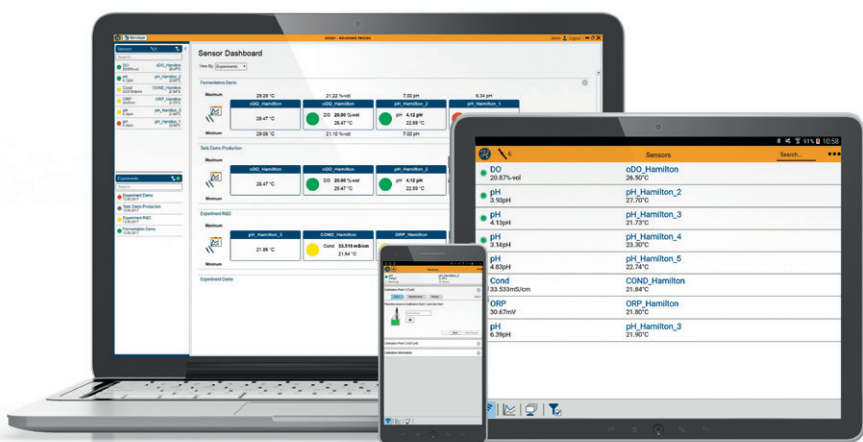


ArcAir Release Information

1 ArcAir 3.5



In January 2021, Hamilton Analytics launches the new ArcAir 3.5 version of its ArcAir application.

ArcAir enables efficient and safe communication for control, validation and management of all Arc sensors (pH, ORP, DO, Conductivity, VCD).

Compared to the previous software versions, ArcAir 3.5 includes :

- ArcAir Improvements for use in GMP environment
- Compatibility with upcoming Arc sensors
- Incyte Arc General Improvements

1.1 ArcAir Improvements for Use in GMP Environment

ArcAir 3.5 version will further improve use event's traceability and data safety for streamlined use in GMP environment.

Feature	Description
New Audit Trail Event's Logs	<ul style="list-style-type: none"> • User log-in/log-out. Those events are logged in both cases: manually or automatically executed. • ArcAir Application for Windows Operating Systems Start/Close • Creation or edit of a new user role • Assignment of new role to a user • ArcAir connection and disconnection from an Arc sensor. Those events are logged in both cases: manually or automatically executed
Updates of User Role's Rights	<ul style="list-style-type: none"> • A new user's role right has been created : «Delete Reports». By default, this right is assigned exclusively to the «Administrator» user role. Each «Delete Report» event is automatically logged in the Audit Trail. • A new user's role right has been created : «System Settings». By default, this right is assigned exclusively to the «Administrator» user role. • The «Operator Level S Password» is now located under «Settings» in ArcAir Backstage

1.2 Compatibility with Upcoming Arc Sensors

Hamilton is committed to bring innovation especially in regards to sensors for biopharma applications. ArcAir 3.5 is ready for the new upcoming Arc sensors, which are going to be launched to further expand the Process Analytics product portfolio.

1.3 Incyte Arc General Improvements

Feature	Description
Verification Routine	The verification routine with Incyte Arc leads to a dead end for the user. This has been fixed.
Auto scale of the y-axes	Now user are able to automatic adjust the scale of the y-axes in the Incyte Arc data logging chart.
Data Logging Changes	<ul style="list-style-type: none">• Now user are not able to perform an inoculation more than once• Instead of entering the start time of the logging it is now able to enter the end time by the user. The date and time in the log file should then be calculated accordingly.
Improve Excel Format	Format in the Excel Sheet for CULTURE TIME and RECORD TIME is adjusted. Time format in Excel Sheet is changed to hhh:mm:ss.
Data Record	The recording has been improved and the gaps in the chart have been eliminated.
X-Scale in the Chart	The x-scale in the chart has been improved after change from one sensor to the other.
Cell Factor Value	The boundary values for the «Cell Factor» setting of Incyte Arc has be changed to 0,01 (lower boundary) and 1000000 (upper boundary).
Unified Naming of Registers	The naming of several register has been unified to the Arc standard.
General Improvements	All known and valid improvement requests provided by users have been implemented.

2 ArcAir 3.4

In July 2020, Hamilton Process Analytics launched the new ArcAir 3.4 version of its ArcAir application. Compared to the previous versions, ArcAir included new features and improvements, grouped as follow:

- ArcAir Performance Improvements with Mobile Devices
- Supports Single Use VCD and Conductivity Arc Sensors
- ArcAir General Improvements

2.1 Performance Improvements with Mobile Devices

ArcAir 3.4 version improve performance with mobile devices.

Feature	Description
Complete Sensor List*	Sensor list on mobile devices has been improved to be stable and avoid online/offline instability of sensors
Sensor List Scrolling*	The scrolling properties have been improved
Connection to Sensor*	Connect to sensor time have been improved by 75%. Connecting failing rate has been improved by 75%
Read Sensor Register*	All information should be read 55% faster than previous software versions
ArcAir Startup Time*	The startup time from ArcAir has been reduced by 38%
Number of Sensors*	Stable running with up to 101 Arc sensors

* tested with Samsung Tab Active 2 and 101 Arc sensors in laboratory environment

NOTE: To reach the performance improvements above we strongly recommend to use the Hamilton Arc View Mobile based on Samsung Tab Active 2 tablets REF 10071113 (with ArcAir Advanced) and REF 10071111 (with ArcAir Basic). Contact our technical support (techsupport.pa.ch@hamilton.ch) for more details.



2.2 Supports Single Use VCD and Conductivity Arc Sensors

Feature	Description
Support Single Use VCD and Conductivity Arc sensors	ArcAir 3.4 now supports the new single use VCD, and Conductivity Arc sensors

2.3 ArcAir General Improvements

Feature	Description
Incyte Arc Improvements	<ul style="list-style-type: none">• Change the format of the event timestamps for log files• Allow the export of the data log files while logging is running• Reset inoculation on the sensor when the stop button is pressed• Change the structure of the process settings drawer• Add new licence for Incyte Arc• Configure the min. and max. for y-axis in the fScan chart
General Improvements	All known and valid improvement requests provided by users have been implemented

3 ArcAir 3.3

No official release. Only for internal use and OEM customers.

4 ArcAir 3.2

4.1 Integration of the New Generation VisiFerm mA and VisiTrace mA DO Sensors

ArcAir 3.2 supports the new generation of Hamilton Optical Dissolved Oxygen Sensors: Hamilton improved upon both sensor and cap design to create the most robust VisiFerm and VisiTrace yet. Upgrading both key pieces allowed the VisiFerm mA to have less frequent calibration, less measurement drift, and longer lifetime than previous optical DO sensors.

ArcAir new features to handle VisiFerm mA and VisiTrace mA sensors are listed in the following table.

Feature	Description
New Calibration, Verification, Product Calibration Wizard with humidity and pressure compensation	In order to perform a perfect air calibration ArcAir enables the compensation of humidity and pressure in the wizards
Sensor, Cap and measurement Quality Indicator	New quality indicators indicate the sensor and cap lifetime separately. The combination of this two quality indicators defines the measurement quality. The calibration and verification reports have been accordingly updated.
Sensor Change Counter	Every change in the sensor will increment the numbers of changes in the sensor and display it in ArcAir. In the audit trail report it is now possible to track backwards changes applied by 3d party configuration tools or systems.
Turn-off LED	Now it is possible to turn off the LED if no measurement is needed
Enter and Display Cap History	Users are now able to scan or enter the cap information in ArcAir after every sensor cap replacement. In ArcAir the history of the last 10 caps are visible for each optical DO sensor
Product Calibration limits are adjustable	The product calibration limits are now adjustable in ArcAir service mode
Encrypted communication with Arc Sensors and Mobiles	ArcAir on mobiles is now able to establish encrypted communication with new VisiFerm mA and VisiTrace mA Arc sensors. Indication for the encrypted version is a lock symbol in the sensor list

The new features are detailed in Arc Operating Instructions (REF 10071115).



4.2 ArcAir General Improvements

The general functionality improvements are listed in the following table.

Feature	Description
Change calibration and verification pictures in Air	<ul style="list-style-type: none">• Due to the humidity and atm. pressure, the calibration and verification pictures have been changed• Calibration set configuration now supports all ArcAir languages
Sensor name for Single Use DO sensors is editable	Now it is possible to change the single use DO sensor name
Add Huawei as new mobile type for ArcAir Mobile apps (China only)	Exclusively for Chinese customers, Huawei Honor tablets are now compatible with ArcAir mobile app
Adapt all validation reports with the new sensor registers	Every new register from the new sensors is now added to the validation reports
Chinese Characters	ArcAir now supports Chinese characters, so Chinese users can type information in the local language
Bug fixes	All known bugs have been fixed

5 ArcAir 3.1

In June 2019, Hamilton Process Analytics launched the 3.1 version of its ArcAir application. Compared to the previous version 2.0.3, ArcAir 3.1 included new features and improvements, grouped as follow:

- Incyte Arc Sensors Integration in ArcAir
- ArcAir Sensor Functionality
- ArcAir General Improvements

5.1 Incyte Arc Sensors Integration in ArcAir

ArcAir 3.1 supports Incyte Arc sensors. Incyte Arc enables real-time, and on-line measurement of permittivity, which correlates with the viable cell density. The Incyte sensor has been especially designed for monitoring the culture of mammalian and insect cells. Online monitoring of permittivity with Incyte enables the early detection of process deviations, may lead to sampling at the right time-point and supports bioprocess control.

ArcAir new features to handle Incyte Arc sensors are listed in the following table.

Feature	Description
ArcAir supports Incyte Arc sensors	<ul style="list-style-type: none">• Sensor Configuration and Verification• Data Recording• Data Display• GMP compliance like all other Arc sensors
Modelling for off-line / on-line correlation	Creation and Validation of a model for improved off-line/on-line correlation on the overall bioprocess (Feature available on demand – for more information please contact your Hamilton Local Service support as described in chapter 3)

The new Incyte Arc features are explained in detail in «Incyte Arc Sensor Operating Instructions» (REF 10072078).

5.2 ArcAir Sensors Functionality

ArcAir new features to operate Arc Sensors families are listed in the table below.

Feature	Description
Conductivity two-point calibration	Arc conductivity sensors (Cond) now have the option for a manual two-point calibration
Change Modbus settings	The additional Modbus settings (Baudrate, Stopbits and Parity) can now be changed in ArcAir

5.3 ArcAir General Improvements

The general functionality improvements are listed in the following table.

Feature	Description
Calibration Set* for all languages	Calibration set configuration now supports all ArcAir languages
Experiments chart**	Overall improvements regarding sensors signal display and experiment data export
Report settings	Report settings can now be configured independently if working with a database updated from older software versions or new one
4-20 mA settings	Overall improvements regarding software stability when configuring 4-20 mA settings
Mobile Device Modbus settings	ArcAir app for mobile devices improvement to guarantee stable app workflow when changing Modbus address
VisiFerm Calibration and Verification Reports	Quality Indicator is now available on all reports, independently of the firmware version
Single-Use ODO sensors coefficients	ODO coefficient is now fixed to two decimal places

*Calibration not required for Incyte Arc

**Not available for Incyte Arc

6 ArcAir 3.0

In January 2019, Hamilton Process Analytics launched the new 3.0 version of its ArcAir software. Compared to the previous version 2.0.3, ArcAir 3.0 included many new features and improvements, grouped as follow:

- FDA CFR 21 Part 11 and EU Annex 11 Compliance
- Enhanced laboratory experiments
- General improvements

6.1 CFR 21 Part 11 and EU Annex 11 Compliance

ArcAir 3.0 (Advanced version), is ready for compliance with guidelines such as the FDA CFR 21 Part 11 for electronic records and electronic signatures, or the Eudralex Volume 4 Annex 11 for computerized systems.

The new features workflow is explained in Arc Operating Instructions (later referred as Operating Instructions, REF 10071115), and the compliance to Guidelines is detailed in Validation and Regulatory Report (chapter 13).

ArcAir Advanced new features include the following table.



Feature	Description
Audit Trail	Computer generated audit trail, to independently record the date and time of GMP relevant user entries and actions
Default User Roles	Pre-defined standard user roles, to facilitate the assignment of access rights to users. The new user roles are: administrator, calibration technician, production technician and quality manager (Operating Instructions chapter 6.10)
New Security settings	Security settings, enabling user's password management (Operating Instructions chapter 6.12). They include: <ul style="list-style-type: none"> • Password length and complexity • Password expiration time • Users automatic log-out interval time
Enhanced Data Safety	Enhanced data safety, through the encryption of the SQL database and assignment of database management rights only to administrators. The database management has been moved from log-in window to the backstage
New Reports	Automated export of reports to a digital archive pre-defined by the user (Operating Instructions chapter 6.19.2)
Electronic signature	Electronic signature, allowing users to sign ArcAir reports in paperless workflow (Operating Instructions chapters 6.18 and 6.19.1). The electronic signatures include the following signature manifestations: <ul style="list-style-type: none"> • User full name and role • Signature reason (report creation/ approval) • Signature date

The features for Part 11 and Annex 11 compliance are available within the ArcAir advanced license. As per table below (Operating Instructions chapter 6.3).

License	Read	Calibrate	Configure	Documentation	Users Management	Audit Trail & Electronic Signature
Free	✓	–	–	–	–	–
Basic	✓	✓	✓	–	–	–
Advanced	✓	✓	✓	✓	✓	✓

6.2 Enhanced Experiments

The user experience of the ArcAir feature «experiments» for laboratory (Operating Instructions chapter 7.1), has been enhanced through the improvements listed in the table below.

Feature	Description
New Clear Button	New button has been introduced to clear all data of an experiments
Improved experiment chart axis	<ul style="list-style-type: none"> • Each of the y-axes in the experiment chart has a possibility to enter the minimum and maximum value for the axis • After entering the min and max value the axis and the corresponding curve in the chart are automatically adjusted • Below the chart there is a new button called «Restore axes» clicking the button removes all custom min and max values from the axes and restores the initial values • Min and max values are in the limits that are provided by the sensor (those are used for the scaling of the axes at the moment) • Tips about how to use the axis zooming function directly displayed when pointing on «i» icon directly in the user interface • Scaling and zooming of chart is preserved when it is closed and the re-opened again • The user interface on ArcAir mobile app has been improved: e.g. font sizes for the axes is optimized for small screens and the values on the y-axes are displayed without decimal places
Other Chart Graphic Improvements	<ul style="list-style-type: none"> • New colors palette for the series • The frame color of the sensors displayed above the chart match the color of the correlating axis • Data points displayed now as circles • Hint about notes has been removed from ArcAir for computers • Pointer displaying information such as measuring point, temperature and time when hovering on the experiment's chart with ArcAir for computers

6.3 General Improvements

The general functionality improvements are in the following table.


Feature	Description
New languages	ArcAir user interface is available in following languages: English, German, French, Spanish, Italian, Chinese (Mandarin) and Hungarian (Magyar)
Parallel communication to sensors possible	ArcAir user level has been updated to meet the request of system integrators. Arc sensors now allow the mobile and the desktop software to establish a connection, even if they have a new version of the firmware and there is already another ArcAir existing connection logged in (with user level S). If a second connection with ArcAir is established it is «read-only»
Pop-up when database is blocked from another user	The ArcAir database can now be accessed by only one instance at a time. If a second instance tries to access the same database an error pop-up window is displayed
Extended Sensor Profile	More settings can be now saved in the sensor profile, such as the modbus baudrate and device address
Cal. Standard sort by manufacturer name	During pH/ORP sensor's calibration it is now possible to choose the calibration standard by manufacturer name
Auto selection of Standards	In ArcAir mobile, the verification standard is now automatically selected according to the information in the barcode after scan: dropdown selection changes automatically
Calibration Successfully View with more information	«Auto Recognized Calibration Standard» is displayed as additional property in the result view after a sensor calibration successfully conducted
Customized Meas. Temperatur Settings is now visible	The «measurement settings» of optical Dissolved Oxygen sensors (oDO) and Conductivity sensors (Cond), enables now the user to define customized temperature setup
Calibration Settings visible for VisiTrace sensors	A new feature, «Calibration settings», has been added for VisiTrace sensors
No duplicated sensors	There are no more duplicated sensors after the creation of a sensor's process group
New Error message when FW update failed	In case of failed Firmware update the error message displayed delivers more descriptive information to facilitate troubleshooting

7 ArcAir Software Update & Upgrade

All users who use ArcAir versions older than latest version can update free of charge.

Detailed information is listed in chapters 7.1 and 7.2.

 **NOTE:** The services and products have to be purchased separately.

 **ATTENTION!** It is sole responsibility of the user to evaluate whether to perform ArcAir update to new software version and evaluate the effort needed to validate the new software update (e.g. for GMP environment). Hamilton provides the present document, as well as the new services described in chapter 7.2 to facilitate such decision.

7.1 ArcAir Computer and Mobile Devices

ArcAir Basic for Windows operating system for computers/laptop/tablets can be updated to latest version following the procedure described in Arc System operating instruction (REF 10071115) chapter 6. The data present on the database will be retained. Users need to be adapted to new user's role system described in chapter 6.1 of present document. Customers who already own ArcAir Advanced from version 2.0.3 can update to ArcAir Advanced 3.5 free of charge. The upgrade from ArcAir Basic to Advanced follow the same procedure of ArcAir 2.0.3, as described in Operating Instructions chapter 6.5.

All customers using ArcAir App for Android or iOS on their own mobile devices can update to version 3.5 through normal App upgrade procedure provided by Google Play Store or Apple App Store. Customers who already own ArcAir Basic from



version 2.0.3 can update to ArcAir Basic 3.5 free of charge. Customers who already own ArcAir Advanced from version 2.0.3 can update to ArcAir Advanced 3.5 free of charge. The upgrade from ArcAir Light to Basic or Advanced can be operated via in-app purchase, as described in Operating Instructions chapter 6.

7.2 Arc View Mobile Update

All customers owning a Hamilton Arc View Mobile Advanced Tablet REF 10071113, as well as Arc View Mobile Basic REF 10071111, can update free of charge the embedded ArcAir App from version 3.0 or successive to the latest one. They just have to follow the procedure described in the Arc System operating instructions (REF 10071115) chapter 6.8. In case further information is required, please contact your Hamilton local service support.

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

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