

Air IDEAL[®] 3P[™]

Traceability Solution

AeroBioCollector
User's Manual


EN



96307 - I - en - 2013/09 — P/N 161150 - 190



BIOMÉRIEUX
INDUSTRY

 LCB 71260 La Salle France

Distributed by :

bioMérieux SA Chemin de l'Orme
69280 Marcy-l'Étoile - France
RCS Lyon 673 620 399
Tel. 33 (0)4 78 87 20 00
Fax 33 (0)4 78 87 20 90
www.biomerieux.com



Revisions

The list of revisions below summarizes replacements or additional pages in your User's Manual

Version	Date of printing	Modifications	Pages modified
A	2001/01	Bilingual (FR / EN)	All
B	2001/04	Multilingual (FR / EN / ES / IT / DE / PT)	All
C	2005/11	Update of the manual (FR / EN / ES)	All
D	2006/03	Update of the manual (FR / EN / ES / IT / DE / PT)	All
E	2008/03	Environmental conditions (FR / EN / ES / IT / DE / PT)	2-12
F	2010/10	Addition of a remote user interface device (RUID) to ensure sampling traceability.	All
G	2011/04	Regulatory modifications: FCC (USA) and IC (Canada).	Pages 2-7, 2-8, 2-11, 2-13 Pages 3-2 and 5-1
H	2011/11	Airflow control	5-1
I	2013/09	<p>Modification of spelling: - <i>airIDEAL</i>® 3P™ Traceability becomes - Air IDEAL® 3P™ Traceability.</p> <p>Software version change from V9 to V10.</p> <p>Modification of agar plate references: 96302 becomes 410175 and 96303 becomes 410174.</p> <p>Deletion of ref 43018</p> <p>Modification of serial number label</p> <p>Addition of figure "Diameter of Petri dishes".</p> <p>Modification of section: - "Characteristics of materials".</p> <p>Modification of sections: - "Cleaning and decontamination procedure" - "Decontamination of the external part".</p>	<p>All</p> <p>Warning</p> <p>3-1</p> <p>3-2</p> <p>3-2</p> <p>3-4</p> <p>3-6</p> <p>5-1 5-2</p>

Warning

The content of this manual is based on the Software release **10**.

This manual is periodically updated. The updates shall be included in the new releases of the Software.

Information supplied in this manual may be subject to modifications before the products described become available.

This manual may contain information or references relating to certain bioMérieux SA products, software or services which are not available in the country of release; this shall not mean that bioMérieux SA intends to market such products, software or services in such country

To request copies of publications or for any technical request, contact bioMérieux SA or your local distributor.

IMPORTANT! *Use of the instrument and manual implies acceptance of the clauses below and the clauses set out in the regulatory booklet. Users are invited to refer to these clauses.*



DANGER! *To ensure user safety, the instrument must be used in accordance with this manual.*

Trademarks

BIOMERIEUX, the blue logo, **3P**, **Air IDEAL** and **Count-Tact** are used, pending and/or registered trademarks belonging to bioMérieux, or one of its subsidiaries, or one of its companies.

ClearKlens IPA is a trademark belonging to Johnson Diversey.

Any other name or trademark is the property of its respective owner.

Table of contents

1	How to use this manual	1-1
	Finding topics and procedures.....	1-1
	Glossary	1-2
	Typographic conventions.....	1-3
	Air IDEAL®3P™ Traceability keypad	1-3
2	Functional description.....	2-1
	Presentation	2-1
	Principle of use	2-1
	Operating principle	2-2
	Performance	2-2
	Collection efficiency validated according to the ISO 14698 standard	2-3
	Physical efficiency testing approach.....	2-3
	Biological efficiency testing approach.....	2-3
	Use in glove boxes	2-3
	Applications	2-3
3	Using Air IDEAL®3P™ Traceability.....	3-1
	Description.....	3-1
	Consumables.....	3-2
	Culture media for general use	3-2
	Irradiated media.....	3-2
	Identification of the instrument.....	3-2
	Front face of the Air IDEAL®3P™ Traceability.....	3-3
	Rear face of the Air IDEAL®3P™ Traceability	3-3
	Keypad	3-4
	Sampling grid.....	3-4
	Configuration for 65, 70 or 90 mm Petri dishes	3-4
	Tripod assembly	3-5
	General specifications	3-6
	Environmental conditions.....	3-6
	Physical features	3-6
	Dimensions.....	3-6
	Mass.....	3-6
	Materials	3-6
	Characteristics of materials	3-6
	Technical characteristics	3-7
	Electrical characteristics	3-8
	Functional specifications.....	3-8
	Unpacking Air IDEAL®3P™ Traceability	3-9
	Recommendations for installation and use.....	3-9
	Sampling positions	3-11
	Screwing on the sampling grid.....	3-12
	Electrical power supply	3-12
	Operation on the battery	3-12
	Low battery signals	3-13
	Charging	3-13
	Operation using mains power	3-14
	Automatic standby	3-14
	Automatic switch off.....	3-14
	Operation in slave mode.....	3-15
	Operation in manual mode	3-15
	Programming.....	3-15
	Programming characteristics	3-15
	Sampling controls	3-15

Table of contents

Air IDEAL [®] 3P [™] Traceability menus	3-16
Turning on Air IDEAL [®] 3P [™] Traceability	3-17
Standby.....	3-18
Turning off Air IDEAL [®] 3P [™] Traceability	3-18
Selection of one of the 4 pre-programmed sample volumes (Menu 1)	3-18
Programming a sample volume not in memory (Menu 2)	3-19
Modification of the 4 pre-programmed sample volumes (Menu 3)	3-20
Programming delayed start-up (Menu 4)	3-22
Programming sequenced sampling (Menu 5)	3-23
Battery autonomy test (Menu 6).....	3-25
Starting sampling	3-26
Stopping the motor	3-28
Setting Air IDEAL [®] 3P [™] Traceability parameters (summary diagram).....	3-29
Maintenance Menu	3-31
Navigation using < + > and< - > keys	3-31
4 Procedure	4-1
Principle	4-1
Procedure	4-1
How to obtain a good quality sample	4-2
Precautions of use	4-2
Sampling in manual mode	4-2
Incubation and reading	4-2
Sampling plan	4-3
Recording and evaluating results	4-3
5 Maintenance	5-1
Preventive maintenance	5-1
Routine servicing	5-1
Cleaning and decontamination procedure	5-1
Sterilization of grids	5-1
Decontamination of external parts	5-2
Decontamination of the air circuit.....	5-2
Decontamination in a glove box.....	5-2
Airflow control	5-2
6 Troubleshooting	6-1
7 Appendix	7-1
Using the reading table.....	7-1
Information on FELLER's law	7-1
Reading tables	7-2

List of figures

Note: Screenshots and figures are given as examples only.

2. Functional description

Figure 2-1: Principle of the impaction biocollector	2-2
---	-----

3. Using Air IDEAL®3P™ Traceability

Figure 3-1: Air IDEAL®3P™ Traceability in its carrying case	3-1
Figure 3-2: Identification of the instrument	3-2
Figure 3-3: Front face	3-3
Figure 3-4: Rear face	3-3
Figure 3-5: Keypad	3-4
Figure 3-6: Diameter of Petri dishes	3-4
Figure 3-7: Sampling head and grid – 65, 70 or 90 mm Petri dishes	3-5
Figure 3-8: Tripod assembly	3-5
Figure 3-9: Sampling positions	3-11
Figure 3-10: Screwing on the sampling grid	3-12

1 How to use this manual

IMPORTANT! Please read the "General safety and regulatory information" booklet provided with the instrument.

Finding topics and procedures

	This manual is divided into 7 chapters.
Table of contents	The table of contents of the manual is located on pages I-1 to I-2. It lists each chapter and the procedures within each chapter.
List of figures	The list of figures for the manual is located on page II-1.
Warnings	Different types of warnings are used throughout the manual: <ul style="list-style-type: none">- for safety reasons (DANGER!),- to ensure that the instruments are maintained in good working condition (CAUTION!),- for regulatory reasons (WARNING!) or,- for optimum performance of operations, procedures, etc. (IMPORTANT!).
Page headers and page footers	<p>Apart from the first page of every chapter, each page of the manual includes a page header and a footer.</p> <p>Each page header includes the chapter title and the title of a procedure or its corresponding description.</p> <p>The footers contain the title of the manual, the name of the product and the page number.</p>

Glossary

ABS	Acrylonitrile butadiene styrene.
AeroBioCollector or Air sampler	Air IDEAL®3P™ Traceability , instrument used to collect and count viable bacterial and fungal particles in a known and precise volume of air.
CFU	Number of Colony Forming Units read on the agar plate. The number of CFU corresponds to the number of clusters that have grown on the agar.
Delayed start-up	Time between pressing the START button and the motor starting up.
Li-ion	Lithium ion
MPN	Most Probable Number of micro-organisms collected. Statistical correction of the CFU value (FELLER's law).
PVDF	Polyvinylidene fluoride.
Ra coefficient	Roughness factor of a surface. It is the arithmetic mean of all profile deviations, positive or negative, compared to the mean line.
RUID	"Remote User Interface Device" Remote control containing the user interface.
Sampling grid	Perforated and calibrated plastic device. The number of orifices, their diameter and arrangement, guarantee a CFU count (positive clusters) and a flow of air corresponding to the motor setting.
Solution Air IDEAL®3P™ Traceability	Air IDEAL®3P™ Traceability (AeroBioCollector) + RUID (remote control) + Air IDEAL®3P™ Traceability software.
Time-delay	Two seconds required by the software to record a parameter.

Typographic conventions

These conventions are used in the different chapters of the manual.

- Press

A bullet point is used to denote an action to be performed.

PROGRAM 1

This typography is used to represent messages which appear on the display.

Air IDEAL[®] 3P[™] Traceability keypad

There are 5 keys on the instrument keypad. (See page 3-4 of the manual).

In this manual, the keys are referred to by their individual names, enclosed in angle brackets "< >".

2 Functional description

Presentation

"Pharmaceutical manufacturing evolves from an art to a science".

This sentence alone from the FDA Guideline "Pharmaceutical cGMPs for the 21st century – A Risk-Based Approach" summarizes the current revolution in the Pharmaceutical industry.

Conscious of these changes and remaining attentive to its customers, bioMérieux decided to improve its **Air IDEAL[®]3P[™] Traceability** AeroBioCollector in order to best respond to these new needs.

The instrument was thus developed and validated in order to provide a tool to the pharmaceutical industry that would guarantee a scientifically proven method of air sampling.

This instrument evidently remains perfectly suited to the enumeration of airborne micro-organisms in less demanding work environments such as agribusiness.

In addition and in order to continue its universal application, **Air IDEAL[®]3P[™] Traceability** is still available in two versions:

- one for the use of culture media in 90 mm diameter Petri dishes,
- the other designed for use with 65 or 70 mm plates.

The aspiration flow-rate of **Air IDEAL[®]3P[™] Traceability** is calibrated at 100 l/min with an impact velocity of less than 20 m/s.

According to good sterilization practices, sampling grids can be sterilized in an autoclave, see "Sterilization of grids" on page 5-1.

Principle of use

Air IDEAL[®]3P[™] Traceability can operate in 2 modes:

- Slave mode: using **Air IDEAL[®]3P[™] Traceability** with the RUID.
- Manual mode: autonomous operation using the keypad.

The present manual describes how to use the instrument in manual mode; for use of the instrument in slave mode, please refer to the RUID User Manual.

Operating principle

Air IDEAL® 3P™ Traceability is an impaction AeroBioCollector used to detect the presence of viable micro-organisms in the environment to be tested, by precise sampling of a given volume of air.

Air is taken up with a turbine through a grid surface. The acceleration of airflow results in the impaction of airborne micro-organisms on the agar. Passage of the air through the grid filters out particles, thereby facilitating the enumeration of CFU (colony forming units) after incubation of the medium.

A reading and statistical correction table is used to convert the number of CFU to the most probable number of micro-organisms collected per m³ of air.

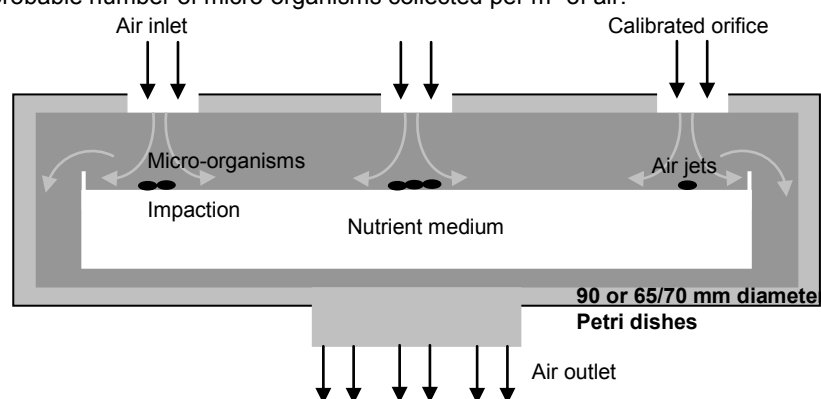


Figure 2-1: Principle of the impaction biocollector

Performance

The performance characteristics of an AeroBioCollector depend on its capacity to collect micro-organisms in the air without compromising their viability during impaction on the agar. This property can be obtained only with a perfect compromise between the high aspiration velocity leading to effective collection, and a sufficiently low impaction velocity to guarantee the revivification of collected micro-organisms.

Air IDEAL® 3P™ Traceability was developed in close cooperation with aeraulics experts in order to optimize this ratio.

Since the industry has increasing needs for scientifically proven methods, bioMérieux commissioned two recognized independent organizations* to validate the physical and biological efficiency of the instrument.

* CETIAT: Centre Technique des Industries Aérauliques et Thermiques/Technical Center of Aeraulic and Thermal Industries
Domaine Scientifique de la Doua, 69603 Villeurbanne, France
HPA : Health Protection Agency - Porton Down - Wiltshire SP4 0JG Salisbury - UK

Collection efficiency validated according to the ISO 14698 standard

Air IDEAL®3P™ Traceability was third party validated by the Health Protection Agency (UK) to meet the requirements of ISO 14698-1 for the control of clean rooms. Both the physical and biological efficiencies of the equipment have been validated according to this standard.

Physical efficiency testing approach

The physical efficiency of an air sampler for collecting airborne bacteria is evaluated by comparison with a membrane filter sampler. Uniform particles of different diameters containing bacterial spores of *Bacillus subtilis var niger* were generated in a controlled room. The physical efficiency of the instrument was determined by comparison with the membrane filtration standard operating side-by-side.

Biological efficiency testing approach

Air sampler inefficiency can either be due to a failure of the sampler to capture particles containing micro-organisms (physical loss), or to inactivation of viable micro-organisms during collection, so that formation of visible colonies on agar will not occur (biological loss).

To address this point, **Air IDEAL®3P™ Traceability** was evaluated for recovery of a mixture of *Bacillus subtilis* (standard indicator for physical loss) and *Staphylococcus epidermidis* (standard indicator for biological loss).

The ratio of *S. epidermidis* / *B. subtilis* for the test samplers was divided by the ratio obtained with the reference standard membrane filter sampler to give a comparative biological efficiency.

Use in glove boxes

In order to be used to test glove boxes, the design and materials of **Air IDEAL®3P™ Traceability** had to be entirely reviewed in order to optimize system air tightness.

In addition and in order to guarantee the optimal operation of the instrument in this application, the system underwent a complete validation in a glove box (SKAN AG, model ARIS glove box).

Applications

Air IDEAL®3P™ Traceability enables precise and reproducible air sampling. The volumes taken can be set in 10 l steps up to a maximum volume of 2000 l.

This sampling range enables the instrument to be used in all types of environments, from sterile zones to more contaminated surroundings and in all applications, e.g. qualification of sterile rooms or daily monitoring.

3 Using Air IDEAL[®] 3P[™] Traceability

Description

Air IDEAL[®] 3P[™] Traceability is supplied in a carrying case. Inside the case is a rigid lid which can be used as a small work surface [dimensions 22.7 x 13.9 cm (8.9 in. x 5.4 in.)].

The instrument is available in two versions:

- for 90 mm agar plates (product no. 410175)
- for 65/70 mm agar plates Count-Tact[®] (product no. 410174)

* For each product number, please refer to the packing list provided with the instrument.



Figure 3-1: Air IDEAL[®] 3P[™] Traceability in its carrying case

* Accessories:

- 65/70 mm Count-Tact diameter additional sampling grid (product No. 96304).
- 90 mm diameter additional sampling grid (product No. 96309).
- Aluminum telescopic tripod with ball joint (product No. 96308).
- Sterile box for transport and incubation of 65/70 mm Count-Tact plates – Kit of 10 (product No. 96301).
- Sterile box for transport and incubation of 90 mm plates – Kit of 10 (product No. 96311^{*}).

*

Availability: consult bioMérieux

Consumables

Air IDEAL®3P™ Traceability is adapted to all types of Petri dishes available on the market: 65, 70 and 90 mm.

Moreover, the use of a large range of ready-to-use culture media – irradiated or classic – developed and manufactured by bioMérieux, the reference in this field, enables you to obtain the best possible performance from the instrument.

The media comply with specific industrial and hospital environmental controls.

Culture media for general use

- TSA 20 x 90 mm plates (product No. 43011) / GTS 100 x 90 mm plates (product no. 43019)
- PCA agar 20 x 90 mm plates (product no. 43558)
- Sabouraud Dextrose agar 20 x 90 mm plates (product no. 43555)
- Sabouraud Dextrose Chloramphenicol agar 20 x 90 mm plates (product no. 43596)
- Count-Tact® agar 20 x 65 mm plates (product no. 43501)
- Count-Tact TSA agar 20 x 65 mm plates (product no. 43582)
- Count-Tact Sabouraud Dextrose Chloramphenicol agar 20 x 65 mm plates (product no. 43580)

Irradiated media

- Irradiated GTS 3P agar 20 x 90 mm plates (product no. 43711)
- Irradiated GTS 3P agar 100 x 90 mm plates (product no. 43169)
- Irradiated GTS 3P agar with neutralizers 20 plates (product no. 43811)
- Irradiated GTS 3P agar with neutralizers 100 plates (product no. 43819)
- Irradiated Count-Tact 3P agar 20 x 65 mm plates (product no. 43691)
- Irradiated Count-Tact 3P agar 100 x 65 mm plates (product no. 43699)
- irradiated Sabouraud Dextrose agar 20 x 90 mm plates (product no. 43554)
- Irradiated Sabouraud Dextrose 3P agar with neutralizers 20 plates (product no. 43814)
- Irradiated Sabouraud Dextrose Chloramphenicol agar 20 x 90 mm plates (product no. 43595)
- Irradiated Count-Tact Sabouraud Dextrose 3P agar with neutralizers 20 plates (product no. 43812)
- Irradiated Count-Tact Sabouraud Dextrose Chloramphenicol agar with neutralizers 20 x 65 mm plates (product no. 43581)

Identification of the instrument

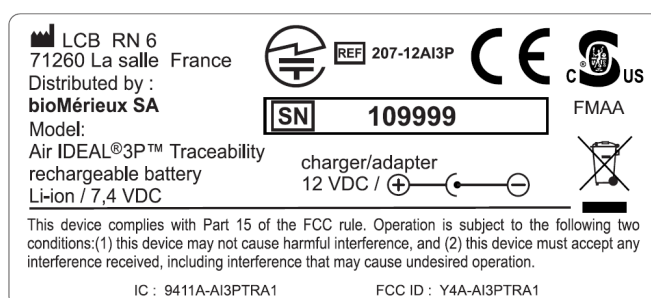


Figure 3-2: Identification of the instrument

Front face of the Air IDEAL®3P™ Traceability



Figure 3-3: Front face

Rear face of the Air IDEAL®3P™ Traceability

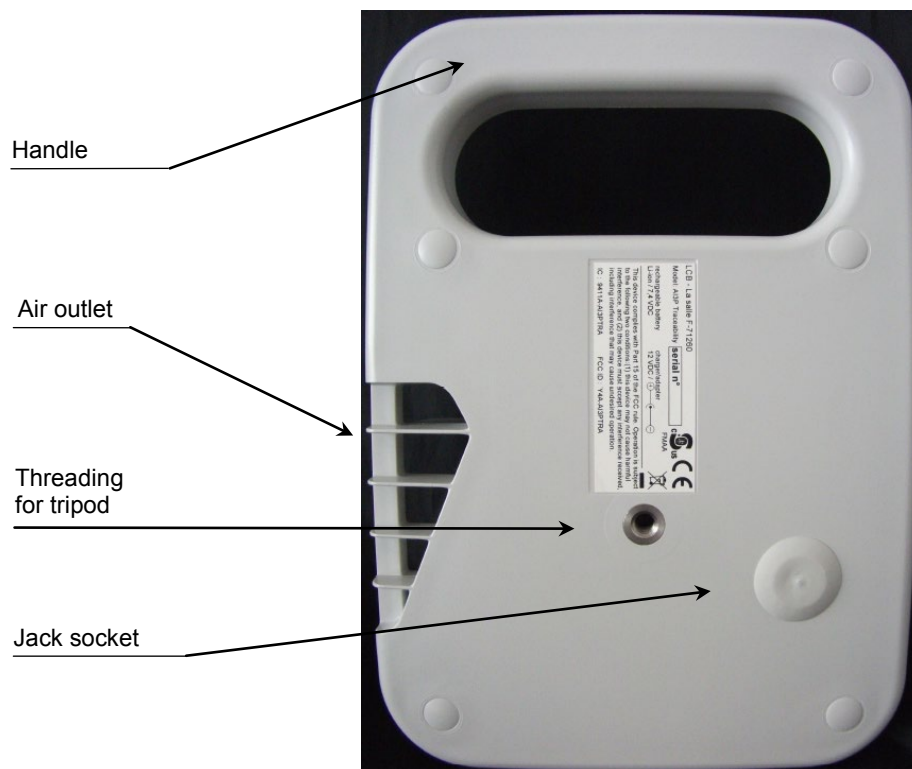


Figure 3-4: Rear face

Keypad

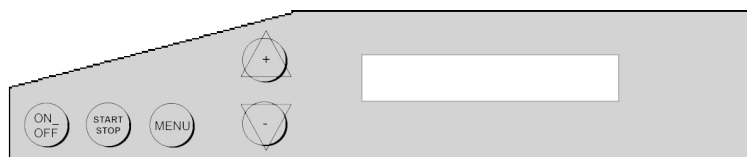


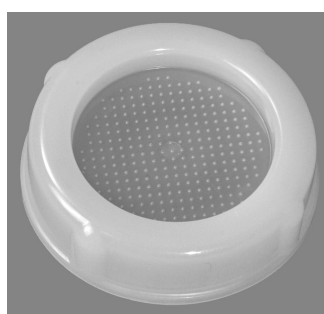
Figure 3-5: Keypad

Sampling grid

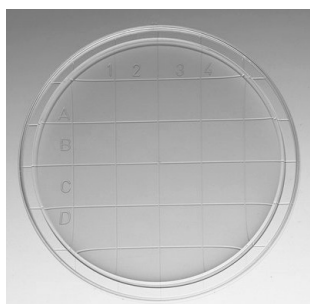
Configuration for 65, 70 or 90 mm Petri dishes



Sampling grid for 65 or 70 mm Petri dishes



Sampling grid for 90 mm Petri dishes



65 or 70 mm (Count-Tact®) Petri dish



90 mm Petri dish

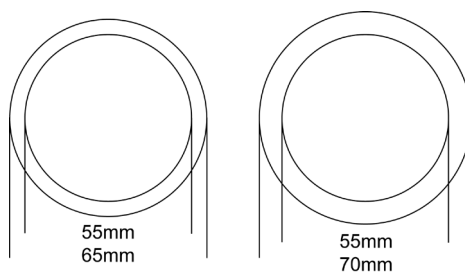


Figure 3-6: Diameter of Petri dishes

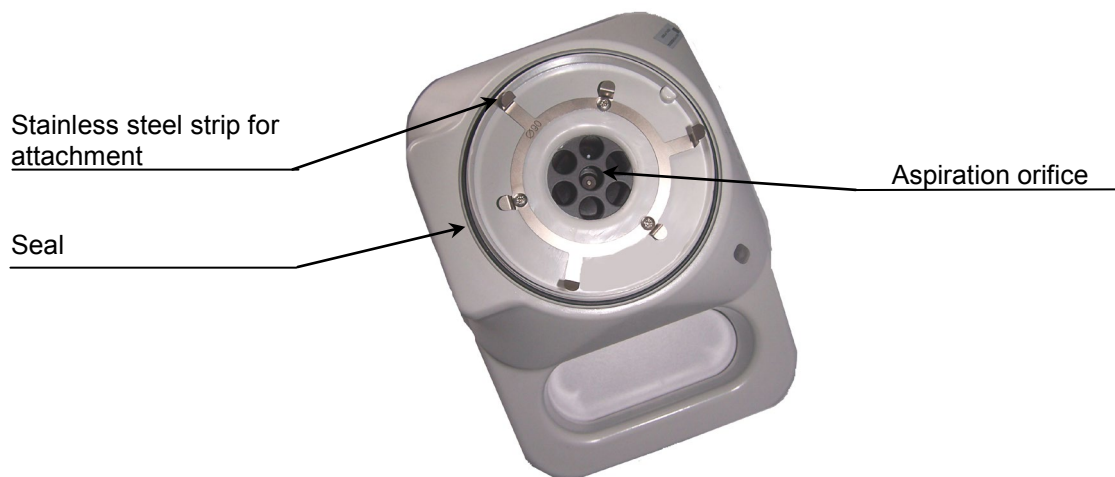


Figure 3-7: Sampling head– 65, 70 or 90 mm Petri dishes

Tripod assembly



Figure 3-8: Tripod assembly

General specifications

Environmental conditions

Normal storage conditions -20° to + 50°C
Inside use in an air class zone, sterile room or glove box.
Normal conditions of use 0 to 40 °C (32 °F to 104 °F)
Relative humidity 0 to 95%
Maximum installation altitude..... < 2 000 m
Standards applicable See product certificate
The instrument must be transported in its specific case.

Physical features

Dimensions

	<i>Instrument alone</i>	<i>Instrument in its case</i>
<i>Height</i>	128 mm (5.03 in.)	301 mm (11.8 in.)
<i>Width</i>	146 mm (5.75 in.)	250 mm (9.84 in.)
<i>Depth</i>	208 mm (8.18 in.)	400 mm (15.75 in.)

Mass

<i>Instrument alone</i>	<i>Instrument in its case</i>	<i>Shipping carton</i>
≈ 1.2 kg	≈ 5.5 kg	≈ 7.1 kg

Materials

ABS/Polycarbonate shell
Polycarbonate keypad
PVDF sampling grid
Stainless steel mounting strips and screws
Elastomer jack protection caps

Characteristics of materials

- Shock resistance: shell and keypad.
- Chemical resistance: to most standard disinfectants (70% isopropanol, hydrogen peroxide, 70% ethanol, quaternary ammoniums).
- Thermal resistance: sampling grid that can be autoclaved using Good Sterilization Practices, see section "Sterilization of grids" on page 5-1.

Note: With increasing numbers of autoclaving cycles, the grids become increasingly yellow-gray, but this has no effect on grid performance.

- Surface finish: Ra coefficient of grid = 0.14 micron.
- Fire resistance: ABS/POLYCARBONATE V0 shell (highest grade of fire resistance).

Technical characteristics

Keypad	Key control.
Display	Liquid crystal display (2 x 16 characters).
Sampling grid	1/8-turn screw-on sampling grid. Possibility of sampling on 90 mm 65/70 mm diameter Petri dishes (specific sampling grids and fixing strips).
User interface	<p>Air IDEAL®3P™ Traceability can operate in 2 modes:</p> <ul style="list-style-type: none">• Slave mode: using Air IDEAL®3P™ Traceability with the RUID.• Manual mode: autonomous operation using the keypad. <p>– 5 buttons for access to all Air IDEAL®3P™ Traceability functions.</p> <p>An LCD screen is used to program the instrument and follow its operation. Messages are in English.</p> <p>– Additional information on instrument operation is given as audible signals.</p> <p>A flashing indicator light indicates, from a distance, the status of the instrument:</p> <ul style="list-style-type: none">– Green flashing indicator light: sampling in progress. The indicator light changes to constant green when sampling is performed successfully. In slave mode the green indicator light continues to flash until sampling is stopped using the RUID.– Slow flashing green indicator light: the battery is charging. The indicator light changes to constant green as soon as the battery has been fully charged.– Constant green indicator light: the instrument is powered on and ready to start sampling in manual or slave mode.– Flashing green/red indicator light: the battery is low.– Flashing or constant red indicator light: a problem has occurred.– Indicator light off: the instrument is powered off. <p>Language used for the software: English</p>
Ergonomics	<p>Ergonomic handle (right hand/left hand).</p> <p>Possibility of stable sampling with the unit in four positions (see page 3-11).</p> <p>Possibility of suspending Air IDEAL®3P™ Traceability with a hook, especially in a glove box.</p> <p>Optionally, the instrument can be mounted on a telescopic tripod equipped with a ball joint enabling the sampling axis to be orientated through an angle of 0° to 90° (from horizontal to vertical), and its height to be adjusted (between 0.7 and 2.50 meters).</p>

Electrical characteristics

Voltage.....7.4 VDC nominal

Power supply1 A max.

Air IDEAL®3P™ Traceability is designed to run on a battery (2 Lithium-ion batteries connected in series, each with a nominal voltage of 3.7 V).

The instrument can also be powered and/or recharged using one of the adapters indicated or an equivalent one.

CAUTION!

The AC-DC power supply adapter must have the following characteristics:

- **Voltage: 12 VDC**

- **Power: 2 A max.**

- **Plug mod. Jack 12.0 x 2.1 mm**

- **AC input voltage corresponding to the characteristics of the power supply in the country where the instrument is installed.**

Note: It is recommended to use the adapter provided with the instrument. You will find the details of its characteristics below.

POWER SUPPLY complying with CEE - UL/CSA standards

INPUT 100 – 240 VAC 0.7 A – 0.4 A 47 – 63 Hz
 UL STD plug or STD European plug

OUTPUT 12 VDC 2 A max.
 d = 2.1 mm JACK plug

Functional specifications

Flow-rate 100 ± 6.4 liters per minute regardless of the grid used.
Flow-rate measured and adjusted according to the bioMérieux quality control protocol reference 96302-protocol.

Autonomy More than or equal to 4 hours, enabling at least 24 consecutive 1000 liter samples to be collected.
Specification valid for a new battery not having undergone a thermal shock or a prolonged period of inactivity.

Charge time It takes 3 hours to fully charge the battery.

Sound level < 50 dB

Security Male plug outlet serves as the power supply sectioning device.

Unpacking Air IDEAL® 3P™ Traceability

The instrument is supplied in a carrying case and box.

* When opening the box:

- Make sure you have all the items described in the packing list.
- Keep the shipping carton in case you need to ship the instrument back to bioMérieux.

CAUTION!

Any damage directly or indirectly resulting from the transport of the instrument without adequate containers will not be covered by the warranty or maintenance contract.



DANGER!

Do not use the instrument in an explosive atmosphere as sparks could cause an explosion.

Recommendations for installation and use

- Install the instrument on a flat, perfectly horizontal surface, on its tripod or by its hook.
- Avoid locations directly exposed to sunlight, excessive heat, damp or dust.
- The instrument must not be used near strong sources of electromagnetic interference.
- Do not use the instrument with its original protective cover cap, but with a grid.

IMPORTANT!

When the instrument is used for the first time, it is imperative to perform 1 battery charge-discharge cycle.

- ***Charge the battery for 3 hours.***
- ***Discharge the battery by performing successive sampling (see page 3-25 "Battery autonomy test (Menu 6)").***
- ***Recharge for 3 hours.***
- ***Make sure the grid holes are not blocked.***

WARNING! *The user's manual or instruction manual for an intentional or unintentional radiator shall caution the user that changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.*

In cases where the manual is provided only in a form other than paper, such as on a computer disk or over the Internet, the information required by this section may be included in the manual in that alternative form, provided the user can reasonably be expected to have the capability to access information in that form.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct interference by one or more of the following measures:

- *Reorient or relocate the receiving antenna.*
- *Increase the separation between the equipment and receiver.*
- *Connect the equipment to an outlet on a different circuit to the one to which the receiver is connected.*
- *Consult the dealer or an experienced radio/TV technician for help.*

WARNING! *Industry Canada requirements:*

RSS-Gen - General Requirements and Information for the Certification of Radio Apparatus, Clause 7.1.2 statement:

Under Industry Canada regulations, this radio transmitter may only operate using an antenna of a type and maximum (or lesser) gain approved for the transmitter by Industry Canada. To reduce potential radio interference to other users, the antenna type and its gain should be so chosen that the equivalent isotropically radiated power (e.i.r.p.) is not more than that necessary for successful communication.

RSS-Gen - General Requirements and Information for the Certification of Radio Apparatus, Clause 7.1.3 statement:

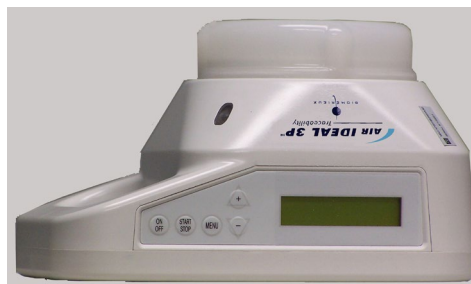
This device complies with Industry Canada licence-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

This device complies with FCC and Industry Canada RF radiation exposure limits set forth for general population (uncontrolled exposure). This device must not be collocated or operating in conjunction with any other antenna or transmitter.

Sampling positions



①



②



③



④

Figure 3-9: Sampling positions

IMPORTANT! *Air IDEAL®3P™ Traceability is delivered with a hook for suspending it in a glove box during decontamination phases. Even though sampling can be done while suspended, it is preferable to position the instrument along the axis of one-way flow at the air outlets. This configuration is the worst case scenario since the air sampled has swept the entire volume of the glove box before emerging. Do not obstruct the air outlet during use to respect operating parameters.*

Screwing on the sampling grid

CAUTION!

Do not insert any foreign objects into the aspiration orifice located under the grid (see page 3-5).

- * To screw on the sampling grid easily,
 - Position the grid on the threading of the shell and turn it clockwise by 1/8 of a turn without forcing or pressing.




Figure 3-10: Screwing on the sampling grid

Electrical power supply

Air IDEAL®3P™ Traceability operates self-sufficiently through a Lithium-ion battery pack. It can also run off the mains using the charger/adaptor.

Operation on the battery

The microprocessor manages and displays the available battery life at all times, on the basis of a theoretical autonomy of 4 hours for sampling cycles of 1000 liters.

As soon as the flashing symbol appears , there are **20 minutes** of autonomous running remaining.

Immediately put the battery on charge; if a sampling cycle is in progress it will be completed just the same.


A sampling cycle cannot start if its duration exceeds the remaining battery life displayed.

Low battery signals


- * When the battery life has expired, the following low battery signals are output:


Visual signal on the welcome message display:

STORED VOL: ZZZL
BATTERY LIFE  XHXX

 Flashing symbol

Visual signal on the sample in progress display:

STORED VOL  ZZZL
SAMPLE VOL: XL

 Flashing symbol

Audible signal when the instrument is turned on: 2 long beeps emitted each time the instrument is powered on.

IMPORTANT! *In slave mode, if the battery is low at the beginning of an analysis, the operator is warned by a message displayed on the RUID (please refer to the remote control user manual).*

Charging

- * To charge the battery,
 - Use the charger supplied or one with the same specifications.
 - During the charging phase, the instrument can be either switched on or switched off.
 - Connect the charger to the instrument jack connector after removing the protection cap.
 - Connect the charger to the power outlet.

The display indicates:

Charge
Battery

The normal time required to completely charge a discharged battery pack is 3 hours.

During the charging phase, it is possible to perform sampling with **Air IDEAL®3P™ Traceability** running off the mains. The charging process will be suspended during sampling and will restart automatically when sampling is finished.

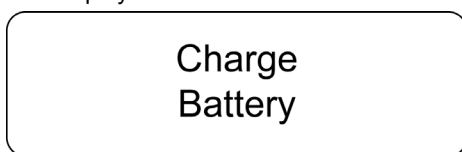
IMPORTANT! *During sampling with Air IDEAL®3P™ Traceability running off the mains, do not disconnect the instrument from the mains as there is a risk of it switching off and the sampling cycle in progress would be definitively lost.*

- * At the end of the operation,
 - Disconnect the charger from the power outlet.
 - Disconnect the charger from the the instrument jack connector.
 - Install the protection cap.
 - Check that the battery life displayed is again 4 hours.

IMPORTANT! *If Air IDEAL®3P™ Traceability is not used for more than 10 days, the battery must be totally recharged (3 hours).*

Operation using mains power

Connection to the mains is carried out in the same way as for charging the battery.
The display indicates:



- Press the <START> or <MENU> button to return to the welcome message.
Then
 - Press the <START> button to start (the volume sampled will be the last recorded).
 - or,
 - Select the sample volume by means of MENU 1 or MENU 2, and then start by pressing the <START> button.
- * To turn off,
 - Disconnect the charger from the Jack socket on the instrument.

IMPORTANT! *During sampling with Air IDEAL®3P™ Traceability running off the mains, do not disconnect the instrument from the mains as there is a risk of it switching off and the sampling cycle in progress would be definitively lost.*

Automatic standby

To preserve the battery life, the instrument automatically goes into standby mode after **5 minutes** of inactivity.

Pressing any key will reactivate the instrument.

The RUID can activate the instrument so that it is ready for sampling.

Automatic switch off

In manual or slave mode, the instrument switches off after **1 hour** of inactivity.

While it is switched off, Air IDEAL®3P™ Traceability cannot communicate with a RUID.

Operation in slave mode

- In slave mode, the **Air IDEAL®3P™ Traceability** is used with a RUID.
- Please refer to the RUID User Manual.

Operation in manual mode

In manual mode the **Air IDEAL®3P™ Traceability** operates autonomously.

Programming

Air IDEAL®3P™ Traceability enables sampling to be programmed and monitored.
This section describes how to program the instrument.

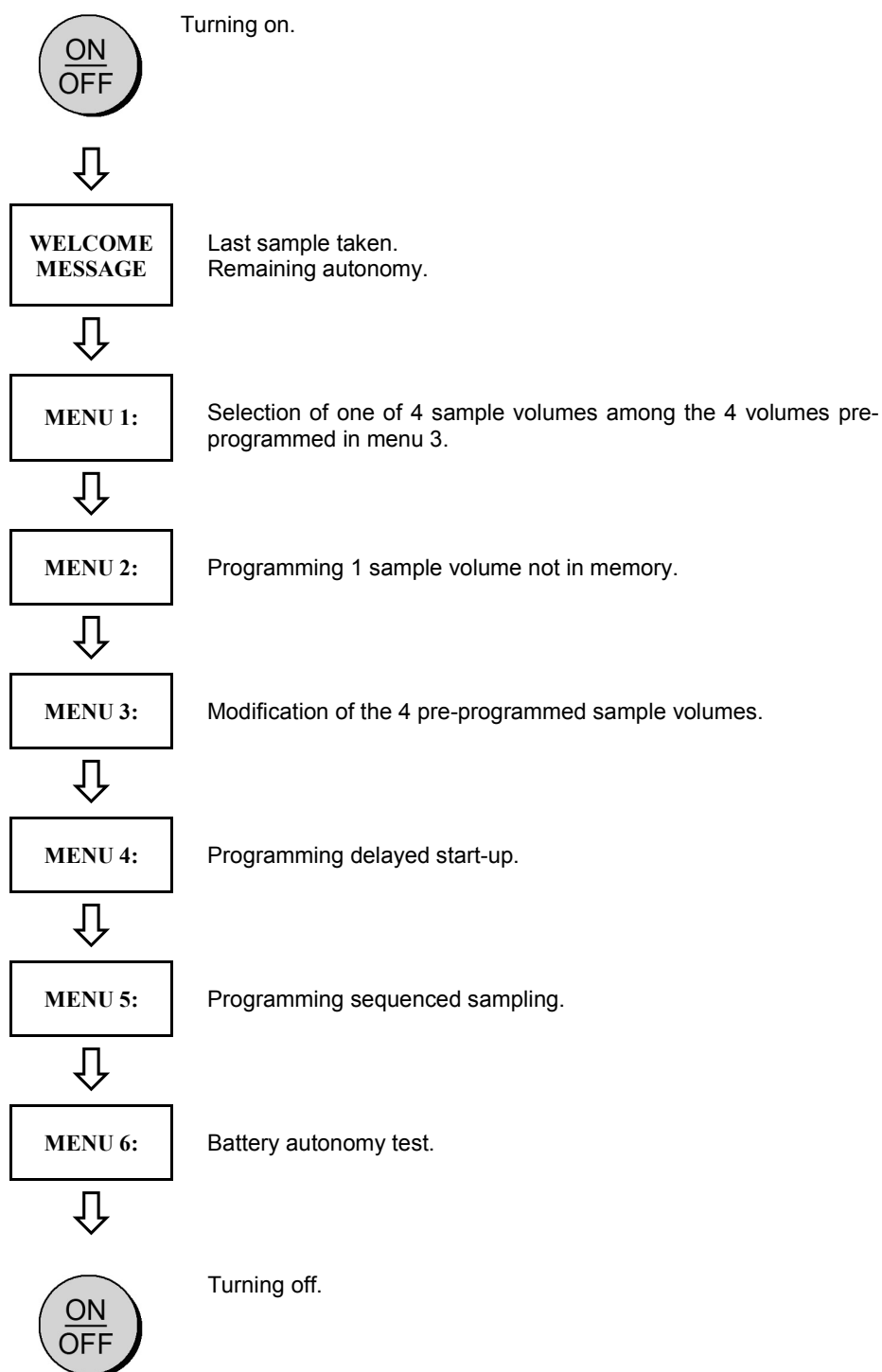
Programming characteristics

- Sample volumes adjustable from 5 to 10 liters in 1-liter steps.
- Sample volumes adjustable from 10 to 2000 liters in 10-liter steps.
- Automatic selection of last sample volume used.
- Storage of 4 sample volumes in the memory.
- Delayed start-up (maximum 60 minutes).
 - 0 to 60 seconds in 1-second steps
 - 1 minute to 60 minutes in 1-minute steps
- Sequenced sampling.

Sampling controls

- Volume counter.
- Volume of air sampled remains on display after sampling is interrupted.
- Sampling status is indicated by an indicator light.
- Possibility of interrupting and resuming a sample in progress (only in manual mode).
- End of sample buzzer (6 short beeps).
- Count-down of time.

Air IDEAL®3P™ Traceability menus



Turning on Air IDEAL®3P™ Traceability




- * To turn on the instrument,
 - Press <ON/OFF>.

The display indicates:

STORED VOL: ZZZL
BATTERY LIFE: XHXX

Note: The  symbol is displayed if a delayed start-up is programmed.

- ZZZL corresponds to the last sample volume recorded.
- XHXX corresponds to remaining battery life.

- * If the symbol  appears:

- Recharge the instrument.

- * If the last sample did not terminate correctly (sampling stopped before the end, protection cap in place of the grid, motor blocked),

AND

- * If the instrument is then switched off or put on standby,

The following message will appear when the instrument is switched on again or is reactivated:

LAST SAMPLING
NOT COMPLETED

In this case, press <MENU> once to display the welcome message.



DANGER!

Do not insert any foreign objects into the motor compartment when the instrument is running.

Standby



- * To put the instrument on standby,
 - Briefly press **<ON/OFF>**, the indicator light must not go off.or
 - Wait for 5 minutes.
- * To reactivate the instrument,
 - Press any key.

Turning off Air IDEAL®3P™ Traceability



- * To turn off the instrument,
 - Press **<ON/OFF>** until the indicator light goes off.

Selection of one of the 4 pre-programmed sample volumes (Menu 1)

- * Factory programming memorizes the following 4 volumes in **Air IDEAL®3P™ Traceability**: 100, 500, 1000, 2000 liters.



- * To select menu 1,
 - Press **<MENU>**.

The display indicates:

MENU 1: CHOSEN
PRESET VOLUME

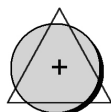
- Press the **< + >** button to select 1 of the 4 volumes memorized.

Example:



- * To select stored volume No. 2 from menu 1,
 - Press <+> twice.

Preset volume 1
XX Litres



Preset volume 2
YYY Litres

- Wait 2 seconds.

Note: If you did not wait for the end of the first timeout, in other words if you pressed another button before the 2 seconds, the new value selected (YYY) is not recorded. The initial value (ZZZ) remains in memory.

The value YYY selected is recorded.

The display indicates:

RECORDED

- * There are 3 possibilities:

- Start sampling immediately by pressing the <START> button.
- Wait: the selected sampling can be started at a later time.
- Press the <ON/OFF> button to turn off the instrument. The volume selected will be displayed the next time it is turned on.

Programming a sample volume not in memory (Menu 2)



- * To select menu 2,
 - Press <MENU> twice.

The display indicates:

MENU 2: CHOSEN
VOLUME XXL

- * To program a new volume,
 - Press < + > or < - > until the desired volume is displayed.

IMPORTANT! *It is imperative to press the < + > or < - > buttons immediately to program a new volume.*

After a 2-second delay, the volume displayed is recorded.

The display indicates:



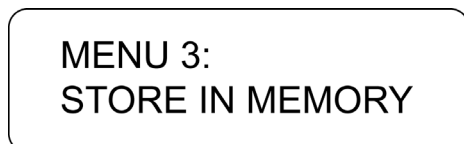
- * There are 3 possibilities:
 - Start sampling immediately by pressing <START>.
 - Wait: the selected sampling can be started at a later time.
 - Press the <ON/OFF> button to turn off the instrument. The volume selected will be displayed the next time it is turned on.

Modification of the 4 pre-programmed sample volumes (Menu 3)



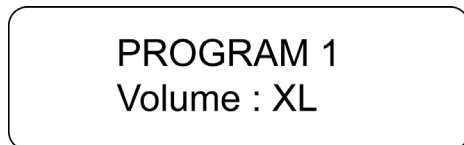
- * To select menu 3,
 - Press <MENU> 3 times.

The display indicates:



- Wait 2 seconds.

The display indicates:



- * To program a new volume for program 1,
 - Press < + > or < - > until the desired volume is displayed.

IMPORTANT! *It is imperative to press the < + > or < - > buttons immediately to program a new volume.*

After a 2-second delay, the volume displayed is recorded.

The display indicates:

PROGRAM 2
Volume : XL

Note: If the <MENU>, < + > or < - >, buttons are not pressed, each of the 4 pre-programmed volumes is displayed every 2 seconds.

- * To program a new volume for program 2,
 - Press < + > or < - > until the desired volume is displayed.

IMPORTANT! *It is imperative to press the < + > or < - > buttons immediately to program a new volume.*

After a 2-second delay, the volume displayed is recorded.

The display indicates:

PROGRAM 3
Volume : XL

- * To program a new volume for program 3,
 - Press < + > or < - > until the desired volume is displayed.

IMPORTANT! *It is imperative to press the < + > or < - > buttons immediately to program a new volume.*

After a 2-second delay, the volume displayed is recorded.

The display indicates:

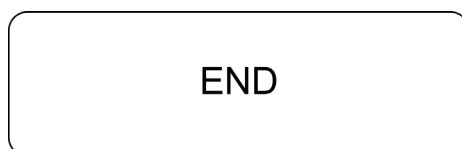
PROGRAM 4
Volume : XL

- * To program a new volume for program 4,
 - Press <+> or <-> until the desired volume is displayed.

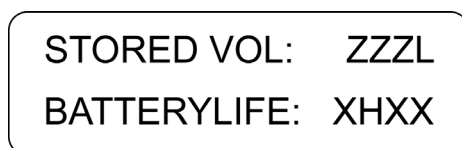
IMPORTANT! *It is imperative to press the <+> or <-> buttons immediately to program a new volume.*

After a 2-second delay, the volume displayed is recorded.

The display indicates:



The screen then returns to the welcome message.



Note: If the <+> or <-> buttons are not pressed, the pre-programmed volumes are sequentially displayed without modification.

- * Possibility of going directly to "MENU 4", once selected volumes are modified:

When "END" is displayed on the screen,

- Immediately press <MENU>.

Menu 4 is displayed.

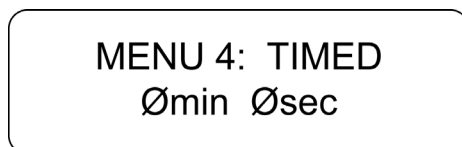
Programming delayed start-up (Menu 4)

- * Delayed start-up can be programmed for up to 60 minutes:
 - 0 to 60 seconds in 1-second steps
 - 1 minute to 60 minutes in 1-minute steps.



- * To select menu 4,
 - Press <MENU> 4 times.

The display indicates:



- * To program a delay value,
 - Press < + > or < - > until the desired delay value is displayed.

IMPORTANT! *It is imperative to immediately press < + > or < - > to program a new volume.*

After 2-seconds, the delay value is recorded.

The display indicates:



The screen returns to the welcome message.



The delay is recorded: the symbol ⌚ appears in the welcome message.

- * There are 3 possibilities:
 - Start sampling immediately by pressing <START>.
 - Wait: the selected sampling can be started at a later time.
 - Press the <ON/OFF> button to turn of the instrument. The volume selected will be displayed the next time it is turned on.

Programming sequenced sampling (Menu 5)

Menu 5 is used to sample a selected volume several times.

- * This sequencing is defined with 3 parameters:
 - The unit volume (of each sequence).
This volume is defined with menus 1 or 2 (see pages 3-18 and 3-19).
 - The number of sequences.
This number is included between 2 and 5.
 - The time interval between each sequence.
It is included between 10 minutes and 4 hours, in 10-minute steps.

- * Total sampling time must be less than 5 hours otherwise an error message will appear.



- * To select menu 5,
 - Press <MENU> 5 times.

The following message appears and the 1st line flashes:

MENU 5: SEQ NB X
VOL ZZZL INTXHXX

The unit volume is shown on the lower left and cannot be modified in this menu.

- * To modify the number of sequences,
 - Press <+> or <-> until the desired number is displayed.
 - Press <MENU> once the number of sequences is selected.

The "INTXHXX" (INTERVAL) field flashes.

- Press <+> or <-> to define the time interval between each sequence.

IMPORTANT! *Check that the remaining battery life is sufficient to carry out complete sampling (base: 10 min/1000 liters).*

- * Once sequenced sampling has been correctly programmed,
 - Press the <START> button to start sampling.

The total duration of sequences and intervals must not exceed 5 hours otherwise an error message will appear:

ERROR
TIME > 5H

- Press <MENU> to return to menu 5.

Correct the settings (number of sequences / delay) so that sampling can be performed.

IMPORTANT! *A sequenced sampling is run from the specific menu, without returning to the main menu.*

If the last sampling was sequenced, the menu 5 screen is displayed when the instrument is turned on.

Battery autonomy test (Menu 6)

This menu is used to verify that the battery is still compliant with specifications of new material (battery life ≥ 4 hours).

The battery autonomy test can be performed using a volume chosen by the operator.

1000 liters is the reference volume for verifying that specifications have been respected (4 hours of battery life for 1000-liter samples).

If the volume generally used is, for example, 100 liters, then it is wiser to perform the test on 100 liter volumes.

- * To check battery life:
 - Note the battery life displayed when the instrument is turned on.
 - Using Menu 1, select a 1000 liter sample volume.
 - Go to Menu 6.



- * To select menu 6,
 - Press <MENU> 7 times.

The display indicates:

MENU 6: AUT. TEST
BATTERY LIFE: XHXX

- Press the <START> button to run the battery discharge cycle.
- * The battery discharge cycle can be stopped as follows:
 - Press <STOP>.
- * To resume at a later time,
 - Press <START>.

CAUTION!

After more than 5 minutes of inactivity, Air IDEAL®3P™ Traceability turns off.

To turn it back on, press  *.*

Starting sampling

CAUTION!

Before starting, check that Air IDEAL®3P™ Traceability is fitted with a sampling grid and not its protective cover otherwise it could undergo irreversible damage which is not covered by the bioMérieux warranty.

- * If the protective cover remains on the instrument, the following alarm message is displayed after several seconds and sampling stops automatically:

REMOVE
PROTECTION COVER

The indicator light flashes red.

- Remove the protection cover.
- Install the grid.
- Press <MENU> to return to the welcome message.

- * To start sampling,
- Turn on the instrument,
 - Press <ON/OFF>.



The indicator light is constant green and the following message appears:

STORED VOL: ZZL
BATTERY LIFE: XHXX

- Press <START/STOP>.



- * During sampling, the display indicates:

STORED VOL: ZZL
SAMPLE VOL: XL

The indicator light changes to flashing green.

The SAMPLE VOL display flashes during the sampling phase and the volume counter is displayed.

- The last sample volume recorded is automatically displayed (shown as ZZL).

- A buzzer indicates the end of sampling (6 short buzzes) and the display returns to the original message with automatic correction of the remaining battery life.

STORED_VOL:_ZZZL
BATTERYLIFE: XHXX

The indicator light changes to constant green. The instrument is free to perform a new sampling cycle.

- * If a delayed start-up has been programmed, the display indicates:

STORED VOL: ZZZL
TIMED: XMin YS

TIMED flashes during the count-down phase.

Note: The motor stops 2 liters before the total volume has been sampled.

- * Last sampling not terminated:

If the instrument was turned off during sampling, the following message appears the next time the instrument is turned on:

LAST SAMPLING
NOT COMPLETED

The indicator light changes to flashing red.

CAUTION!

In this case, the user must take all necessary precautions to deal with this interrupted sampling.

- Press <MENU> to return to the welcome message.

Stopping the motor



- Press <START/STOP>.

Note: It is always possible to stop a sampling operation in progress by pressing <START/STOP>.

If the motor is stopped during the program, i.e. during the delayed start-up count-down phase or during the sampling phase, the value displayed freezes and the display continues to flash.

STORED VOL: ZZZL

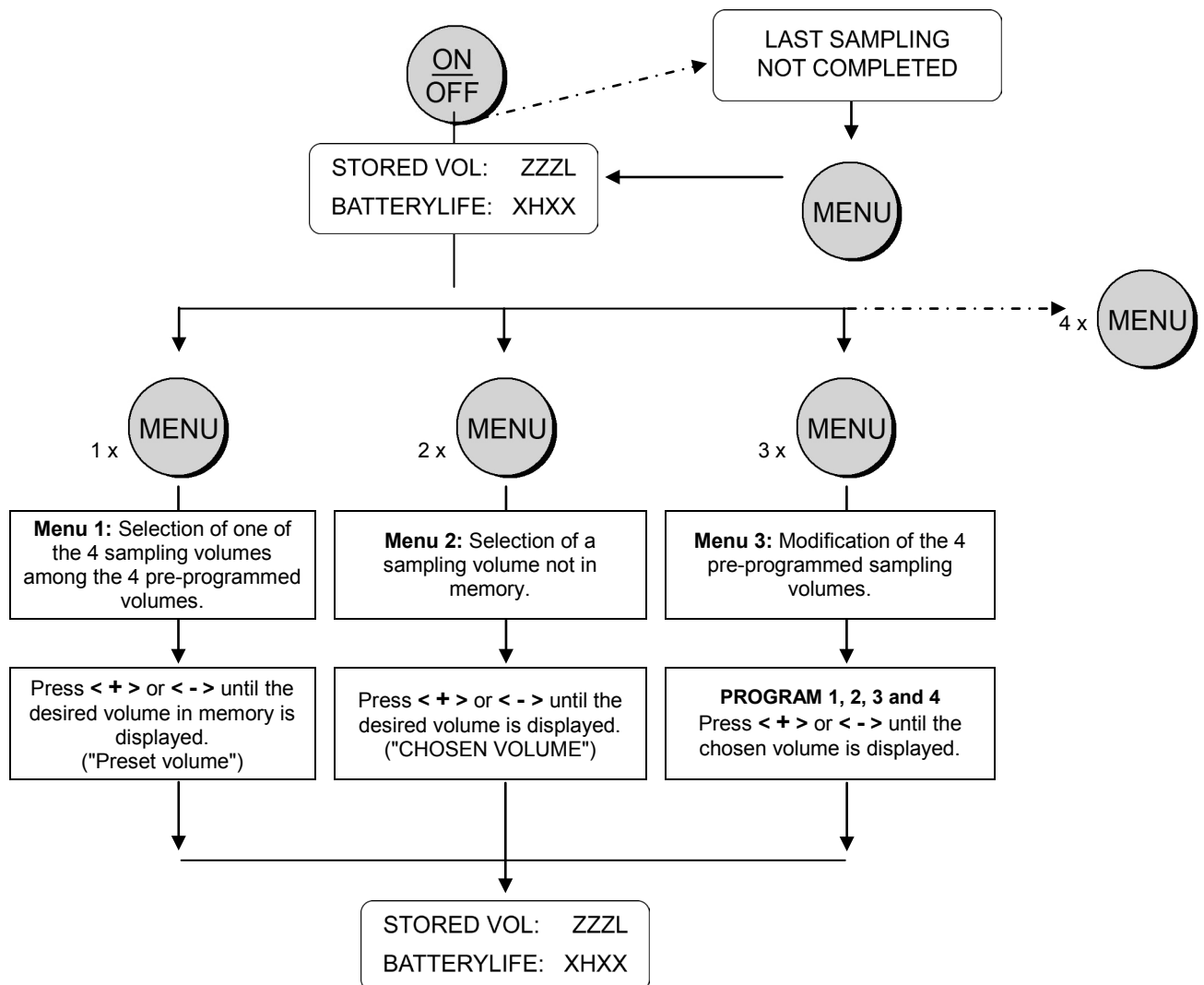
SAMPLE VOL: XL

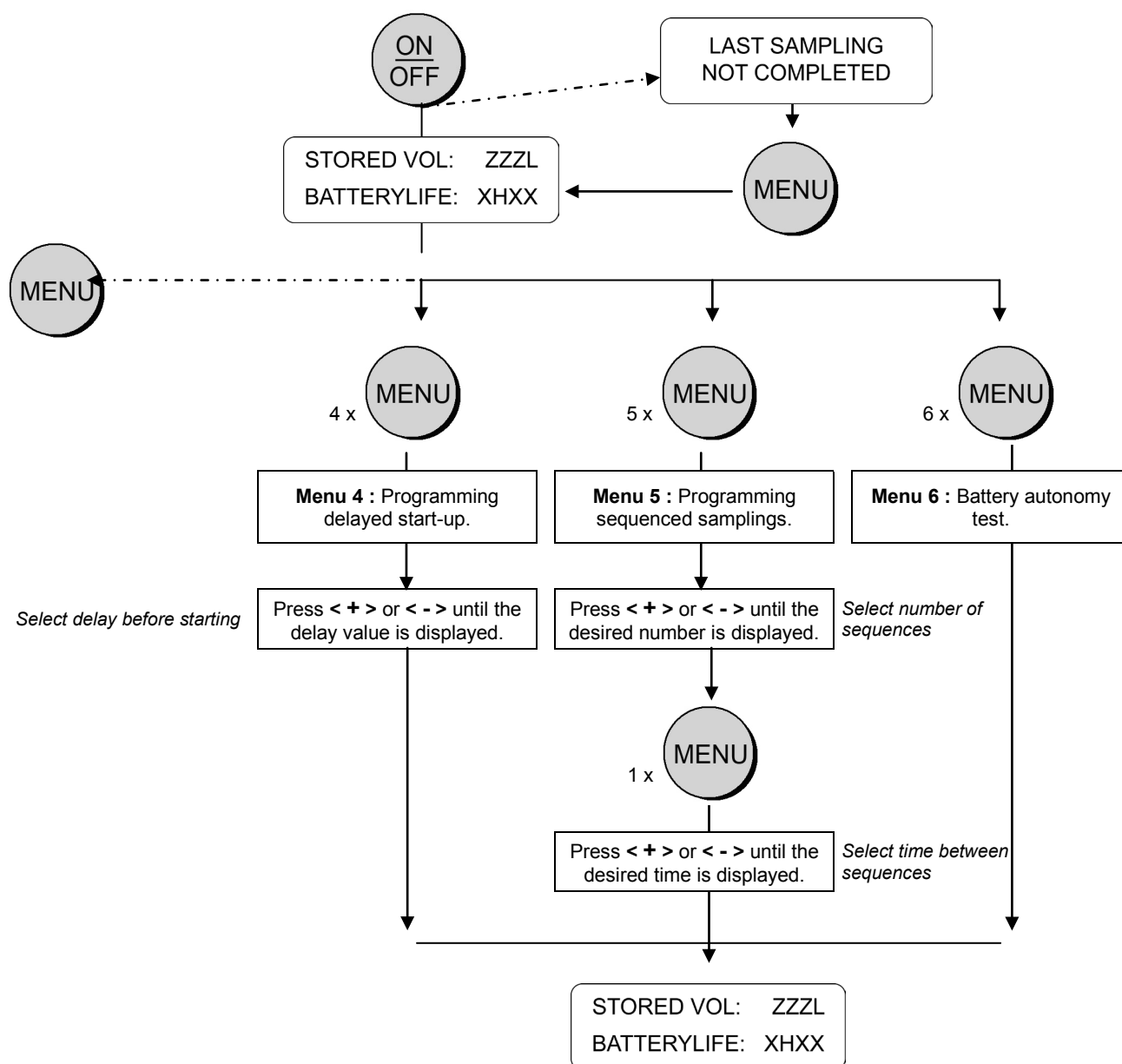
- * To resume sampling,
- Press <START/STOP>.

If the motor is restarted after being stopped during a program, the program will resume from the point where it was stopped.

Note: If stoppage during sampling is more than 5 minutes, the instrument will go into standby mode and the sampling program will not be able to resume.

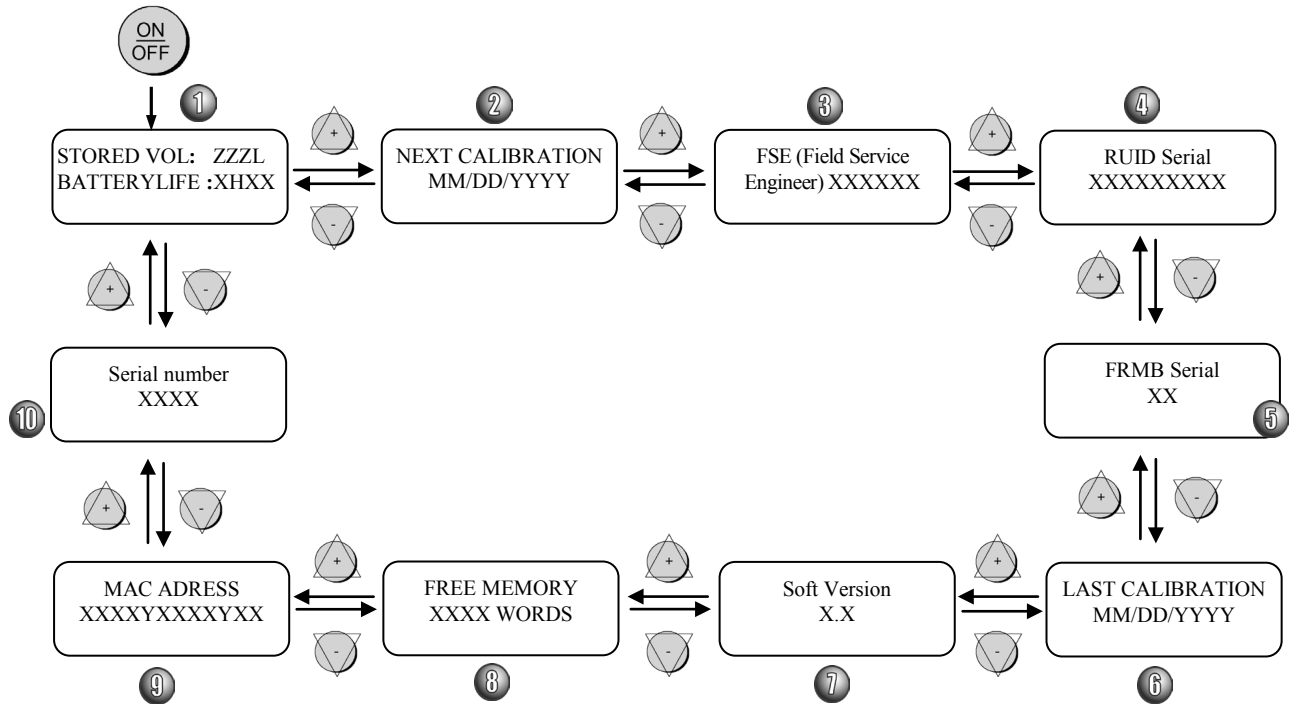
Setting Air IDEAL[®] 3P[™] Traceability parameters (summary diagram)





Maintenance Menu

Navigation using < + > and < - > keys



IMPORTANT! This information can be viewed by the user, but it can only be updated by bioMérieux Technical Assistance or the local bioMérieux representative.

- 1 Welcome message
- 2 Date of next calibration (Month/Day/Year)
- 3 ID of operator who performed calibration
- 4 Serial number of RUID used for calibration
- 5 Flow Rate Measurement Bench serial number
- 6 Date of last calibration
- 7 **Air IDEAL®3P™ Traceability** firmware version
- 8 **Air IDEAL®3P™ Traceability** available memory size
- 9 MAC address (Media Access Control)
- 10 **Air IDEAL®3P™ Traceability** serial number

4 Procedure

Principle

Implementation and following of a procedure to measure aerobiocontamination corresponds to a process based on prevention, which involves:

- Evaluating the current level and standard of hygiene and controls.
- Selecting the critical areas to be controlled.
- Establishing a reference level and an alert level for each of the critical points.
- Developing a sampling plan.
- In manual mode, preparing a document for recording air sampling results.
- In slave mode, recording of air sampling results using the RUID.
- Preparing a plan for corrective action in case of deviation.

The result of sampling should provide information on the level of risk, global hygiene conditions and environment.

Procedure

The procedure must be adapted to the actual conditions in which air sampling will take place (contaminated areas, clean areas, sterile areas, etc.)

When strictly followed, the procedure guarantees good quality sampling and should include:

- Operators' qualifications.
- Names of qualified operators.
- Hygiene of operators (clothes, hands, etc.).
- Protocol for disinfection of the AeroBioCollector.
- Detailed steps of the procedure.

Procedure

How to obtain a good quality sample

How to obtain a good quality sample

Precautions of use

- Check the condition of the instrument and sampling grid.
- When unscrewing and screwing on the sampling grid, avoid touching the perforated zone.

The choice of medium depends on the area to be controlled and the type of micro-organism to be isolated.

The agar in 90 mm Petri dishes, must be at least 2.5 mm thick at the center and have a flat surface. It should not present dehydration or humidity droplets.

- During sampling, avoid any unnecessary movement, do not pass in front of the instrument or cough etc.
- Begin by collecting from low contaminated areas.
- Collect several samples in each zone in order to obtain results that can be used for statistical studies.
- Clean the instrument after use and sterilize sampling grids.
- Recharge the battery if necessary.
- Place the instrument in its carrying case and store it in a suitable place.

Sampling in manual mode

Note: For slave mode, please refer to the RUID User Manual.

- Turn on the instrument.
- Check the remaining battery life.
- Place the instrument on a flat surface (work bench, table, etc.) in a vertical or horizontal position, or set it up on its tripod.
- Select the sample volume according to the critical area to be controlled.
- Remove the protective cover or the sampling grid.
- Record the date, time and sample location on the Petri dish.
- Place the Petri dish with its cover between the attachment clips and make sure it is correctly positioned.
- Remove the Petri dish cover and place it on a clean surface.
- Screw on the sampling grid corresponding to the type of plate used.
- Perform sampling.
- The instrument indicates the end of sampling (6 beeps and a constant green indicator light).
- Unscrew the sampling grid.
- Carefully remove the Petri dish without touching the agar.
- Put the cover back on the Petri dish used.
- Put the protective cover back on.

Incubation and reading

The Petri dishes must be placed in the incubator as rapidly as possible.

After incubation, read as follows:

- Count the number of CFU (Colony Forming Units) which have grown and refer to the reading table for the final result (see page 7-1).
- If results are not acceptable, proceed with colony identification to orientate corrective action.

Sampling plan

The sampling plan must be drawn up very carefully and followed strictly. The aim is to guarantee that the values obtained are comparable. Any discrepancy between values should reveal a variation in aerobiocontamination.

A sampling plan must include:

- the critical points to be controlled
- the following must be mentioned for each point controlled:
 - the time and frequency,
 - the micro-organism(s) to be isolated,
 - the media used,
 - the revivification conditions,
 - the sample volume,
 - the number of samples per area controlled,
 - the reference level and the alert level,
In practice, the alert level can be fixed at 3 times the reference level.
 - sampling conditions (temperature, hygrometry, staff numbers, activity, etc.).

Recording and evaluating results

The person in charge of controlling the quality of air collects the results recorded.

- Results which give expected values are validated.
- If unacceptable results are obtained, corrective action may be necessary.

The document for recording results must include:

- date and time of sample,
- operator's name,
- critical point controlled,
- the situation of the control in relation to the activity (production cycle, pre or post-operative, etc.),
- detailed stages of the procedure,
- level of internal activity (number of people present, number of lines running, etc.),
- thermohygrometric conditions (real or reference),
- micro-organism to be isolated,
- culture medium used,
- incubation conditions (duration, temperature),
- date and time of incubation,
- date and time of reading,
- reference level and alert level,
- result: acceptable/unacceptable,
- decision: validation/ corrective action.

5 Maintenance

Preventive maintenance

CAUTION!



No preventive maintenance needs to be performed by the user.

If an anomaly occurs on your instrument, call bioMérieux or your local distributor. Do not open the shell of the instrument.

Always use a replacement battery of the same type (Li-on 7.4 V – 4.4 to 5Ah) to avoid the risk of explosion.

Used batteries must be returned to bioMérieux or your local distributor.

Routine servicing

The routine servicing operations to be carried out by the user are:

- Battery charging.
- Cleaning and disinfection.
- Sampling grid sterilization.

Cleaning and decontamination procedure

All parts, including the case (inside and outside), can be cleaned with soapy water, rinsed and dried.

The stainless steel strip for attachment of Petri dishes can be dismantled for cleaning.

IMPORTANT! *Do not use concentrated peracetic acid, acetone or chlorinated solvents (chloroform, etc.) on the shell or keyboard.*

Sterilization of grids

Air IDEAL® 3P™ Traceability is delivered with a set of 5 grids. They can be sterilized by autoclaving at 134°C for 18 min.

bioMérieux has validated that the grid specifications and performance are not altered after autoclaving up to:

- 40 times at 134°C for 18 minutes
- 200 times at 121°C for 20 minutes

After autoclaving 14 times or more, the grid may begin to turn yellow and may become difficult to screw onto the instrument.

IMPORTANT! *Do not sterilize under a flame.*

Decontamination of external parts

All the external parts of the instrument can be decontaminated with most of the usual disinfectants at the usual effective concentration (70% isopropanol, hydrogen peroxide, 70% ethanol, quaternary ammonium).

Decontamination of the air circuit

Decontamination of the instrument according to this protocol with ClearKlens IPA (Johnson Diversey) has been validated by bioMérieux. A summary of this validation is available on request.

- * Decontamination protocol:
 - Spray twice with 70% isopropyl alcohol with the motor off: one spray at the air inlet, the other at the outlet.
 - Allow to react for 15 minutes before using the instrument.

Decontamination in a glove box

Air IDEAL® 3P™ Traceability was specially developed for use in production or control glove boxes. The suitability of this instrument for use in glove boxes was evaluated by the SKAN AG "Center of Competence for Isolator Technology".




- * Two parameters were tested:
 - The capacity of the instrument to withstand standard decontamination cycles in glove boxes.
 - The capacity of a standard decontamination cycle to disinfect the different types of materials that compose the instrument.
- A summary of this validation is available on request.





Airflow control

The airflow control must be performed once a year from the date of the last control or adjustment.

IMPORTANT! *The airflow control must be performed by bioMérieux Technical Assistance or the local bioMérieux representative.*

6 Troubleshooting

Indicator light status	Error message	Possible cause	Action in MANUAL mode	Action in SLAVE mode
Flashing red	LAST SAMPLING NOT COMPLETED	Sampling is interrupted in MANUAL mode.	Press <MENU> to return to the welcome message.	Press <MENU> to return to the welcome message.
	LAST SAMPLING NOT COMPLETED	Sampling is interrupted in SLAVE mode.	N/A	Acknowledge the fault on the RUID and stop the sampling cycle with the RUID that was used to start it.  If this RUID is not available, press <MENU> for 10 seconds on the instrument and then select "Yes" to return to the welcome message.
	ERROR BATTERY LIFE	There is insufficient battery life to perform the sampling program.	Connect the instrument to the mains power so that sampling can start or put the battery on charge.	Acknowledge the fault on the RUID and then connect the instrument to the mains so that sampling can start, or to charge the battery.
	ERROR TIME > 5H	The total duration of sequenced samplings programmed in MENU 5 has exceeded 5 hours.	Reprogram so that the total duration does not exceed 5 hours.	Not applicable as the fault is detected when the sampling campaign is programmed on the PC application.
	Flashing volume is displayed	Sampling has been accidentally interrupted by the operator.	To continue sampling, press <START> . The volume collected will flash on the display. To stop sampling, press <STOP> .	Acknowledge the fault on the RUID and then close the sampling cycle with the RUID that was used to start it.  If this RUID is not available, press <MENU> for 10 seconds on the instrument and then select "Yes" to return to the welcome message.  Sampling cannot continue. The volume collected flashes on the instrument.
	Screen is frozen on "MENU 6"	The battery autonomy test started from MENU 6 has been interrupted using the <STOP> key.	To continue the battery autonomy test, press <START> .	Not applicable as the battery autonomy test can only be performed in MANUAL mode.
	REMOVE PROTECTION COVER	Sampling has been interrupted as the protective cover has been detected.	Replace the protective cover with the grid and then press <MENU> to return to the welcome message. If the message appears when the protective cover has been removed, please contact your supplier.	Acknowledge the fault to allow another sampling cycle to start. Close the sampling cycle using the RUID. Replace the protective cover with the sampling grid in order to start sampling. If the message appears when the protective cover has been removed, contact your supplier.

Indicator light status	Error message	Possible cause	Action in MANUAL mode	Action in SLAVE mode
	MOTOR JAMMED	Sampling has been interrupted as the motor has jammed.	Inspect the black grid under the Petri dish retaining claws. Press <MENU> to return to the welcome message.	Inspect the black grid under the Petri dish retaining claws. Acknowledge the fault using the RUID.
	CALIBRATION DATE EXPIRED	The calibration date has expired.  Can only be detected by the RUID in slave mode.	Not applicable as the instrument cannot detect when the calibration date has expired. Sampling can be performed.	Use the RUID to acknowledge the fault and allow another sampling cycle to start.  Even if the calibration date is not updated, the instrument returns to the welcome message and is able to perform the programmed sampling cycle. However, the calibration date expiry is recorded in the sampling data.
Green / Red flashing	Welcome message with battery symbol crossed out and sound signal (2 long beeps).	Battery is low.	Charge the instrument battery. Sampling is allowed, unless the remaining battery life is shorter than the battery life required to perform the requested sampling cycle.	Charge the instrument battery. Sampling is allowed, unless the remaining battery life is shorter than the battery life required to perform the requested sampling cycle.
Constant red	SERIAL NUMBER UNKNOWN	The serial number is undefined.	Contact your supplier.	Contact your supplier.
	NO CALIBRATION DATA	No calibration data stored in the instrument memory.	Contact your supplier.	Contact your supplier.
Off	Screen off	Sampling has been interrupted as the instrument was disconnected from the mains power	Reconnect the instrument to the mains and press <ON/OFF> to turn it on.  Sampling cannot continue.	Reconnect the instrument to the mains and press <ON/OFF> to switch it on. Acknowledge the fault on the RUID to allow another sampling cycle to start and then close the sampling cycle using the RUID.  Sampling cannot continue.
	Screen off	Battery is low.	Charge the battery.	Charge the battery.

7 Appendix

Using the reading table

The following reading tables indicate the most probable number of micro-organisms collected per plate (MPN collected) with respect to the number of agglomerates of colonies counted on the agar (CFU read).

The **MPN** value is calculated from the **CFU** count, using FELLER's law. This statistical correction corresponds to the random passing of bacteria through the orifices of the grid.

It quantifies for each "visited" orifice, (i.e. for each cluster counted) and as a function of the total number of clusters counted, the most probable number of bacteria which make up the cluster concerned, i.e. the number of bacteria having passed through the same orifice.

The application of the statistical correction assumes that the CFU count on the agar concerns the number of colony clusters, i.e. the number of orifices with a positive impact, without distinguishing, within a given cluster, the number of confluent colonies of which it is made up.

In order to determine the most probable number of micro-organisms collected per cubic meter, the most probable number of micro-organisms collected per plate (MPN collected) must be multiplied by 1000 and divided by the volume sampled in liters.

Example: Volume of air sampled = 50 liters
 CFU count: 120
 MPN value: 159, 380905
 Result expressed as the MPN collected per cubic meter = $159 \times 1000 / 50 = 3180$

Information on FELLER's law

The formula for FELLER's law is the following:

$$\text{MPN} = N \cdot (1/N + 1/N-1 + 1/N-2 + \dots + 1/N-\text{CFU}+1)$$

where:

MPN = most probable number of bacteria having passed through the orifices of the grid

N = number of orifices on the grid.

CFU = colony forming units, value obtained by the laboratory.

In the case of a sampling grid for which the passage of a particle through a given orifice of the grid is purely random, there is a probability that, during a sampling cycle, **several** particles pass through the **same** orifice and are therefore counted as a **single and unique** CFU, while other orifices are not passed through by any particles.

The closer the CFU count obtained by the laboratory is to N, (total number of orifices on the grid), the higher the probability is.

Moreover, the notion of probability density arises:

Example: for a given CFU value:

- there is a probability p_2 that the same orifice is passed through by 2 particles
- there is a probability p_3 that the same orifice is passed through by 3 particles
- there is a probability p_i that the same orifice is passed through by i particles etc...

The probability p_i decreases as i increases.

It is therefore particularly relevant to apply the statistical correction using FELLER's law when high CFU values are read, i.e. close to N , i.e. in the case of agar plates almost completely saturated with colonies.

IMPORTANT! *In practice, and whenever possible, to minimize statistical correction, it is recommended to adjust the sample volume so that the CFU count does not exceed 100.*

Reading tables

CFU count	corrected MPN	CFU count	corrected MPN	CFU count	corrected MPN	CFU count	corrected MPN
1	1	37	39,770782	73	85,202311	109	140,067796
2	2,003788	38	40,933063	74	86,582519	110	141,766514
3	3,011392	39	42,100464	75	87,969954	111	143,476191
4	4,022843	40	43,273030	76	89,364690	112	145,196971
5	5,038168	41	44,450808	77	90,766807	113	146,928997
6	6,057399	42	45,633844	78	92,176381	114	148,672418
7	7,080565	43	46,822184	79	93,593494	115	150,427385
8	8,107697	44	48,015878	80	95,018225	116	152,194051
9	9,138825	45	49,214973	81	96,450657	117	153,972575
10	10,173982	46	50,419519	82	97,890875	118	155,763115
11	11,213197	47	51,629564	83	99,338962	119	157,565836
12	12,256504	48	52,845161	84	100,795006	120	159,380905
13	13,303935	49	54,066359	85	102,259094	121	161,208491
14	14,355523	50	55,293211	86	103,731317	122	163,048769
15	15,411300	51	56,525769	87	105,211764	123	164,901916
16	16,471300	52	57,764087	88	106,700528	124	166,768113
17	17,535557	53	59,008218	89	108,197703	125	168,647546
18	18,604105	54	60,258218	90	109,703385	126	170,540403
19	19,676979	55	61,514142	91	111,217670	127	172,446878
20	20,754215	56	62,776047	92	112,740659	128	174,367167
21	21,835848	57	64,043990	93	114,272451	129	176,301474
22	22,921913	58	65,318028	94	115,813148	130	178,250003
23	24,012448	59	66,598221	95	117,362856	131	180,212966
24	25,107490	60	67,884629	96	118,921679	132	182,190578
25	26,207075	61	69,177312	97	120,489727	133	184,183059
26	27,311241	62	70,476332	98	122,067108	134	186,190635
27	28,420028	63	71,781750	99	123,653934	135	188,213536
28	29,533473	64	73,093631	100	125,250320	136	190,251998
29	30,651617	65	74,412039	101	126,856380	137	192,306261
30	31,774498	66	75,737039	102	128,472234	138	194,376574
31	32,902158	67	77,068698	103	130,098001	139	196,463188
32	34,034636	68	78,407081	104	131,733803	140	198,566362
33	35,171976	69	79,752259	105	133,379766	141	200,686362
34	36,314217	70	81,104300	106	135,036016	142	202,823459
35	37,461403	71	82,463274	107	136,702683	143	204,977931
36	38,613577	72	83,829254	108	138,379898	144	207,150062

CFU count	corrected MPN	CFU count	corrected MPN	CFU count	corrected MPN	CFU count	corrected MPN
145	209,340144	176	288,153475	207	400,832773	238	600,854201
146	211,548478	177	291,131003	208	405,401739	239	610,669016
147	213,775369	178	294,142367	209	410,050862	240	620,861324
148	216,021131	179	297,188344	210	414,783004	241	631,461324
149	218,286089	180	300,269739	211	419,601186	242	642,502990
150	220,570571	181	303,387386	212	424,508594	243	654,024729
151	222,874919	182	306,542148	213	429,508594	244	666,070184
152	225,199481	183	309,734919	214	434,604748	245	678,689231
153	227,544613	184	312,966627	215	439,800826	246	691,939231
154	229,910685	185	316,238232	216	445,100826	247	705,886600
155	232,298072	186	319,550732	217	450,508989	248	720,608822
156	234,707163	187	322,905162	218	456,029823	249	736,197057
157	237,138356	188	326,302598	219	461,668120	250	752,759557
158	239,592059	189	329,744156	220	467,428990	251	770,426224
159	242,068695	190	333,230999	221	473,317879	252	789,354796
160	244,568695	191	336,764332	222	479,340606	253	809,739411
161	247,092504	192	340,345413	223	485,503397	254	831,822744
162	249,640581	193	343,975550	224	491,812921	255	855,913653
163	252,213397	194	347,656105	225	498,276335	256	882,413653
164	254,811436	195	351,388500	226	504,901335	257	911,858098
165	257,435198	196	355,174214	227	511,696207	258	944,983098
166	260,085198	197	359,014794	228	518,669891	259	982,840241
167	262,761966	198	362,911853	229	525,832053	260	1027,006907
168	265,466048	199	366,867077	230	533,193165	261	1080,006907
169	268,198007	200	370,882228	231	540,764593	262	1146,256907
170	270,958423	201	374,959151	232	548,558711	263	1234,590241
171	273,747897	202	379,099776	233	556,589014	264	1367,090241
172	276,567046	203	383,306125	234	564,870264	265	1632,090241
173	279,416508	204	387,580319	235	573,418651		
174	282,296943	205	391,924581	236	582,251984		
175	285,209031	206	396,341248	237	591,389915		

