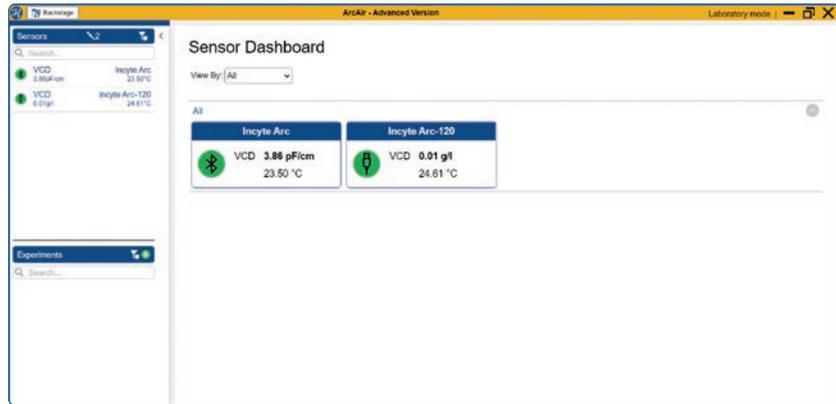


Figure 18: Overview of connected Sensors on the Sensor Dashboard. The Sensor List is found in the upper left corner.

- To connect to the Incyte Arc sensor click one the VCD sensor on either the *Sensor Dashboard* or the *Sensor List* (in the upper left corner). When the sensor is connected, the Info Tab of the sensor is displayed (see Figure 16).
- Verify the sensor functionality and status on the computer, mobile device or process control system with the *Sensor Quick View/ Info*.
  - If the Incyte Arc sensor is connected to the PCS via 4-20 mA, create a *Communication Validation Report* by navigating to the *Communication Validation* Tab and follow the instructions on the screen.

**NOTE:** The sensor status light may be red initially, as the sensor cannot measure correctly in air. Upon insertion in conductivity solution or medium, the sensor status may stay in yellow warning-state, as no scan fitting, or correlation-calculation can be done without cells/microorganisms.

## 6.4.1 Info

The Info Tab is divided into the following areas: *Sensor Quick View*, *Status*, *Measurement Value*, *Measurement Point*, *Information* and *Userspace*.

### 6.4.1.1 Sensor Quick View

This section holds Information like the *Serial No.*, the *Ref. Number*, the *Measuring Point*, the *Current Measurement* and the *Sensor Health*.

- Current Measurement:** shows the currently measured Viable Cell Density (VCD), Conductivity and Temperature.
- Sensor Health:** displays information about the life cycle and the quality of the Sensor. In addition to the operating hours and the number of sterilization (SIP) and cleaning cycles (CIP), the Quality Indicator is also indicated here.

**NOTE:** The Quality Indicator is updated with every verification (see chapter 8.1). It can, for example, increase in value after a recommended cleaning.

- Warnings and Errors:** This part shows a detailed listing of existing errors and warnings.

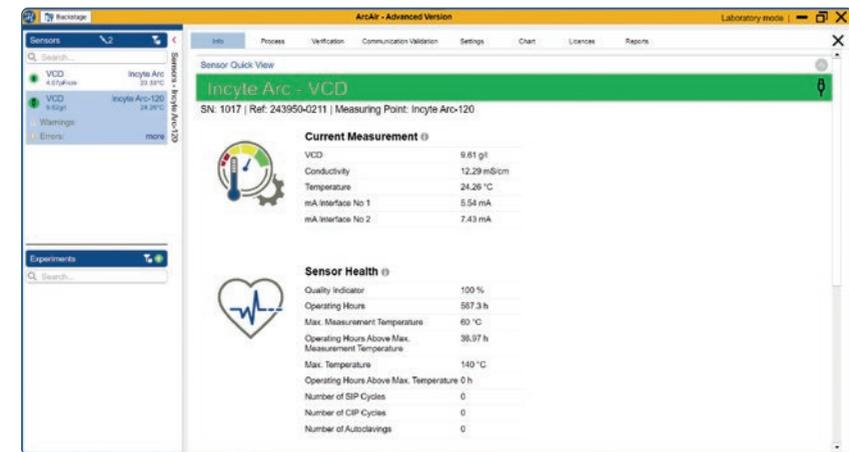


Figure 19: Info screen of the connected Incyte Arc sensor – Quick View



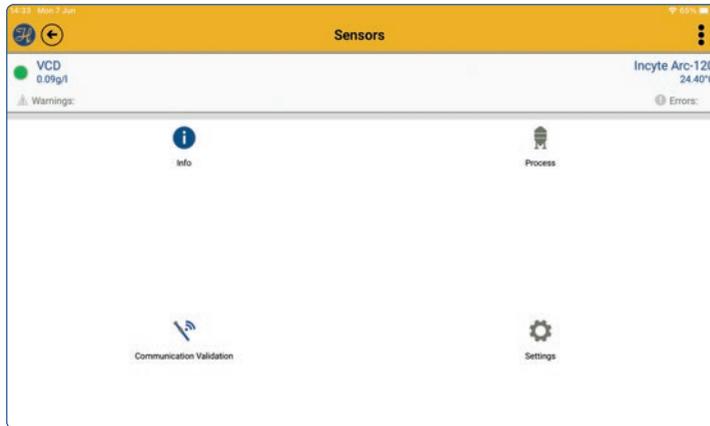


Figure 20: Dashboard on mobile Version

### 6.4.1.2 Status

Displays information about the life cycle and the quality of the sensor. In addition to the operating hours, the number of sterilization (SIP) and cleaning cycles (CIP), the *Quality Indicator* is also indicated here.

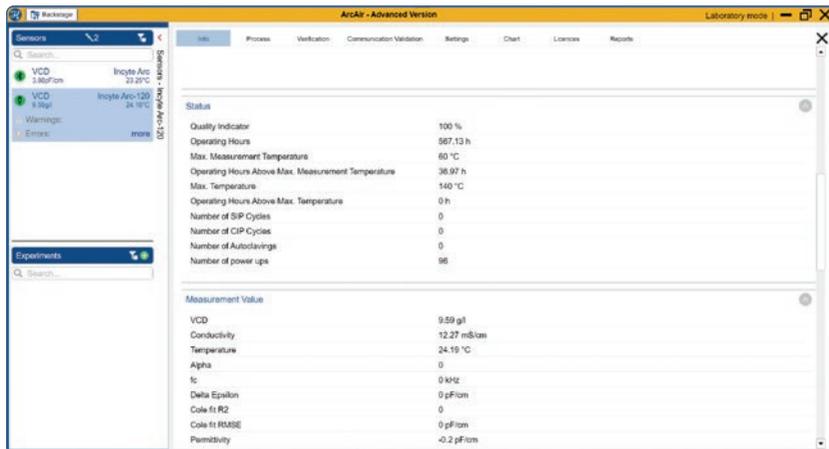


Figure 21: Example of the Information Tab with Status and Measurement Value.

### 6.4.1.3 Measurement Value

In this section the currently measured Viable Cell Density (VCD), conductivity and temperature is displayed. It also holds information about the current values of  $\alpha$ ,  $f_c$  and delta Epsilon are shown, as well as the cell factor and the offset.

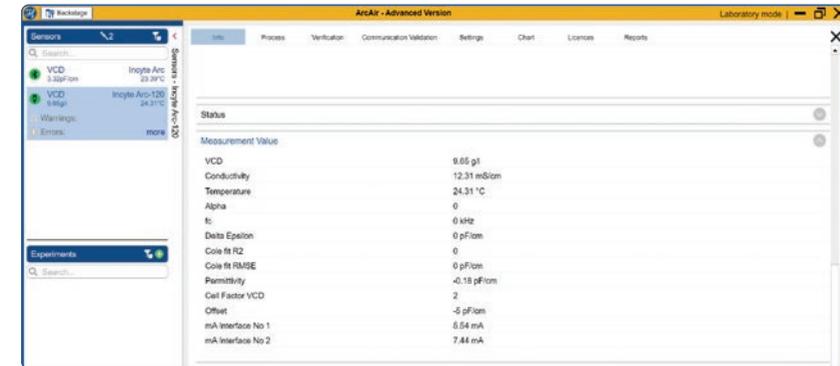


Figure 22: Example of the Information Tab with Measurement Value.

### 6.4.1.4 Measuring Point

It is possible to define a name for this sensor to ensure a better recognition of the sensor when more than one sensor is connected.

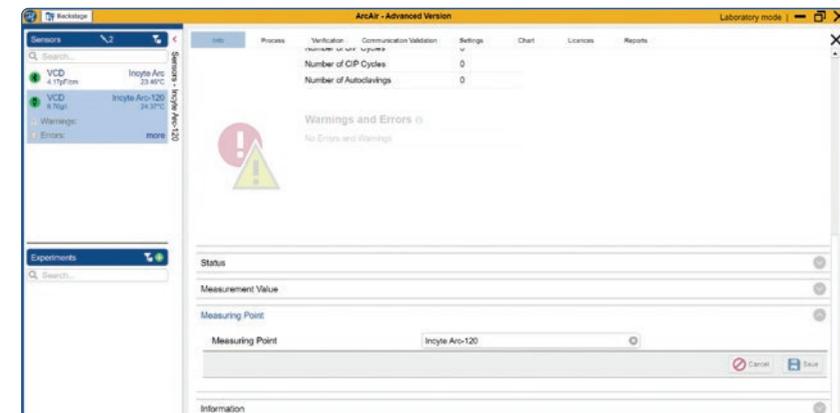


Figure 23: Example of the Information Tab with Measurement Point.



### 6.4.1.5 Information

This section holds information that characterizes the sensor. For example: Name, Ref. No, SN, Sensor ID, Sensor Length, Lot, Lot Date, Firmware Version and – Date as well as the material of the electrodes.

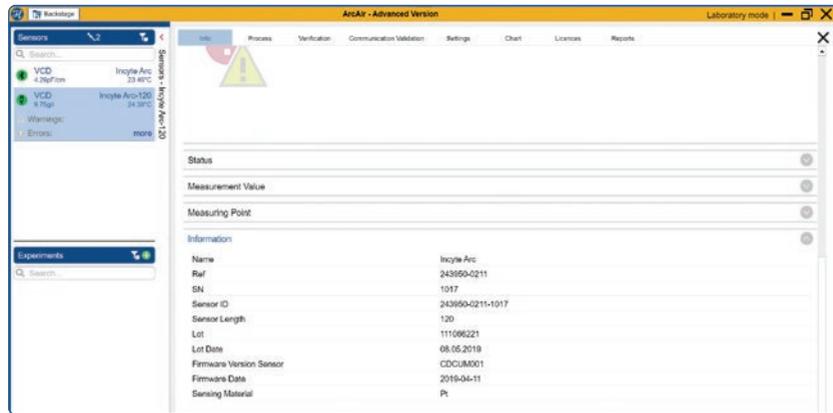


Figure 24: Example of the Information Tab with Info.

### 6.4.1.6 Userspace

Free space to place notes. E.g., Bioreactor ID.

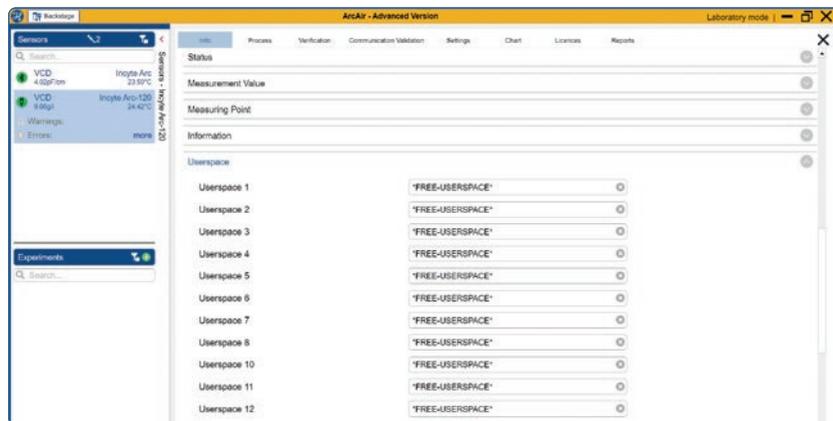


Figure 25: Example of the Information Tab with Userspace.



### 6.4.2 Process

This section contains all the settings that are intended for sensor use during the process. For the Incyte Arc sensors, this includes manual and auto cleaning.

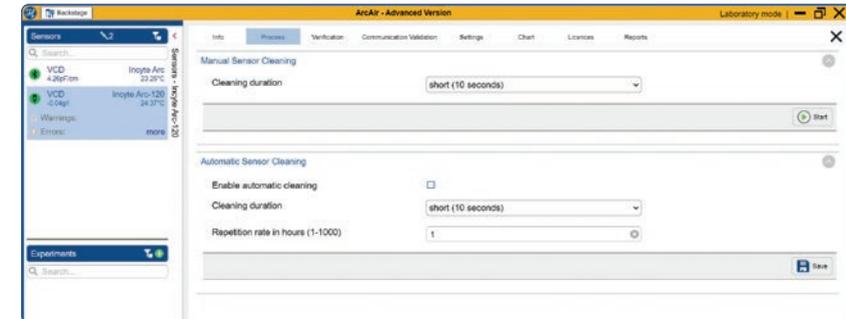


Figure 26: Example Screen of Process Settings

#### 6.4.2.1 Manual Sensor Cleaning

**NOTE:** The timing of the use of this function should be chosen with care. The signal may be unstable up to two hours after cleaning.

This cleaning option is designed to remove cells from the electrodes if cell deposition on the probe is suspected in the process (fouling). This is done by applying a high current to the electrodes, which results in the formation of bubbles that would carry the overlying cells away. A detailed description of the procedure can be found in the chapter 8.2.1.

#### 6.4.2.2 Automatic Sensor Cleaning

For processes where cell attachment is a known problem, this cleaning can be used to set a cleaning of different length at regular intervals during the process. This is done by applying a high current to the electrodes, which results in the formation of bubbles that would carry the overlying cells away. A detailed description of the procedure can be found in the chapter 8.2.2.

**NOTE:** The timing of the use of this function should be chosen with care. The signal may be unstable up to two hours after cleaning.

### 6.4.3 Verification

The verification provides the possibility to check the reproducibility of the sensor in order to exclude a drift. Where verification can be found in a GMP process is described in chapter 5.5 «Incyte Arc in GMP». This needs to be validated with individual customer process requirements.

The 12880µS/cm conductivity standard is required for verification (Ref 238988). Regardless of the outcome of the verification, it is checked whether the electrodes of the sensor require conditioning, for which Solution B (Ref 243742) is required. A detailed description of the procedure can be found in the chapter 8.1.

### 6.4.4 Communication Validation

Under Communication Validation, it is possible to validate the 4-20 mA Communication and custom tolerances. In addition, it is possible set up the 4-20 mA or the Modbus communication. The Settings mA Interface No 1 and 2 as well as the Setting Modbus are the same that can be found in Settings. See chapter 6.4.5.6, chapter 6.4.5.7 and chapter 6.4.5.8 for further information.

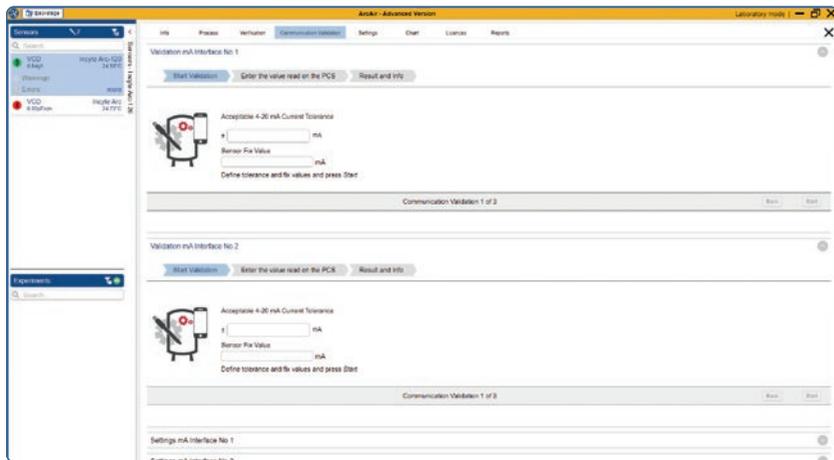


Figure 27: Example Screen for Communication Validation

### 6.4.5 Settings

This menu item contains settings related to the sensor and signal processing. They are described in more detail below.

#### 6.4.5.1 Configuration Report

The Configuration Report documents all sensor properties (e.g. temperature range) together with settings made by the user (e.g. cell factor and offset) in a table-like form. The reports can be viewed under the Report drawer and exported as PDF.

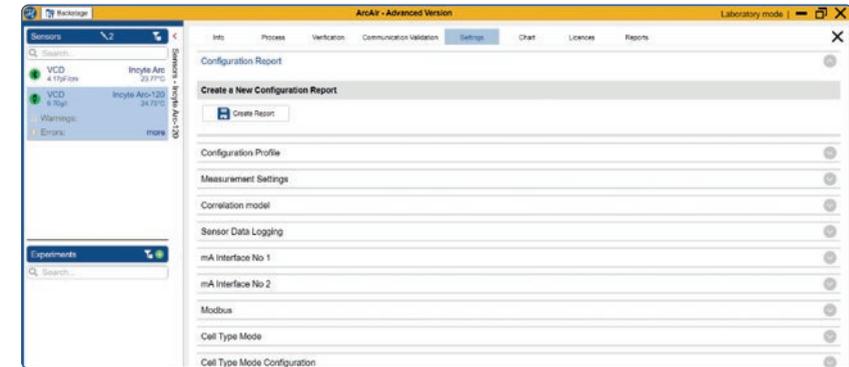


Figure 28: Example of the Setting section – Configuration Report

#### 6.4.5.2 Configuration Profile

Additionally the Configuration Report (see chapter 7.18) and Profile (see chapter 7.16) can be exported, as described in the ArcAir System Manual (Ref 100071115).

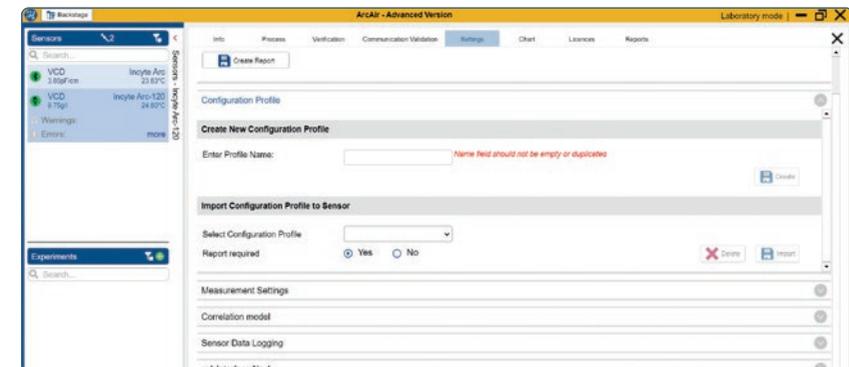


Figure 29: Example of the Setting section – Configuration Profile



### 6.4.5.3 Measurement Settings

All important settings that are based on the measurement of the Incyte Arc can be found in this section. To activate the changes, click the save button at the bottom. An example screen is displayed with Figure 30.

An overview:

| Setting                             | Description   |
|-------------------------------------|---|
| Measuring Point                     | Name of the <i>Measuring Point</i>  |
| VCD                                 | According to the <i>Measurement Unit</i> 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                      |
| 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                                  |
| Numbers of Autoclaving              | Increment it to record how many autoclaving the sensor has had  |

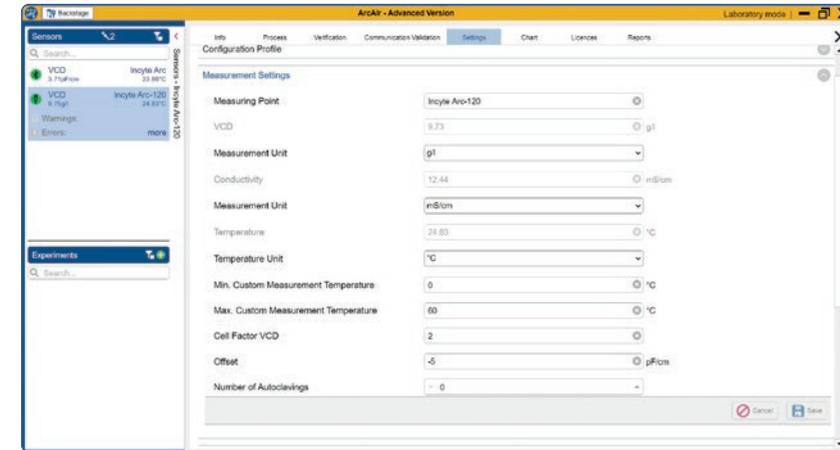


Figure 30: Example of the Setting section – Configuration Profile

### Measuring Point

Can be used for a better overview in the Sensor List, Dashboard or Experiment. It can also be changed on the Sensor Quick View in chapter 6.4.1.1.

### Measurement Unit

The setting of the unit for temperature, conductivity and permittivity can be done here. The measured value and unit are displayed at the same time.

The Incyte Arc sensor is measuring the permittivity. This can be converted into another unit with the help of an offset and a cell factor, using an off-line correlation. The unit is defined by the user and can be entered here. Default setting: [pF/cm].

E.g., an off-line correlation was done using an off-line measurement that results in [g/l]. Using the *Correlation Factor* of 3 and the offset (*Mark Zero*) of 0.5 on a permittivity value of 2 pF/cm will give a viable cell density of 4.5 g/l.

$$\begin{aligned}
 (\text{Permittivity} - \text{Offset}) \left[ \frac{\text{pF}}{\text{cm}} \right] \times \text{Correlation Factor} \left[ \frac{\text{unit}}{\text{pF/cm}} \right] &= \text{Celldensity}[\text{unit}] \\
 (2 - 0.5) \left[ \frac{\text{pF}}{\text{cm}} \right] \times 3 \left[ \frac{\text{g/L}}{\text{pF/cm}} \right] &= 4.5 \left[ \frac{\text{g}}{\text{L}} \right]
 \end{aligned}$$



**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 <sup>6</sup> 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 |

### Min. and Max. Custom Measurement Temperature

Use the settings here to customize the min and max of the measurement temperature settings. By default, they are set from 0°C to 60°C.

**NOTE:** No measurement of permittivity and conductivity is performed at a temperature higher than 60°C medium temperature to protect sensing part and enhance the sensor lifetime.

### Cell Factor VCD

Enter the cell factor to correlate the permittivity signal to viable cell density here. The cell factor can be changed during an Experiment ( Experiment italic). A change of cell factor is tracked in the experiment-documentation. Make sure the measurement unit adapted to the cell factor.

### Offset

A manual offset can be entered here. In addition, the *Mark Zero* button can be used in the *Experiment*. To reset the offset, set the value to zero or click *Clear Zero* in the *Experiment*.

### Number of Autoclavings

As it is not possible to increase the autoclavation cycles automatically, the cycles can be changed manually using the pointers on the left and right side of the text box. In addition, this can be changed in the chapter 6.4.5.11 Cleaning Cycles as well.

### 6.4.5.4 Correlation model

Using the frequency scan of Incyte Arc it is possible to improve the off-line/in-line correlation for reproducible processes (e.g. production or pilot plant), on the overall process, especially during the plateau and death-phase of a bioprocess. The model is created in the ArcAir Data Modeling using previous recorded process data sets. 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 edited.

1. Go to the «Import Correlation Model» and select the correlation file exported from ArcAir Data Modeling (.incal).
2. Press «Import».
3. Go to the «Current applied Correlation Model».
4. Check that «Creation Date and Time» as well as «Checksum Value» are the same like in the selected model.
5. Press «Activate»



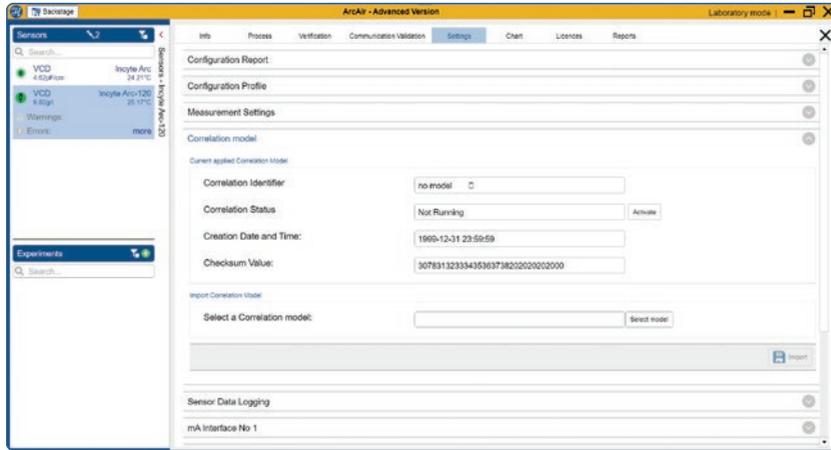


Figure 31: Example of the Setting section – Correlation model

#### 6.4.5.5 Sensor Data Logging

In addition to ArcAir recording by cultivation data with the *Experiment* (chapter 7.1 Experiment Functionality) 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.

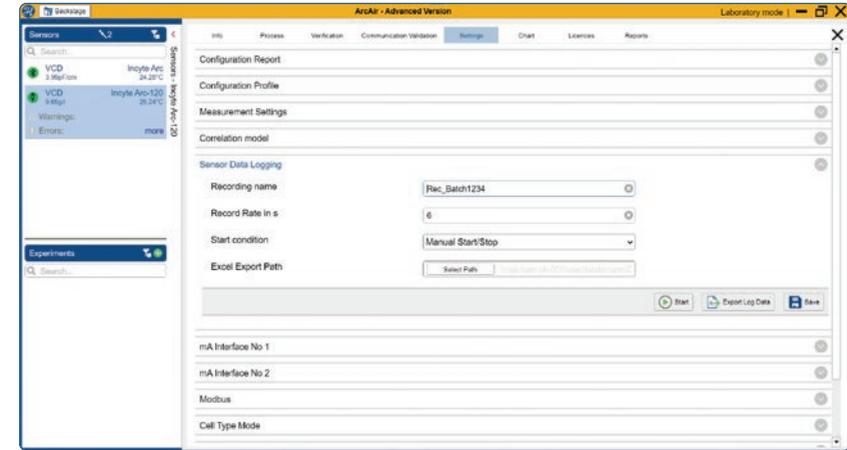


Figure 32: Example of the Setting section – Sensor Data Logging

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 33). A pop up window will appear asking about reset inoculation. Please select yes, if no inoculation has been done for this run (Figure 34). 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 7.2.3 Inoculate or Figure 33).
  - 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 35).

Depending on the settings of point 3. The *Sensor Data Logging* will be started or stopped (see Figure 35 and Figure 36). 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 35).



Figure 33: 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                    |

| Planned Record Rate | Record Rate for ArcAir (S) | Resulting in max. Record Time |
|---------------------|----------------------------|-------------------------------|
| 15 minutes          | 900                        | 85.21 days                    |
| 30 minutes          | 1800                       | 170.63 days                   |

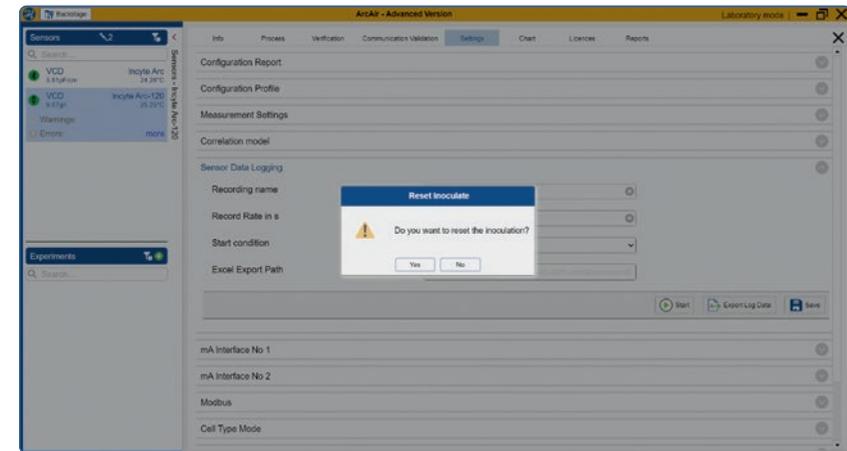


Figure 34: Example Screen of Sensor Data Logging using a Manual Start Option

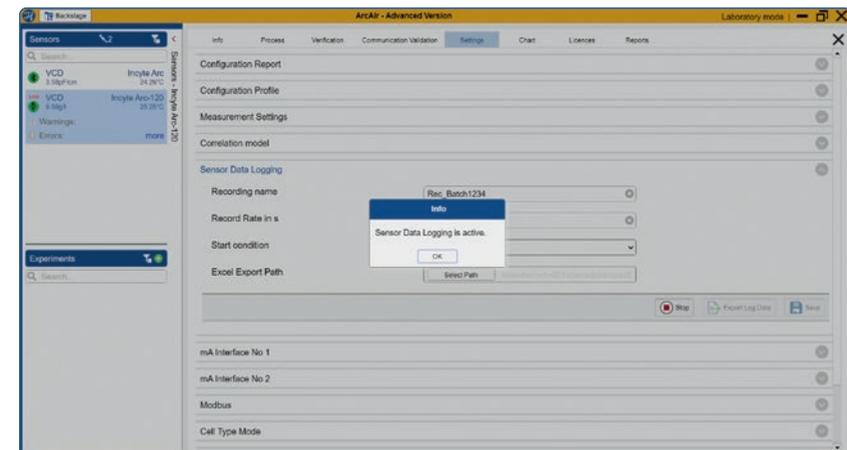


Figure 35: Example Screen of activated Sensor Data Logging



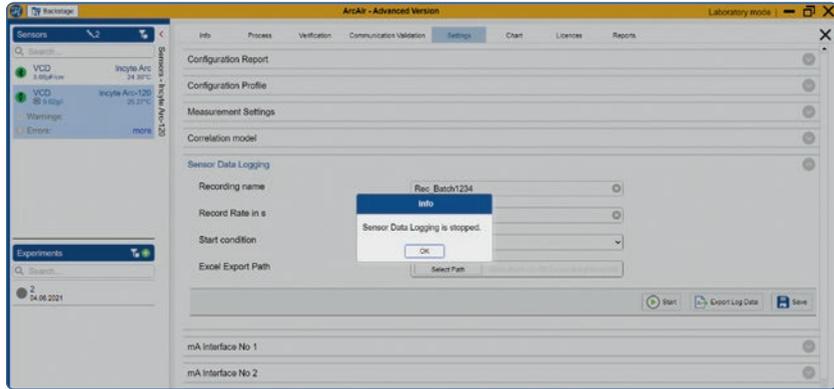


Figure 36: Example Screen of inactivated Sensor Data Logging

### 6.4.5.6 mA Interface No 1

This section offers the possibility to arrange one of the 4–20 mA communication. To activate the changes, click the save button at the bottom.

**NOTE:** The Arc Wi 2G Adapter BT (Ref 243470) is required to get a 4–20 mA signal.

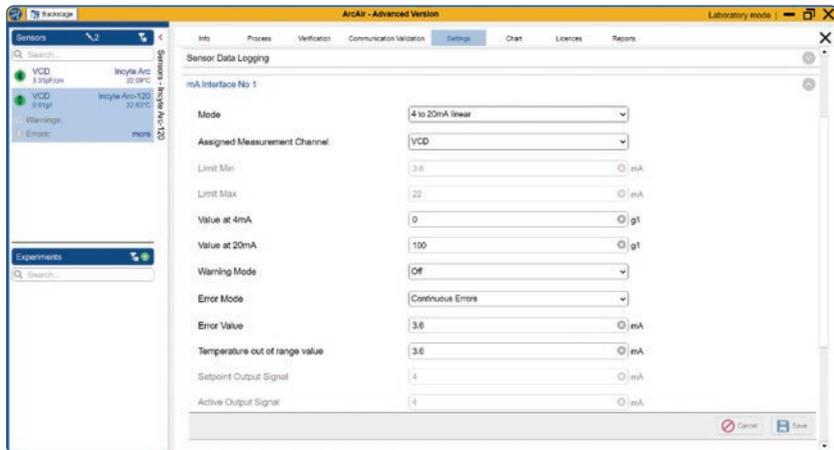


Figure 37: Example Screen of mA Interface No 1

### Mode

The 4-20 mA section can be operated with the mode linear, fixed or off.

| Mode             | Description  |
|------------------|--|
| 4 to 20mA linear | Linear correlation of 4-20 mA and permittivity or cell density as well as conductivity |
| 4 to 20mA fixed  | Can be used for testing the 4-20 mA signal transmission                                |
| Off              | Disables the current on the 4-20 mA lines  |

### Assigned Measurement Channel

Only one of the three available variables (VCD/permittivity, conductivity or temperature) can be assigned to each interface. The value passed via VCD/permittivity depends on the settings in Measurement Settings. Depending on the settings, the permittivity is transferred with or without cell factor and the offset (*Mark Zero*).

### ‘Value at 4mA’ and ‘Value at 20mA’

Define the limits of the value range of *Assigned Measurement Channel* and assign them to 4 or 20 mA. E.g.: *Assigned Measurement Channel*: VCD; value range: [0; 100 g/l]; Value at 4 mA: 0 g/l; Value at 20 mA: 100 g/l.

### Warning Mode

| Mode                | Description  |
|---------------------|--|
| Off                 | No warnings will be output                             |
| Continuous Warnings | All warnings will be transferred on the 4-20 mA signal |

### Error Mode

| Mode              | Description  |
|-------------------|--|
| Off               | No errors will be output                             |
| Continuous Errors | All errors will be transferred on the 4-20 mA signal |

### Error Value

Define a current to be output when an error occurs.

### Warning Value

Define a current to be output when a warning occurs.



### Temperature out of range value

Define a current to be output when temperature is out of specified range.

#### 6.4.5.7 mA Interface No 2

A second 4-20 mA interface can be defined for a second measurement variable. The meaning of the settings correspond to those listed in the previous chapter. See chapter 6.4.5.6 for more details.

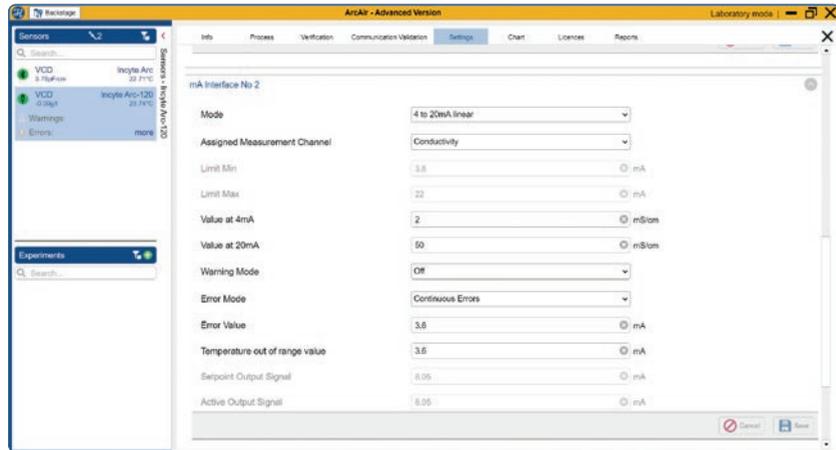


Figure 38: Example Screen of mA Interface No 2

#### 6.4.5.8 Modbus

A connection via Modbus is possible with an Arc Wi Adapter BT. A short overview of the setting options are listed below. To activate the changes, click the save button at the bottom.

| Setting        | Value range                 | Description  |
|----------------|-----------------------------|--|
| Device Address | 1-32                        | The device address is a unique address that allows communication with up to 31 sensors on one bus. |
| Baudrate       | 19200, 38400, 57600, 115200 | The baudrate is used to specify the transmission speed. It is defined in baud/second.              |

| Setting  | Value range     | Description   |
|----------|-----------------|---|
| Parity   | None, Even, odd | Parity is used to control the transmission of individual data bytes. This check refers to the sum of all bits in a data byte. |
| Stopbits | 1, 2            | The sum of the data byte must be 11 bits. If no parity is set, 2 stopbits must be set.  |

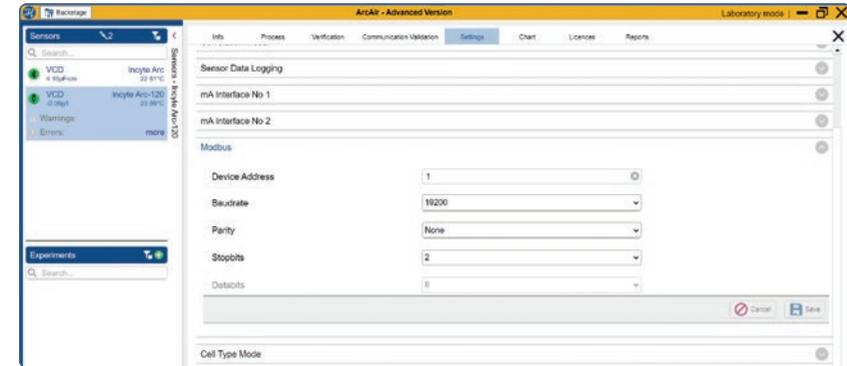


Figure 39: Example Screen of Modbus – showing the standard settings

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

**NOTE:** If a Firmware ending with 001 is used on the sensor, all changes on the settings are saved with the next Power Up. Any Firmware higher will save the changes immediately and the connection to the sensor may be lost.

#### 6.4.5.9 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 chapter 6.4.5.10 *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 to hit counter in Dual Scan Mode | Time needed to hit counter in Scan Mode |
|------------------------------------|-----------------------|--|---|
| Low                                | 32                    | 32 s   | 96 s                                    |
| Middle                             | 64                    | 64 s   | 192 s                                   |
| High                               | 128                   | 128 s  | 384 s                                   |

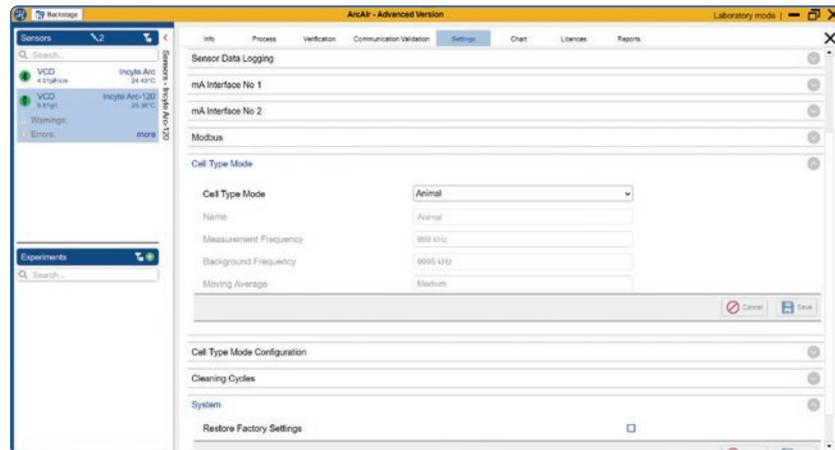


Figure 40: Example of the Setting section – Cell Type Mode

### 6.4.5.10 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».

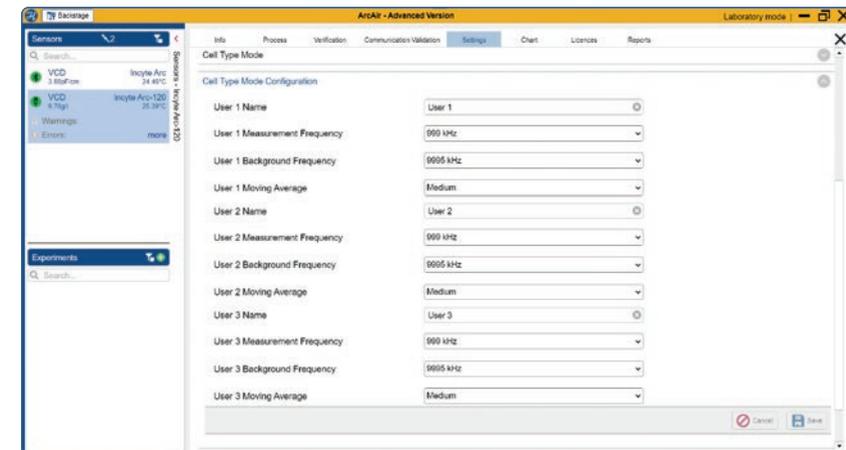


Figure 41: Example of the Setting section – Cell Type Mode Configuration



### 6.4.5.11 Cleaning Cycles

Under this menu item, settings can be made for Cleaning in Place or Sterilization in Place. Furthermore, the counters for autoclaving can be increased here, as these cannot be counted automatically by the system.

#### Define the Sterilization Cycle Conditions

Define the conditions to automatically count the SIP and CIP cycles. SIP and CIP definitions are set as standard, but can be customized (see Figure 42). The cycles can be changed manually using the pointers on the left and right side of the text box. The standard temperature settings for SIP between 120 and 140 °C for a duration of 20 minutes and CIP between 80 and 100 °C for over 20 minutes. To activate the changes, click the save button at the bottom.

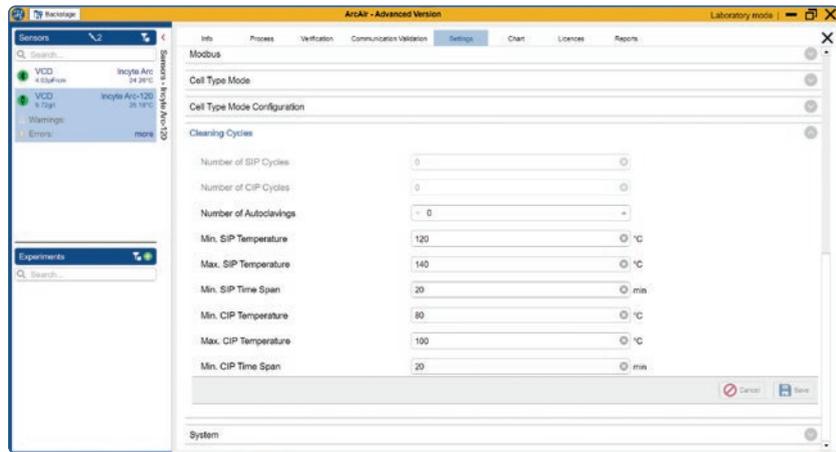


Figure 42: Example of the Setting section – Cleaning Cycles

#### Increase the number of Autoclavings

As it is not possible to increase the autoclaving cycles automatically, the cycles can be changed manually, using the pointers on the left and right side of the text box (see Figure 42). In addition, this can be changed in the chapter 6.4.5.3 Measurement Settings as well.

### 6.4.5.12 System

To delete all user settings and configuration navigate to this point, tick the box «Restore Factory Settings» and press «Save».



### 6.4.6 Chart

In this menu area, the measurement of the Incyte Arc 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, Incyte Arc can be combined with other sensors in an *Experiment*. See chapter 7.1 for more details.



Figure 43: Example Screen of Chart section – This Functionality has been moved to the Experiment Section

### 6.4.7 Licences

This menu area provides an overview of the licenses and their functional range (see Figure 44). This area is currently under construction. The functionality of the Incyte Arc sensors is not affected.

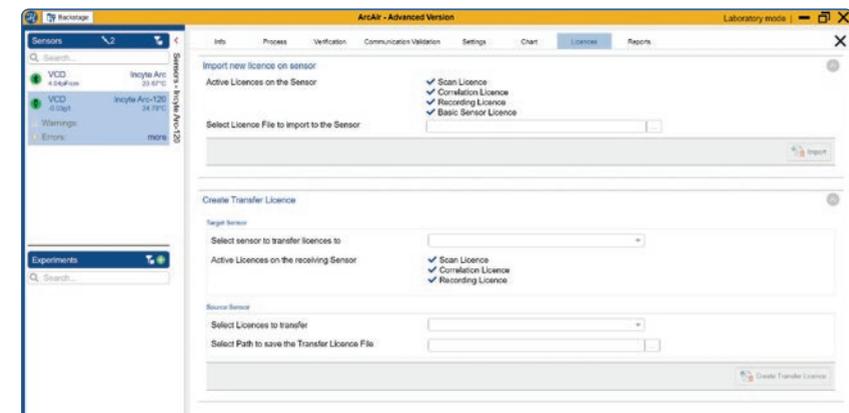


Figure 44: Example Screen of Licences Section

### 6.4.8 Reports

All reports created via ArcAir are saved under this menu item (see Figure 45). The reports can be managed here. An export as PDF is possible.

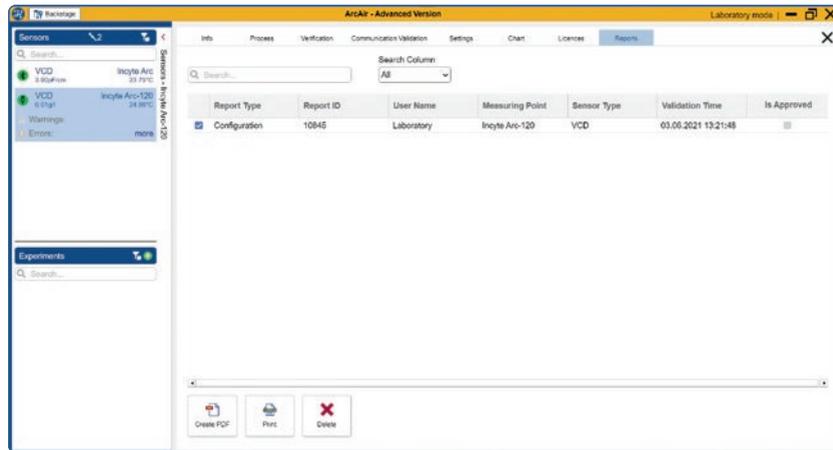


Figure 45: Example Screen of Reports

## 7 Operation – How to get started

In this chapter a detailed description of the recommended settings for integrating an Incyte Arc sensor into an *Experiment* will be given. In most cases, reference is made to previous chapters where the detailed settings and procedures are described. This chapter stands out due to its brevity.

### 7.1 Experiment Functionality

With the 3.6 version of ArcAir six sensors can be combined in one *Experiment*. For this purpose, the chart function of the Incyte Arc sensors has been transferred to the *Experiment* function.

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.

#### 7.1.1 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*.

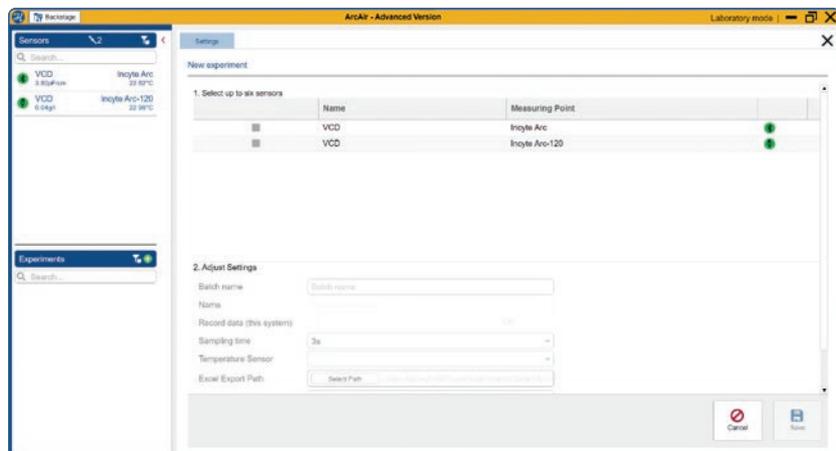


Figure 46: Example Screen – New Experiment

## 7.1.2 Introduction into Experiment Functionality

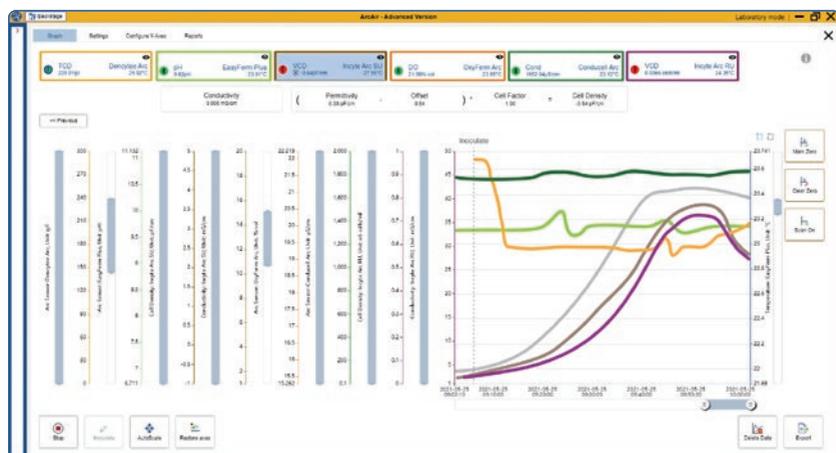


Figure 47: Example Screen of Experiment

There are a few points to consider when using the Incyte Arc sensors in combination with other Arc sensors in an *Experiment*. Incyte Arc sensors 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 Incyte Arc sensors 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 48 Name: Incyte Arc-120 is displayed in orange). Individual sensors can be hidden by using the little eye icon next to the sensor name (see Figure 48).



Figure 48: 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 49 – Selected sensor: Incyte Arc, 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 49), 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.

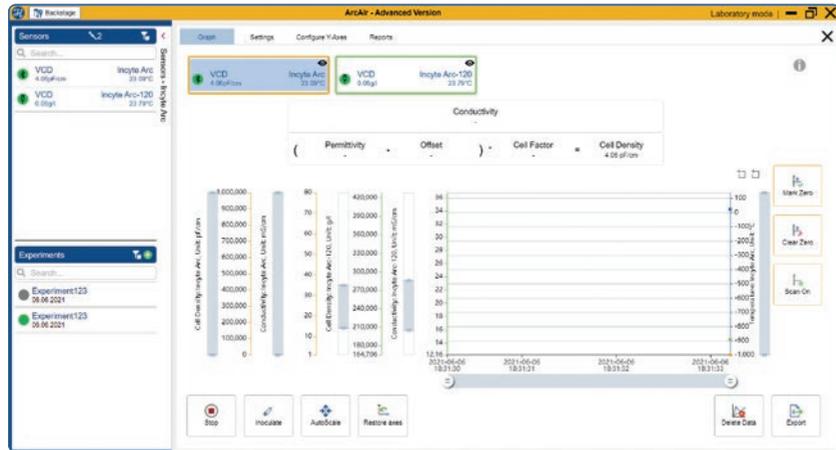


Figure 49: Example of two Sensors in an Experiment

### 7.1.3 Incyte Arc Settings for an Experiment

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

| Checklist                | Subject              | Short description   | See Chapter for further information:   |
|--------------------------|----------------------|---|--|
| <input type="checkbox"/> | Off-line Correlation | The permittivity signal of the Incyte Arc can be transferred to the viable cell number via different correlation attempts. Check if a cell factor or a AADM model is required | Cell Factor: 6.4.5.3 Measurement Settings<br>AADM Model: 6.4.5.4 Correlation model |
| <input type="checkbox"/> | Cell type Mode       | Set a filter adapt the sensor to Experiment conditions.   | Default: 6.4.5.9 Cell Type Mode<br>Custom: 6.4.5.10 Cell Type Mode Configuration   |
| <input type="checkbox"/> | 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.   | 6.4.5.5 Sensor Data Logging  |

## 7.2 Getting Started with an Experiment

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

| Checklist                | Subject              | Short description   | Where to click   | Additional Information         |
|--------------------------|----------------------|---|--|--------------------------------|
| <input type="checkbox"/> | Scan Functionality   | Switch the Scan on or off, if needed during the Experiment  | <br>or<br> | 7.2.2 Scan Functionality       |
| <input type="checkbox"/> | Set an offset        | 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.     | <br>or<br> | 7.2.1 Mark Zero and Clear Zero |
| <input type="checkbox"/> | 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.                  |   | 7.2.3 Inoculate                |
| <input type="checkbox"/> | Add a comment        | Click on a measurement point to add a comment when needed.  |  |                                |
| <input type="checkbox"/> | Set the y-Axes Skale | Navigate to «Configure Y-Axes» in the upper part of the Experiment. Select Cell density. Set an expected Min and Max.; recommendation: Min: -10 Max: 100 (pF/cm; e6/mL; g/l) and click save |  |                                |

**⚠ 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.**



## 7.2.1 Mark Zero and Clear Zero

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 chapter 6.4.5.3 *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.

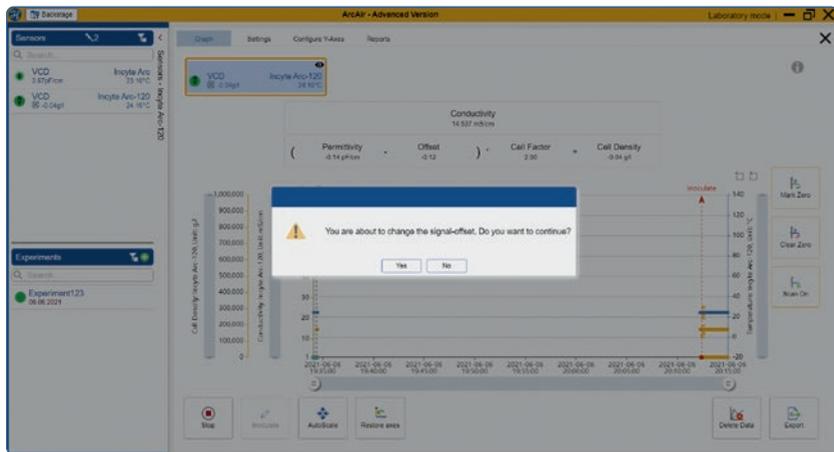


Figure 50: Example Screen if Mark Zero was clicked after Inoculation

## 7.2.2 Scan Functionality

All frequencies of the Incyte Arc can be used by switching on the Scan Functionality (see chapter 5.2.2 for further information) 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.

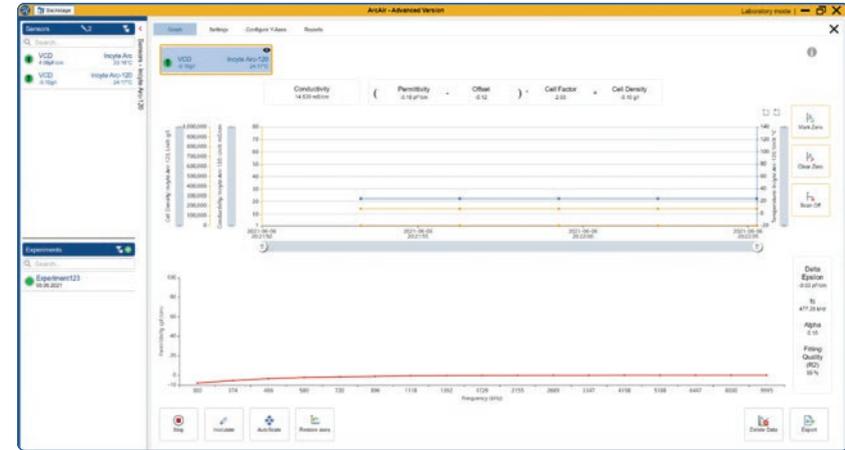


Figure 51: Example Screen with switched on Scan during an Experiment

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 will prevent from hitting this button by accident (see Figure 52).

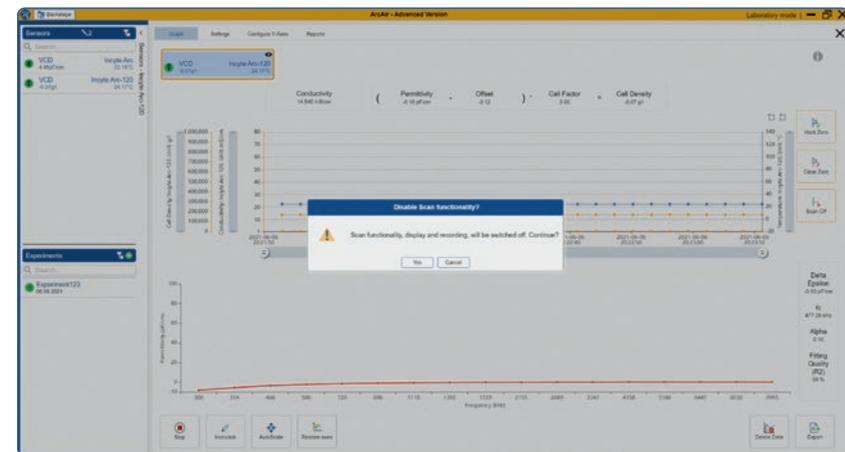


Figure 52: Example Screen when Scan is switched off during an experiment



### 7.2.3 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 54). ArcAir is reporting if the inoculation was successful after clicking the inoculation button (see Figure 53).

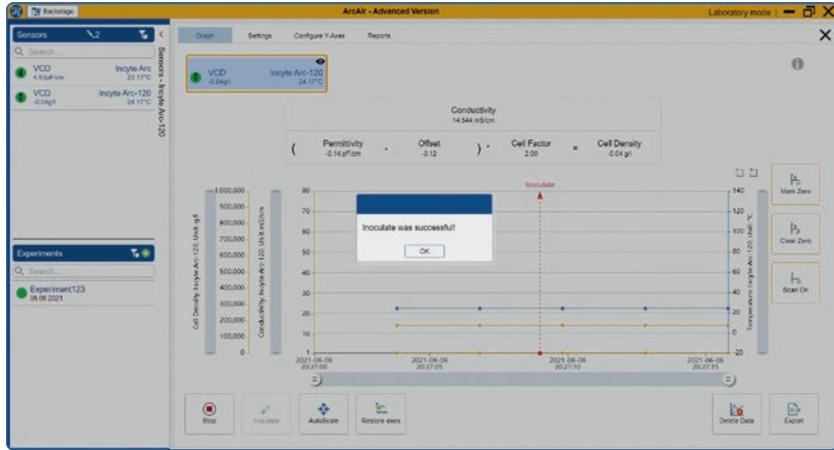


Figure 53: Example Screen when Inoculation was successful

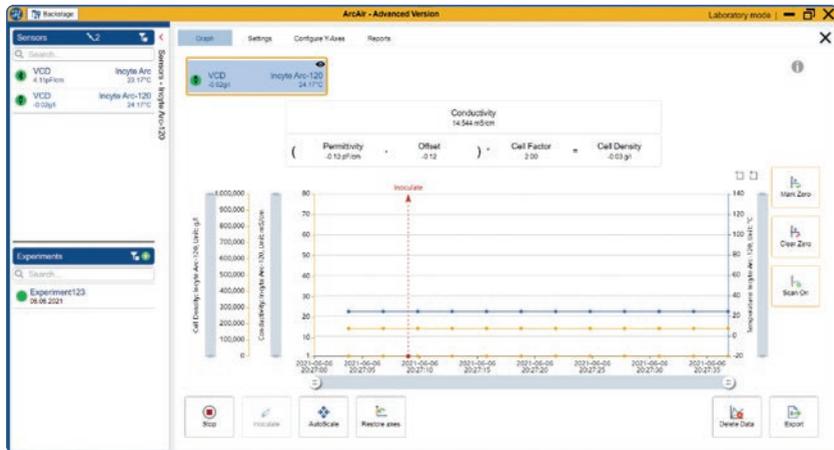


Figure 54: Example Screen with marked time point after Inoculation in the Experiment, Inoculation button is now grey and not clickable.

### 7.2.4 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.

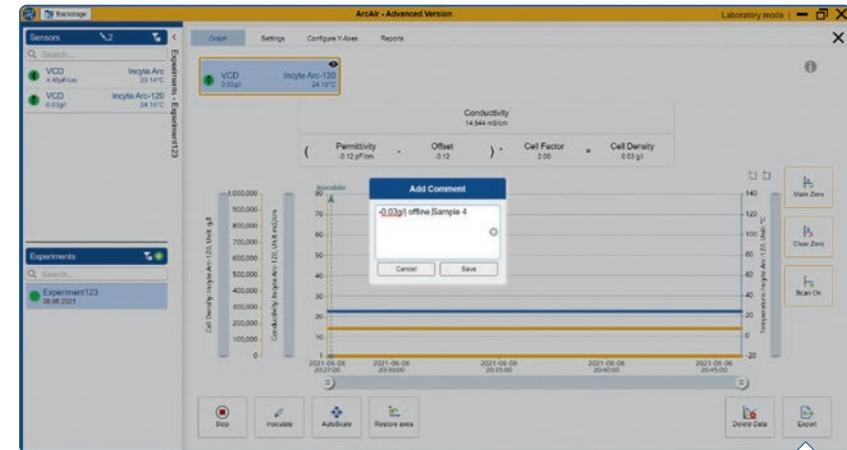


Figure 55: Example Screen of a comment added during an Experiment

|     | 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  | Finesse                  | 9994Hz          |              |         |              |              |
| 15  | High                     | 9994Hz          |              |         |              |              |
| 16  | Moving Average           | 64.00           |              |         |              |              |
| 17  |                          |                 |              |         |              |              |
| 18  | [[EVENTS]]               |                 |              |         |              |              |
| 19  | 2021-06-06 20:27:00      | Start Recording |              |         |              |              |
| 20  |                          |                 |              |         |              |              |
| 21  | Measuring Point Sensor   | Inocyte Arc-120 |              |         |              |              |
| 22  | Temperature Measurment   | Inocyte Arc-120 |              |         |              |              |
| 23  |                          |                 |              |         |              |              |
| 24  | [[MEASURE]]              |                 |              |         |              |              |
| 25  | Date                     | Record Time     | Culture Time | Comment | Conductivity | Permittivity |
| 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  | 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        |
| 159 | 2021-06-06               | 20:33:42        | 0:6:44       | 0:6:29  | 14.54        | -0.12        |

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 55).



## 7.2.5 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.



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.

# 8 Maintenance

## 8.1 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:

$$\Delta\varepsilon = 0 \text{ pF/cm} \pm 5 \text{ pF/cm}$$

Measured in Hamilton's 12880  $\mu\text{S/cm}$  Conductivity Standard (Ref 238988) at Dual Frequency with an  $f_{\text{meas}}$  at 1MHz.

When a sensor fails a verification, a recommendation can be made to readjust the sensor. In the case of an Incyte Arc Verification, a cleaning (similar to 6.4.2.1 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.

**NOTE:** To run a sensor verification ArcAir Advanced is required.

**NOTE:** If a verification report is to be generated, make sure that no offset and no cell factor is set.

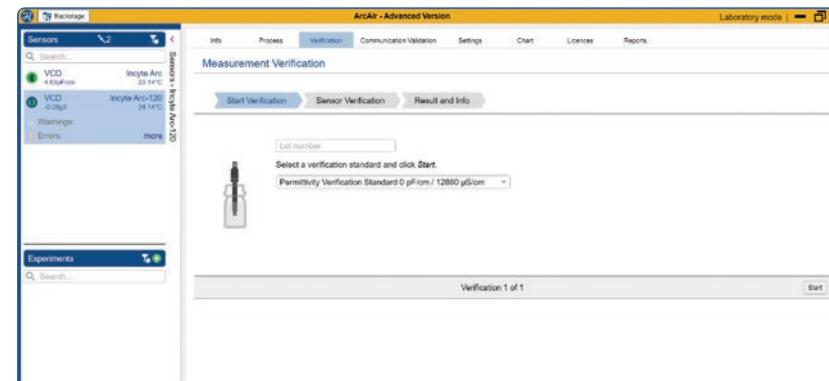


Figure 56: Starting Screen of Verification

Start a *Verification* place the sensor in Hamilton's 12880  $\mu\text{S/cm}$  Conductivity Standard (Ref 238988). Make sure that there is enough space around the sensor tip (1cm towards each side). Make sure there are no bubbles around the sensor tip, especially after the *Manual Cleaning*. Shake the sensor a little to remove the bubbles.

Open ArcAir and navigate to the *Verification* menu (Figure 56). Enter the Lot Number of the conductivity standard to have it tracked in the *Verification Report*.

Click «Start» to start the Stabilization (see Figure 58). This needs 180 s/ 3 min.

If the Verification is passed click «Save» Report and navigate to *Report* to download the Report.

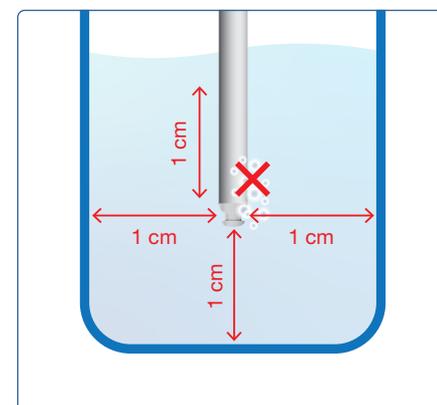


Figure 57: Distance to the sensor tip during verification



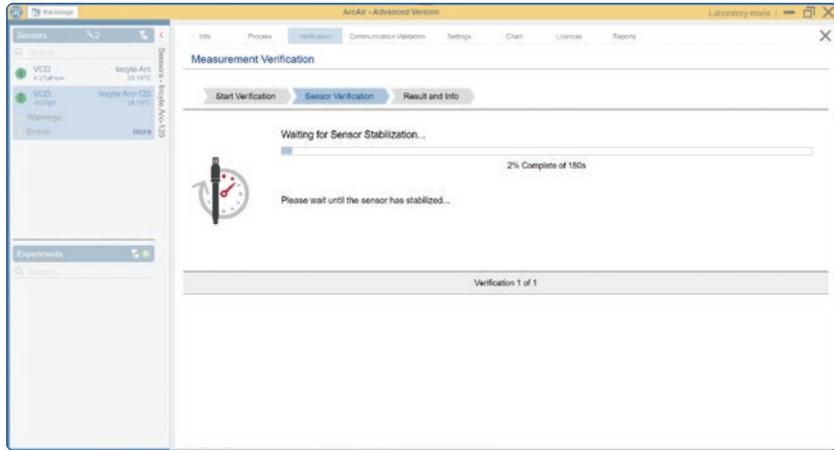


Figure 58: Stabilization of Verification in ArcAir

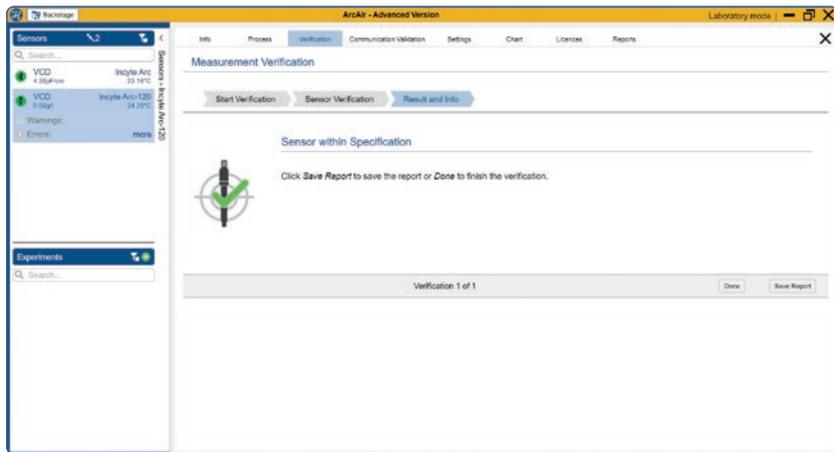


Figure 59: Example for passed Verification

**NOTE:** If a manual cleaning has been done, the Quality Indicator may increase.

## 8.2 Cleaning

Sensor cleaning refers to an electrochemical cleaning pulse to the platinum electrodes. Sensor cleaning does NOT replace CIP or SIP processes. After every bioprocess and after cleaning by CIP it is recommended to use verification to see if cleaning is required. If a cleaning is recommended, follow the steps in ArcAir to recondition the sensor (electrodes) as close as possible to its factory condition. Saturated Sodium Sulfite Solution also available from Hamilton as Solution B (Ref 243742) is required.

Both types of cleaning (*Manual Cleaning* - chapter 8.2.1 and *Auto Sensor Cleaning* – chapter 8.2.2) can also be used during the process.

The *Automatic Sensor 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.

### 8.2.1 Manual Cleaning

If desired a «manual cleaning» can be performed. Hamilton's Saturated Sodium Sulfite Solution also called Solution B (Ref 243742) is needed.



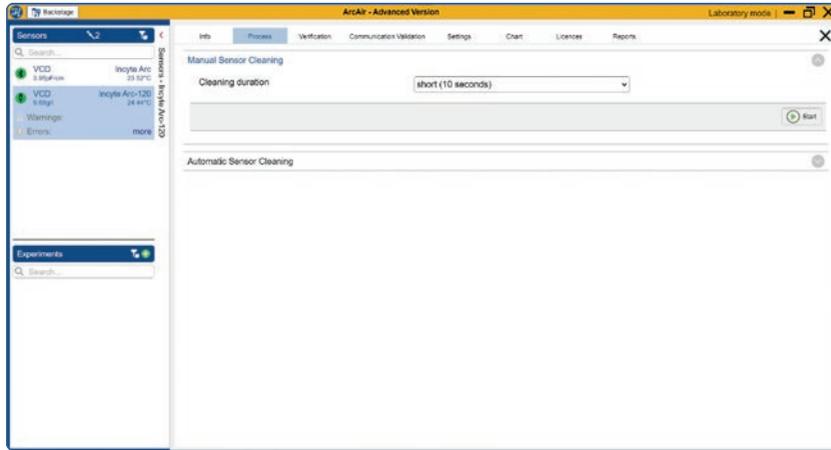


Figure 60: Manual Sensor Cleaning in ArcAir

1. After cleaning and decontamination (CIP), immerse the PEEK sensor tip in a sodium sulfite solution of 15 g/ml ( $\text{Na}_2\text{SO}_3$ ) or Solution B (Ref 243742)
2. Connect the Incyte Arc sensor with the power supply, e.g. by using the Arc USB Power Cable (Ref 243490) on a standard USB port.
3. Navigate to the «Process» in ArcAir.
4. Select «Manual Sensor Cleaning».
5. Select «short cleaning» or «Long cleaning».
6. Press «Start».
7. Wait for the required time.
8. Remove the Sensor from the solution and rinse the residual sodium sulfite with deionized water.
9. Perform the «Sensor Verification» (see chapter 6.4.3).

**NOTE:** Manual cleaning can be performed at a specific time during cultivation as described here, or as cleaning procedure in Saturated Sodium Sulfite Solution to maintain a clean electrode prior to a cultivation.

## 8.2.2 Automatic Sensor Cleaning

**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.

1. Navigate to the «Process».
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».

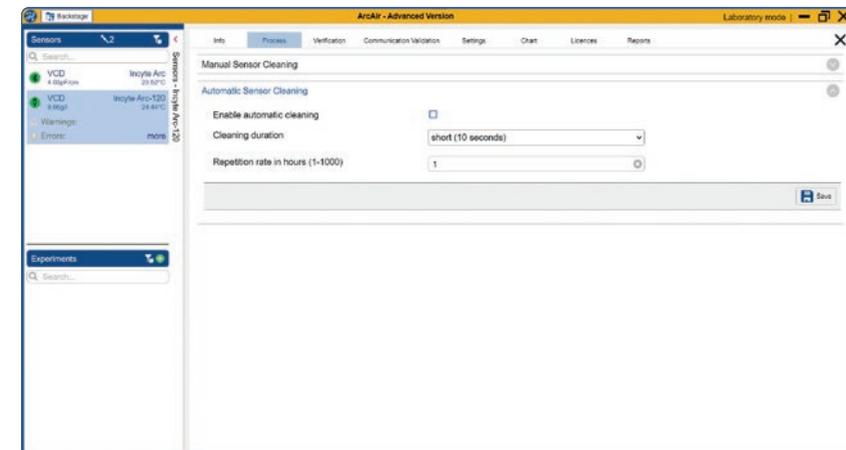


Figure 61: Automatic Sensor Cleaning in ArcAir

## 8.3 Calibration

A calibration by the customer of the Incyte Arc sensor is from the current state of technology and knowledge not intended.

## 8.4 Firmware Update

The backstage area of the ArcAir software contains the drawer for the firmware update. Both the Arc sensors and the Accessories can be updated via this menu item.

 NOTE: Please refer to chapter 8.8 in the ArcAir System Manual (Ref 10071115).

# 9 Troubleshooting

Periodic maintenance routines need to be run in order to ensure safe and reliable operation and measurement of Arc sensors and accessories. Make sure that there is no mechanical damage on the sensor tip.

An overview about the sensor condition is indicated by the sensor status.

1. Connect the Incyte Arc sensors by using the Arc USB Power Cable (Ref 243490) on a standard USB port.
2. Control the status in the *Sensor Quick View* or *Sensor List*.
3. Please refer to the troubleshooting section to interpret the status.



The sensor is performing correctly.  
No errors or warnings have been registered.



At least a warning has been registered.  
Verify the sensor warnings in Sensor Status.



At least an error has been registered.  
Verify the sensor errors in Sensor Status. The Incyte Arc sensor will show 0 pF/cm



Offline

Figure 62: Description of the traffic lights on the ArcAir

The sensor's quality indicator is influenced by:

- Warnings
- Errors
- Verification procedure running in Arc Air

 NOTE: Quality Indicator – The quality indicator provides information about the measurement performance rated between 100 and 30 %. At every verification (see chapter 6.4.3), 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 cleaning, please contact Hamilton Technical Support.

## 9.1 Quick Tips

| Description   | Possible Solutions   |
|---|--|
| Sensor is not displayed in ArcAir                               | <ul style="list-style-type: none"> <li>• When opening the Software make sure the filters of the Sensor List apply to the sensor connected. Incyte Arc is configured to Baudrate 19'200. In case the Baudrate is changed, ArcAir may not recognize the sensor. In this case go to the Backstage area &gt;&gt; «Settings» &gt;&gt; «Wired connection» and select the Baudrate, Parity and Stopbit according to settings of ArcAir. Press «Save».</li> <li>• To connect the Incyte Arc sensor, a Product Version 01 of the Arc USB Power Cable (Ref 243490) is required. This version has a connector for the optional power supply.</li> <li>• For automatic sensor login a unique and global Operator Level S password for all Arc sensors is required. Please make sure you have set the same Operator Level S Password for all Arc sensors in the ArcAir application under Backstage/Settings/Operator Level S Password.</li> </ul> |
| Wrong reading on the process control system                     | Switched off power supply (24 V ± 10%) or disconnected sensor, can cause wrong reading on the process control system.  |
| No connection possible, but sensor is displayed in sensor list. | Check if the sensor is displayed offline as well. If so, delete the offline sensor and try to connect again.   |

## 9.2 Sensor Self-Diagnostic

Arc sensors provide a self-diagnostic functionality to detect and identify the most common sensor malfunctions. All interfaces, analog 4–20 mA or digital Modbus, as well as connection to the PC may provide warning and error messages. The analog 4–20 mA interface can be configured according to the NAMUR recommendations to indicate an abnormal event (see chapter 6.2.2 and chapter 6.4.5.6). Use ArcAir for monitoring the sensor status and for troubleshooting. The following types of messages are provided by the self-diagnosis function.

 **NOTE:** Errors must be addressed and corrective action is immediately necessary.

 **NOTE:** Warnings must be acknowledged. Corrective action is depending on the root cause. The warning will be displayed continuously until the corrective action is successfully completed.

 **NOTE:** For additional information about the sensor status and the diagnostics features refer to the sensor's operation instruction manual or the Incyte Arc Programmers Manual (Ref 695251).

## 9.3 Sensor State

### 9.3.1 Warnings

| Description                           | Warning               | Cause   | Solution                           |
|---------------------------------------|-----------------------|---|------------------------------------|
| Out of calibration range: lower limit | Conductivity too low  | The conductivity is below the specified range, so no measurement of the permittivity is possible. | Increase conductivity (> 1 mS/cm)  |
| Out of calibration range: upper limit | Conductivity too high | The conductivity is above the specified range, so no measurement of the permittivity is possible. | Decrease conductivity (< 80 mS/cm) |

| Description                             | Warning   | Cause   | Solution   |
|---|---|---|--|
| SNR too high                            | External interferences detected   | The permittivity measurement is disturbed by external electrical interferences.                 | Please check your environment and ground the sensor as described in chapter 4.3  |
| Preamp overtemp (analog supply off)     | Ambient temperature too high, no measurement is possible                          | Electronic overheat because of high ambient and process temperature.                            | Please ensure temperature conditions below 90 °C.  |
| Power supply too weak (measurement off) | Power too low, no measurement 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           | 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          | 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.   |
| FSCAN fitting poor input data (R2)      | 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. |
| T reading below lower limit             | Temperature too low, no measurement possible                                      | The temperature is below the specified range, so no measurement of the permittivity is possible | Make sure that the temperature is within the range that is defined   |
| T reading above upper limit             | Temperature too high, no measurement possible                                     | The temperature is below the specified range, so no measurement of the permittivity is possible | Make sure that the temperature is within the range that is defined   |



| Description           | Warning                                    | Cause                                      | Solution  |
|-----------------------|--|--|---|
| Recording Memory full | Memory full, no further recording possible | The internal memory of the sensor is full. | Please download the data (see chapter 10.4.9.2) and re-connect the sensor |

### 9.3.2 Error

| Description                  | Error                               | Cause  | Solution                                  |
|------------------------------|-------------------------------------|--|---|
| Temperature sensor defective | No temperature measurement possible | Temperature measurement not possible, please contact your Hamilton Responsible | Please contact your local representative. |
|                              | Any other error                     | Sensor is not working as intended  | Please contact your local representative. |

## 9.4 Getting technical Support

If a problem persists even after you have attempted to correct it, contact Hamilton's Customer Support: Please refer to the contact information at the back of this Operating Instructions.

## 9.5 Returning the Sensor for Repair

Before returning an Arc sensor to Hamilton for repair, contact our Customer Service (correct reference) and request a Returned Material Authorization (RMA) number. Do not return an Arc sensor to Hamilton without an RMA number. This number assures proper tracking of your sensor. Arc sensors that are returned without a RMA number will be sent back to the customer without being repaired. Decontaminate the Arc sensor 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 sensor.

## 10 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](http://www.hamiltoncompany.com)，章節過程分析，符合性聲明

## 11 Hardware compatibility

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

## 12 Services

### Overview of service offers



Online service



Technical support



Initial Operation/Calibration



Qualification (IQ/OQ)



Service packages



Maintenance



Training



## 13 Ordering Information

### 13.1 Sensor



| Ref         | Product Name            |
|-------------|-------------------------|
| 243950-0211 | Incyte Arc 120 – Expert |
| 243950-0212 | Incyte Arc 220 – Expert |
| 243950-0213 | Incyte Arc 320 – Expert |
| 243950-0214 | Incyte Arc 420 – Expert |

**Description:** ASensor with the full capability of running Dual Frequency Measurement and Scan (including measurement export), owning the possibly to run Cole-Cole Fitting and off-line/on-line correlation (ArcAir Data Modeling). Full GMP compliance is provided with and ArcAir Advanced.

### 13.2 Parts and Accessories



| Ref    | Product Name         |
|--------|----------------------|
| 243460 | Arc Wi 1G Adapter BT |

**Application:** The Arc Wi 1G Adapter BT provides the wireless communication between the Arc sensors and mobile devices via Bluetooth 4.0.



| Ref    | Product Name         |
|--------|----------------------|
| 243470 | Arc Wi 2G Adapter BT |

**Application:** Arc Wi Adapter to convert Modbus to 4-20 mA signal and enable Bluetooth communication for sensor configuration.



| Ref       | Product Name  |
|-----------|---|
| 243490-01 | Arc USB Power cable USB / VP 8 for direct connection to the sensor                            |
| 243490-02 | Arc USB Power cable USB / M12 – 8 pole for connection to the sensor with Arc Wi 2G BT Adapter |

**Application:** The Arc USB Power Cable provides power supply via USB port for Arc sensors and digital communication to Hamilton’s PC software for monitoring, configuration, calibration and firmware updates. Supplied with optional power supply, in case the computer does not provide enough energy to power the sensor. USB 2.0 provides enough power.



| Ref    | Product Name                     | Length |
|--------|----------------------------------|--------|
| 355320 | 3 m Cable M12-8 Pole / open End  | 3 m    |
| 355321 | 5 m Cable M12-8 Pole / open End  | 5 m    |
| 355322 | 10 m Cable M12-8 Pole / open End | 10 m   |

**Application:** The Sensor Cable M12 – open end is designed for connection to a data recorder, indicator, control unit or PCS (Process Control System) with analog I/O.



| Ref    | Product Name              |
|--------|---------------------------|
| 243499 | Arc Wireless Converter BT |

**Application:** Designed for wireless communication between ArcAir and Incyte Arc sensor.

| Ref    | Product Name                       |
|--------|------------------------------------|
| 242333 | Arc Wireless Converter BT Advanced |

**Application:** Designed for wireless communication between ArcAir and Incyte Arc sensor. Includes license to activate ArcAir Advanced features, including the GMP ones.





| Ref      | Product Name                                  |
|----------|---|
| 10071111 | Arc View Mobile Basic for non-Ex environments |

**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's quick guide.

| Ref      | Product Name                                     |
|----------|--|
| 10071113 | Arc View Mobile Advanced for non-Ex environments |

**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's quick guide.



| Ref      | Product Name             |
|----------|--------------------------|
| 10089359 | Arc Modbus OPC Converter |

**Description:** Designed for OPC UA communication between Incyte Arc and SCADA System.

### 13.2.1 Accessories for Verification

| Ref    | Product Name                                  |
|--------|---|
| 238988 | Conductivity standard 12880 µS/cm, Basic Line |

**Description:** Referred as Permittivity Verification Standard; 0 pF/cm; 12,88 mS/cm. Required to verify the proper function of the sensor during the sensor verification procedure.



# 14 Glossary

|                            |  |
|----------------------------|--|
| Alpha                      | Parameter calculated according to Cole-Cole equation (for details see chapter 5.2.2).  |
| Arc Data Model             | The same as Model, or Correlation Model, describes the model build using the ArcAir Data Correlation Software. This model can be transferred on the sensor to allow an improved correlation on the complete process. |
| Arc Data Modeling Software | Software Tool to create and validate models to improve off-line/in-line correlation of reproducible processes, using the (Incyte Arc) Scan.  |
| Batch                      | Refers to the data recorded during a process, maybe the in-line (culture file) and/or off-line data.   |
| Calibration                | The sensor come factory calibrated, where electronics and sensor-shaft are aligned over the specified conductivity, permittivity and frequency range. For further information see chapter 8.3.                       |
| Capacitance Measurement    | Measurement principle of Incyte Arc, please refer to chapter 5.2 for details.  |
| Characteristic frequency   | Parameter calculated according to Cole-Cole equation (for details see chapter 5.2.2).  |
| CIP                        | Cleaning in place of a bioreactor.   |
| Cole fit R2                | Confidence rating of the parameters calculated according to Cole-Cole equation. It is the statistical calculated R2 error of the fit (for details see chapter 5.2.2).  |
| Cole fit RM SE             | Absolute error of the parameters calculated according to Cole-Cole equation. The error is based on a statistical calculation (for details see chapter 5.2.2).  |
| Correlation                | Correlation of the dual frequency measurement, or based on Scan data with the off-line method. Sometimes referred as cell factor (in the dual frequency measurement) or Model (in the Scan measurement).             |
| Correlation Model          | The same as Model, or Arc Data Model, describes the model build using the ArcAir Data Correlation Software. This model can be transferred on the sensor to allow an improved correlation on the complete process.    |
| Culture                    | Refers to a bioprocess, cell culture or fermentation.  |
| Delta epsilon              | Parameter calculated according to Cole-Cole equation (for details see chapter 5.2.2).  |
| Fouling                    | Unwanted attachment of cells to surfaces, e.g. the sensor surface.   |

|                          |  |
|--------------------------|--|
| Inoculation              | Inoculation is the marking the time point after the cells have entered the cultivation system. This event is unique and occurs once in a process cycle. For further information see chapter 7.2.3  |
| Model                    | The same as Arc Data Model, or Correlation Model, describes the model build using the ArcAir Data Correlation Software. This model can be transferred on the sensor to allow an improved correlation on the complete process.            |
| Moving average           | The moving average is a mean value of a defined amount of measurements over time.  |
| MVDA                     | Multivariate data analysis. This technique is used to perform off-line/on-line correlation on the Scan data in ArcAir Data Modeling Software.  |
| Off-line                 | Samples taken from the bioreactor and measured separately - with time offset and spatial distance.   |
| On-line                  | Refers to the Incyte measurement, in real-time, done in-line, in-situ, or at-line.   |
| PCS                      | Stands for Process Control System and is available at customer site. It is a computerized system for a process plant for autonomous control of the process.  |
| Permittivity Measurement | Measurement principle of Incyte Arc, please refer to chapter 5.2 for details.  |
| Record Rate              | Defines the time between two measuring points, which are recorded independently by ArcAir and stored on the sensor head. For further details see chapter 6.4.5.5.  |
| Sampling time            | Defines the time between two measuring points recorded by ArcAir in an Experiment.   |
| SCADA                    | Stands for Supervisory Control and Data Acquisition. It is a control system architecture that has layered control option for managing and operating project-driven processes. The PCS is on level one of five of the control operations. |
| Sensor ID                | Is a combination of the Ref Number in addition with the Serial Number and is a unique characterization of the Sensor. It can be found in the Tab of «Info» under «Information».  |
| SIP                      | Sterilization in place of a bioreactor. Mainly used for bigger bioreactors that do not fit into an autoclave and use for example an external steam line for sterilization.   |



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