

# Air IDEAL<sup>®</sup> 3P


User's Manual

EN



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 LCB 71260 La Salle FRANCE

**EC REP**

**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](http://www.biomerieux.com)

**CE**



# Revisions

The list of revisions below summarizes replacements or additional pages in your **Air IDEAL 3P** User's Manual.

Version	Date of printing	Modifications	Page (s) modified
A	01/2001	Bilingual (FR / EN)	All
B	04/2001	Multilingual (FR / EN / ES / IT / DE / PT)	All
C	11/2005	Update of the manual (FR / EN / ES)	All
D	03/2006	Update of the manual (FR / EN / ES / IT / DE / PT)	All
E	03/2008	Environmental conditions (FR / EN / ES / IT / DE / PT)	2-12
F	-	Not used	-
G	-	Not used	-
H	-	Not used	-
I	10/2012	Addition of figure "Diameter of Petri dishes".  Modification of section: - "Characteristics of materials".  Modification of sections: - "Cleaning and decontamination" - "Decontamination of the external part".  Airflow control	3-5  3-7  5-1  5-2



## Warning

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The content of this manual is based on the Software release **V2**.

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.*

## Trademarks

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**BIOMERIEUX, the blue logo, 3P, Air IDEAL 3P 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

<b>1</b>	<b>How to use this manual</b>	<b>1-1</b>
	Finding topics and procedures .....	1-1
	Glossary .....	1-2
	Typographic conventions .....	1-3
	The Air IDEAL 3P keypad .....	1-3
<b>2</b>	<b>Functional description</b>	<b>2-1</b>
	Presentation .....	2-1
	Operating principle .....	2-1
	Performance .....	2-2
	Collection efficiency validated according to the ISO 14698 standard .....	2-2
	Physical efficiency testing approach .....	2-2
	Biological efficiency testing approach .....	2-2
	Use in glove boxes .....	2-2
	Applications .....	2-2
<b>3</b>	<b>Using Air IDEAL 3P</b>	<b>3-1</b>
	Description .....	3-1
	Consumables .....	3-2
	Culture media for general use .....	3-2
	Irradiated media .....	3-2
	Identification of the instrument .....	3-3
	Front face of Air IDEAL 3P .....	3-3
	Rear face of Air IDEAL 3P .....	3-4
	Keypad .....	3-4
	Configuration for 65, 70 or 90 mm Petri dishes .....	3-5
	Tripod assembly .....	3-6
	General specifications .....	3-7
	Environmental conditions .....	3-7
	Physical features .....	3-7
	Dimensions .....	3-7
	Mass .....	3-7
	Materials .....	3-7
	Characteristics of materials .....	3-7
	Technical characteristics .....	3-8
	Keypad .....	3-8
	Display .....	3-8
	Sampling grid .....	3-8
	User interface .....	3-8
	Ergonomics .....	3-8
	Electrical characteristics .....	3-9
	Functional specifications .....	3-9
	Flow-rate .....	3-9
	Autonomy .....	3-9
	Charge time .....	3-9
	Sound level .....	3-9
	Security .....	3-9
	Unpacking Air IDEAL 3P .....	3-10
	Packing list .....	3-10
	Recommendations for installation and use .....	3-11
	Sampling positions .....	3-12
	Screwing on the sampling grid .....	3-13
	Electrical power supply .....	3-14
	Operation on internal battery .....	3-14
	Low battery signals .....	3-14
	Charging .....	3-15

## Table of contents

---

Operation using the power line .....	3-15
Automatic switch off.....	3-15
Programming.....	3-16
Programming characteristics .....	3-16
Sampling controls .....	3-16
Additional information .....	3-16
Air IDEAL 3P menus.....	3-17
Turning on Air IDEAL 3P .....	3-18
Turning off Air IDEAL 3P .....	3-18
Selection of one of the 4 pre-programmed sample volumes (Menu 1) .....	3-19
Programming a sample volume not in memory (Menu 2) .....	3-20
Modification of the 4 pre-programmed sample volumes (Menu 3).....	3-20
Programming delayed start-up (Menu 4) .....	3-23
Programming sequenced sampling (Menu 5).....	3-24
Battery autonomy test (Menu 6) .....	3-25
Starting sampling .....	3-26
Stopping the motor .....	3-28
Setting Air IDEAL 3P parameters (summary diagram).....	3-29
<b>4 Procedure</b> .....	<b>4-1</b>
Principle .....	4-1
Procedure.....	4-1
How to obtain a good quality sample .....	4-2
Precautions of use.....	4-2
Sampling .....	4-2
Incubation and reading .....	4-2
Sampling plan .....	4-3
Recording and evaluating results .....	4-3
<b>5 Maintenance</b> .....	<b>5-1</b>
Preventive maintenance.....	5-1
Routine servicing.....	5-1
Cleaning and decontamination .....	5-1
Sterilization of grids .....	5-1
Decontamination of the external part.....	5-1
Decontamination of the air circuit .....	5-1
Decontamination of the air circuit .....	5-1
Decontamination in a glove box.....	5-2
Airflow control.....	5-2
<b>6 Troubleshooting</b> .....	<b>6-1</b>
<b>7 Appendix</b> .....	<b>7-1</b>
Using the reading table .....	7-1
Information on FELLER's law.....	7-1
Reading tables .....	7-2

## Notes



# List of figures

**Note:** *Screen captures and figures are given as examples only.*

## 2. Functional description

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

## 3. Using Air IDEAL 3P

Figure 3-1: Identification of the instrument.....3-3

Figure 3-2: Front face .....3-3

Figure 3-3: Rear face.....3-4

Figure 3-4: Keypad .....3-4

Figure 3-5 : Diameter of Petri dishes .....3-5

Figure 3-6: Sampling head and grid – 90 mm Petri dishes .....3-6

Figure 3-7: Tripod assembly .....3-6

Figure 3-8: Air IDEAL 3P in its carrying case.....3-10

Figure 3-9: Sampling positions .....3-12

Figure 3-10: Screwing on the sampling grid.....3-13



# 1 How to use this manual

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

## Finding topics and procedures

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This manual is divided into 7 chapters.

### Table of contents

The main table of contents of the manual is located on pages V-1 to V-2. It lists each chapter and the procedures and/or topics contained in the manual.

### List of figures

Page V-3 contains the list of figures found in this manual.

### Warnings

Different types of warnings are used throughout the manual:

- 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

Apart from the first page of every chapter, each page of the manual includes a page header and a footer.

Each page header includes the chapter title and the title of a procedure or its corresponding description.

These titles are located on the outside of the page so that you can thumb through the pages to quickly locate a chapter or a procedure.

The footers contain the title of the manual, the name of the product and the page number.

### Notes

This manual contains a certain number of notes that are used to emphasize a procedure or certain information.

## Glossary

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<b>ABS</b>	Acrylonitrile butadiene styrene.
<b>Aerobiocollector or Air sampler</b>	Instrument used to collect and count viable bacterial and fungal particles in a known and precise volume of air.
<b>CFU</b>	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.
<b>Delayed start-up</b>	Time between pressing the START button and the motor starting up.
<b>MPN</b>	Most Probable Number of microorganisms collected. Statistical correction of the CFU value (FELLER's law).
<b>NiMH</b>	Nickel Metal Hydride.
<b>PVDF</b>	Polyvinylidene fluoride.
<b>Ra coefficient</b>	Roughness factor of a surface. It is the arithmetic mean of all profile deviations, positive or negative, compared to the mean line.
<b>Sampling grid</b>	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.
<b>Time-delay</b>	2 seconds required by the software to record a parameter.

## Typographic conventions

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

- Press

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

ABC 123

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

## The Air IDEAL 3P keypad

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There are 5 keys on the **Air IDEAL 3P** 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 cGMP for the 21<sup>st</sup> 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** aerobiocollector in order to best respond to these new needs.

**Air IDEAL 3P** 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.

**Air IDEAL 3P** evidently remains perfectly suited to the enumeration of airborne microorganisms in less demanding work environments such as agribusiness.

In addition and in order to continue its universal application, **Air IDEAL 3P** 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** is calibrated at 100 L/min with an impact velocity of less than 20 m/s. According to good sterilization practices, the sampling grids can be sterilized in an autoclave, see section "Sterilization of grids" on page 5-1.

### Operating principle

**Air IDEAL 3P** is an impaction aerobiocollector, used to detect the presence of viable microorganisms 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 microorganisms 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 microorganisms collected per m<sup>3</sup> of air.

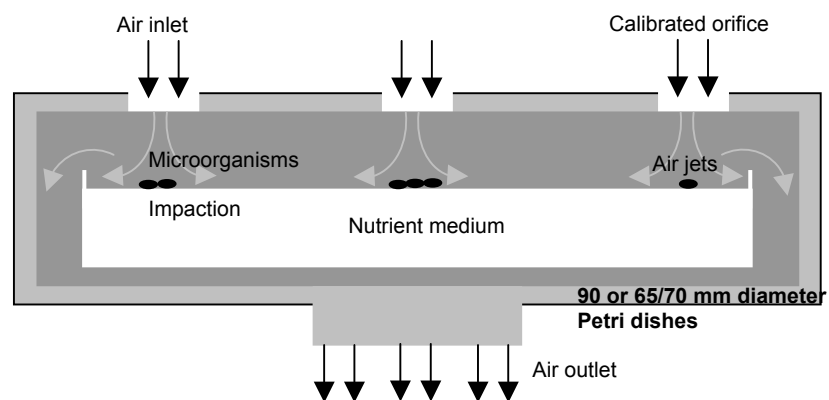


Figure 2-1: Principle of the impaction biocollector

## Performance

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The performance characteristics of an aerobiocollector depend on its capacity to collect microorganisms 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 microorganisms.

**Air IDEAL 3P** 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 **Air IDEAL 3P**.

### Collection efficiency validated according to the ISO 14698 standard

**Air IDEAL 3P** 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 **Air IDEAL 3P** 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** 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** had to be entirely reviewed in order to optimize system air tightness.

In addition and in order to guarantee the optimal operation of **Air IDEAL 3P** in this application, the system underwent a complete validation in a glove box (SKAN AG, model ARIS glove box).

## Applications

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**Air IDEAL 3P** enables the precise and reproducible sampling of air. The volumes taken can be set in 10 L steps up to a maximum volume of 2000 L.

This sampling range enables **Air IDEAL 3P** 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.

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\* 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



## 3 Using Air IDEAL 3P

### Description

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**Air IDEAL 3P** is supplied in a carrying case. Inside the case there 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.)].

**Air IDEAL 3P** is available in two versions:

- for 90 mm agar plates (product No. 96302)
- for 65/70 mm agar plates (product No. 96304)

★ Each reference includes:

- an **Air IDEAL 3P** aerobiocollector fitted with a protective cover.
- 5 sampling grids
- an AC/DC charger-adaptor (see page 3-9) for the internal battery.
- 4 jack protection caps.
- a hook for suspending the instrument.
- Documentation:
  - User's manual
  - Product certificate
  - Adjustment certificate
  - Control certificate

*Note:* For product No. 96303 only, a stainless steel blade is supplied for use with 70 mm diameter Petri dishes.

★ Accessories:

- 65/70 mm 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 mm plates – Kit of 10 (product No. 96301)
- Sterile box for transport and incubation of 90 mm plates – Kit of 10 (product No. 96311\*)

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\* Availability: consult bioMérieux

## Consumables

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**Air IDEAL 3P** 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 **Air IDEAL 3P**.

The media comply with specific industrial and hospital environmental controls.

### Culture media for general use

- 20 TSA 90 mm plates (product No. 43011)/100 TSA 90 mm (ref. 43019)
- 20 PCA agar 90 mm plates (product No. 43558)
- 20 Sabouraud dextrose agar 90 mm plates (product No. 43555)
- 20 Sabouraud dextrose chloramphenicol agar 90 mm plates (product No. 43596)
  
- 20 count-Tact agar 65 mm plates (product No. 43501)
- 20 count-Tact TSA agar 65 mm plates (product No. 43582)
- 20 count-Tact Sabouraud dextrose chloramphenicol agar 65 mm plates (product No. 43580)

### Irradiated media

- 100 TSA irradiated 90 mm plates (product No. 43557)
- 20 TSA irradiated 90 mm plates (product No. 43131)
- 100 TSA with neutralizing agents 90 mm plates (product No. 43562)
- 20 Sabouraud dextrose irradiated agar 90 mm plates (product No. 43554)
- 20 Sabouraud dextrose chloramphenicol irradiated agar 90 mm plates (product No. 43595)
- 20 count-Tact irradiated agar 65 mm plates (product No. 43491)
- 100 count-Tact irradiated agar 65 mm plates (product No. 43492)
- 20 count-Tact Sabouraud dextrose chloramphenicol agar 65 mm plates (product No. 43581)
- 20 count-Tact 3P irradiated agar 65 mm plates (product No. 43691)
- 100 count-Tact 3P irradiated agar 65 mm plates (product No. 43699)

Identification of the instrument

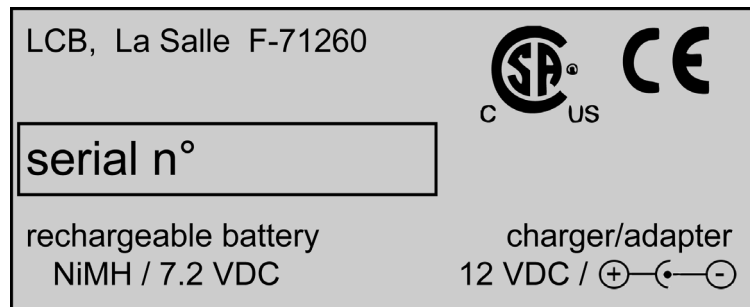


Figure 3-1: Identification of the instrument

Front face of Air IDEAL 3P



Figure 3-2: Front face

Rear face of Air IDEAL 3P

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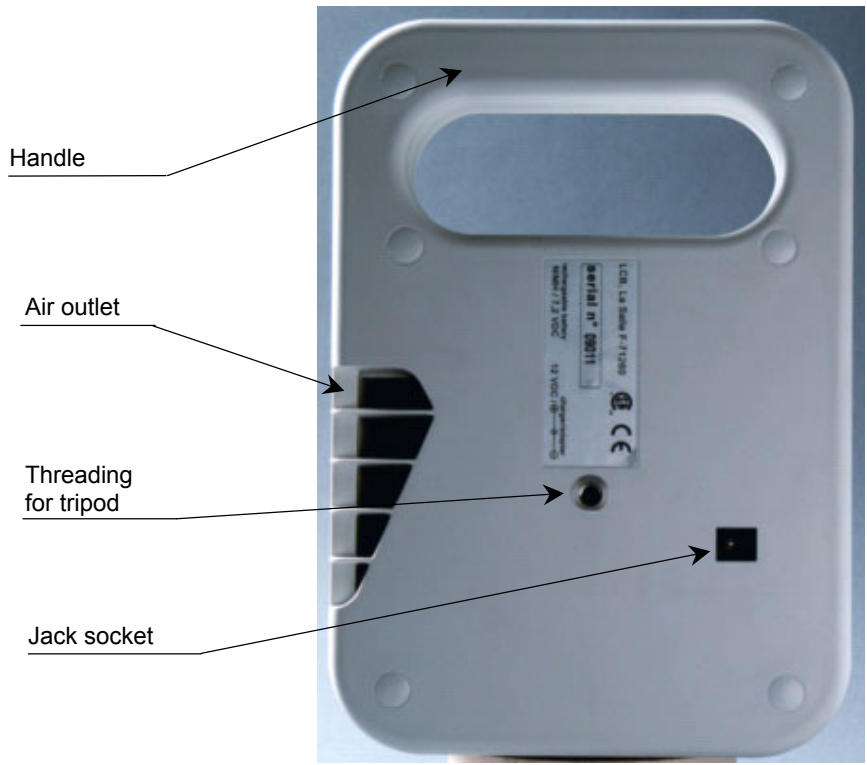


Figure 3-3: Rear face

Keypad

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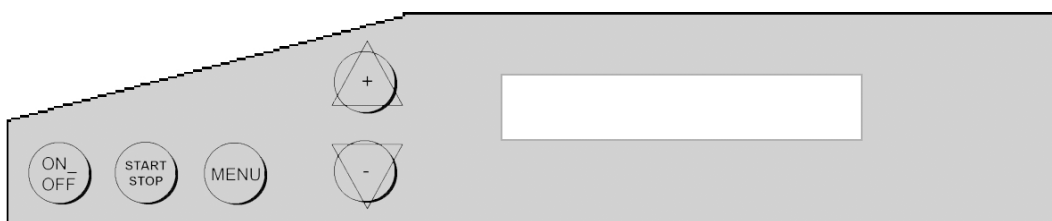
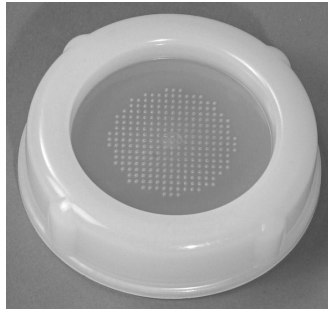
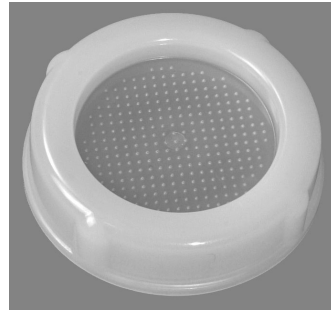


Figure 3-4: Keypad

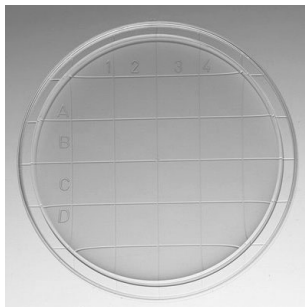
**Configuration for 65, 70 or 90 mm Petri dishes**



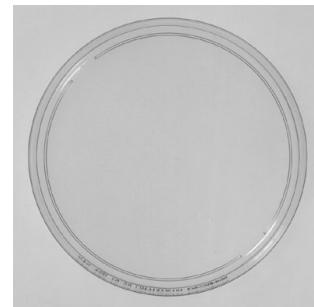
Sampling grid for 65, 70 mm Petri dishes



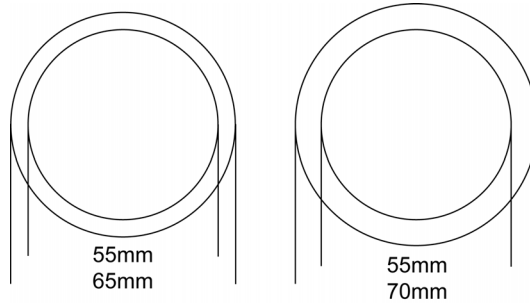
Sampling grid for 90 mm Petri dishes



Count-Tact® agar plate



90 mm Petri dish



**Figure 3-5 : Diameter of Petri dishes**

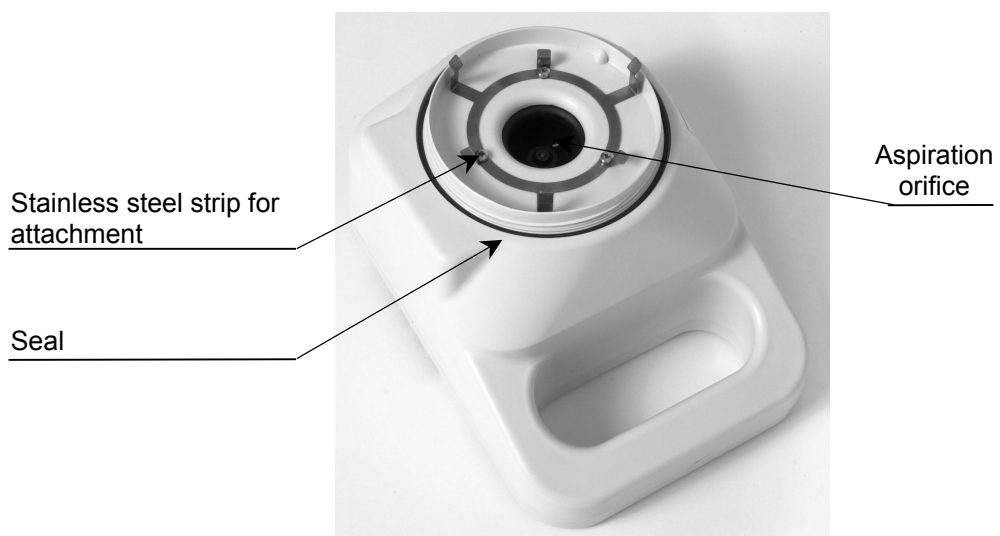


Figure 3-6: Sampling head and grid – 90 mm Petri dishes

### Tripod assembly

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Figure 3-7: 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>
≈ 1,3 kg	≈ 5,6 kg	≈ 7.1 kg

#### Materials

- \* ABS 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 (18 minutes at 134°C in water saturated vapor).

*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 V0 shell (highest grade of fire resistance).

## Technical characteristics

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### Keypad

- Key control.

### Display

- Liquid crystal display (2 x 16 characters).

### Sampling grid

- 1/8<sup>th</sup> of aturn screw-on sampling grid.
- Possibility of sampling on 90 mm 65/70 mm diameter Petri dishes (specific sampling grids and fixing strips).

### User interface

- 5 buttons for access to all **Air IDEAL 3P** functions.
- An LCD screen is used to program the instrument and follow its operation. Messages are in English.
- Additional information on instrument operation is given as audible signals.

### Ergonomics

- Ergonomic handle (right hand/left hand).
- Possibility of stable sampling with the unit in four positions (see page 3-12).
- Possibility of suspending **Air IDEAL 3P** with a hook, especially in a glove box.
- Optionally, **Air IDEAL 3P** 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).



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## Electrical characteristics

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Voltage ..... 7.2 VDC nominal

Power supply ..... 1 A max.

**Air IDEAL 3P** is designed to run on a battery (6 NiMH batteries connected in series, each with a nominal voltage of 1.2 V).

**Air IDEAL 3P** 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: 1.5 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 Air IDEAL 3P. You will find the details of its characteristics below.*

### POWER SUPPLY UL/CSA

INPUT ..... 120 VAC/60Hz 0.8 A max. USA STD plug

OUTPUT ..... 12 VDC 1.5 A max. JACK plug.

### POWER SUPPLY complying with standards

INPUT ..... 230 VAC/50Hz 0.8 A max. European STD plug

OUTPUT ..... 12 VDC 1.5 A max. JACK plug.

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## Functional specifications

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### Flow-rate

- 100 ± 6.5 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 l samples to be taken.
- Specification valid for a new battery not having undergone a thermal shock or a prolonged period of inactivity.

### Charge time

It takes 14 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

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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.*

### Packing list

---

- an **Air IDEAL 3P** aerobiocollector fitted with a protective cover.
- 5 sampling grids
- a hook for suspending the instrument
- 4 jack protection caps
- an AC/DC charger-adaptor (see page 3-9) for the internal battery.
- Documentation:
  - User's manual
  - Product certificate
  - Adjustment certificate
  - Control certificate



Figure 3-8: Air IDEAL 3P in its carrying case

## Recommendations for installation and use

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- 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 14 hours.*
- *Discharge the battery by performing successive sampling (see page 3-25 "Battery autonomy test (Menu 6)").*
- *Recharge for 14 hours.*
- *Make sure the grid holes are not blocked.*

## Sampling positions

---



①



②



③



④

Figure 3-9: Sampling positions

**IMPORTANT!** *Air IDEAL 3P 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 Air IDEAL 3P 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

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**CAUTION!** Do not insert any foreign objects into the aspiration orifice located under the grid (see pages 3-6).

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

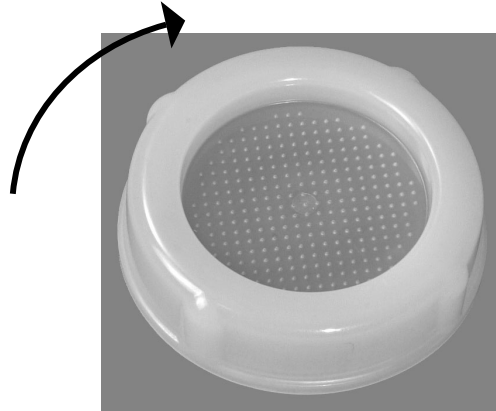


Figure 3-10: Screwing on the sampling grid


## Electrical power supply

---

**Air IDEAL 3P** operates self-sufficiently through an internal nickel metal hybrid battery pack.  
**Air IDEAL 3P** can also run connected to a charger/adapter.

### Operation on internal battery

---

The microprocessor manages and displays the available autonomy at all times, on the basis of a theoretical autonomy of 4 hours for sampling cycles of 1000 liters. In the case of sampling cycles of less than 1000 liters, it is advisable to put the battery on charge as soon as the flashing symbol appears: .

### Low battery signals


- ★ When the autonomy 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

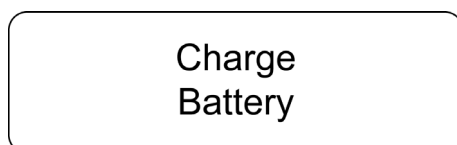
*Audible signal each time the instrument is turned on: 2 long beeps*

**CAUTION!** *During this battery low phase, Air IDEAL 3P remains in its normal operating condition until the sampling cycle in progress is finished. Before performing a new sampling cycle, recharge the battery.*

## Charging

- ★ To charge the battery,
  - Use the charger supplied or one with the same specifications.
  - During the charging phase, **Air IDEAL 3P** can be either switched on or switched off.
  - Connect the charger to the **Air IDEAL 3P** jack connector after removing the protection cap.
  - Connect the charger to the power outlet.

The display indicates:



The normal time required to completely recharge a discharged battery pack is 14 hours.

It is possible to perform sampling when the battery is being charged on the main power supply.

- ★ At the end of the operation,
  - Disconnect the charger from the power outlet.
  - Disconnect the charger from the **Air IDEAL 3P** jack connector.
  - Install the protection cap.
  - Check that the available autonomy displayed is again 4 hours.

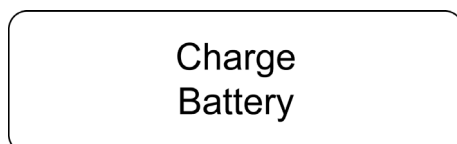
**IMPORTANT!** *If Air IDEAL 3P is not used for more than 10 days, the battery must be totally recharged (14 hours).*

---

## Operation using the power line

Connection to the power line is carried out in the same way as for charging the internal 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 of **Air IDEAL 3P**.

During operation on the power line, the internal battery is on charge.

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

---

## Automatic switch off

In order to save the available charge on the internal battery, the unit switches off automatically after **5 minutes** of inactivity.

## Programming

---

**Air IDEAL 3P** enables samplings 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.
- Possibility of interrupting and resuming a sample in progress.
- End of sample buzzer (6 short beeps).
- Count-down of time.

### Additional information

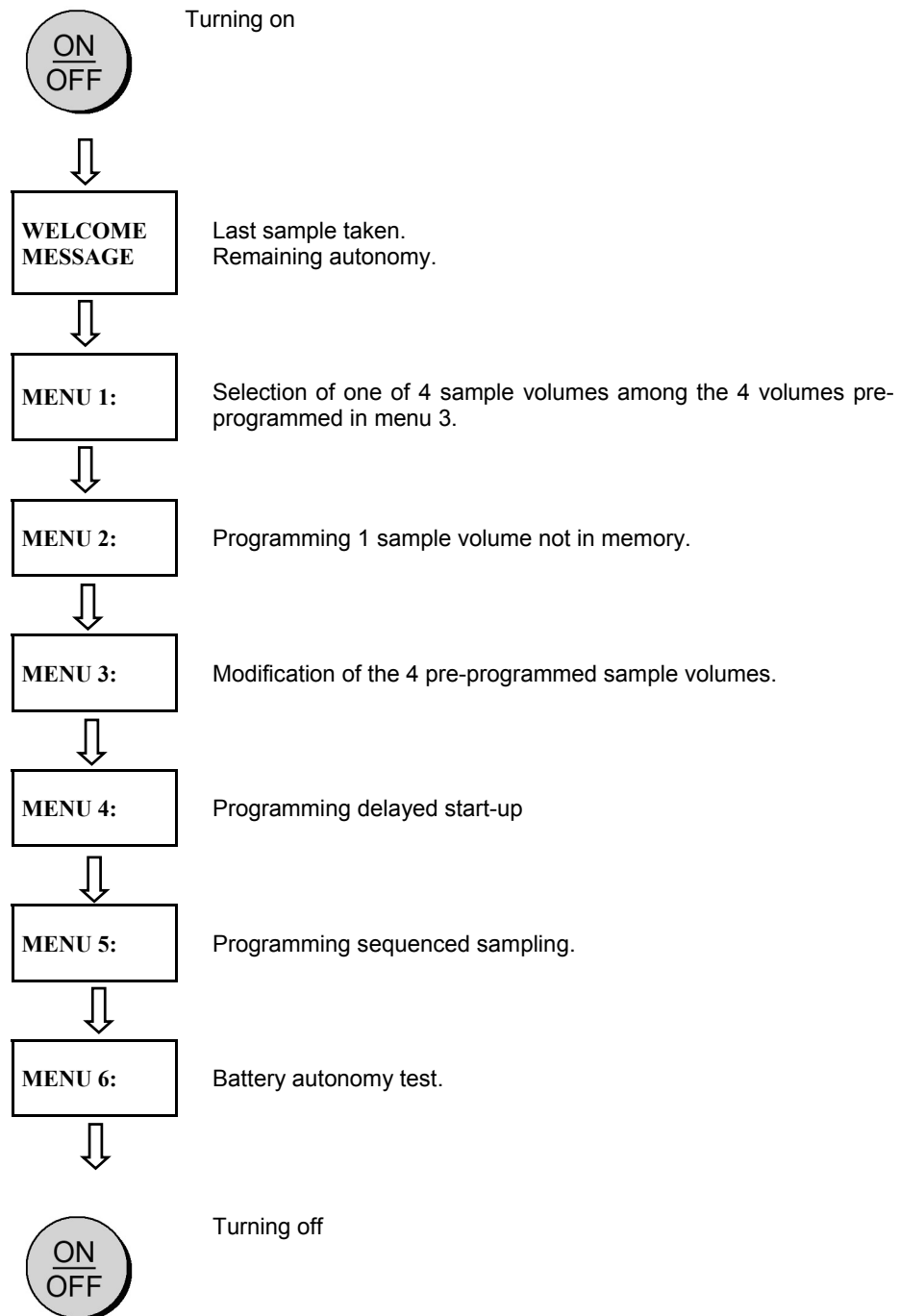
---

- Symbol displayed and audible alarm (2 long beeps) at the end of battery autonomy.
- Automatic stop and message displayed if the protective cover was not removed.
- Display of remaining battery life (indicative value).
- Automatic switch-off of display after 5 minutes of inactivity.
- Language: English.



**Air IDEAL 3P menus**

---



## Turning on Air IDEAL 3P


---



- \* To turn on **Air IDEAL 3P**,
  - 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 autonomy.

- \* If the symbol  appears:
  - Recharge **Air IDEAL 3P**.

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

LAST SAMPLING  
NOT COMPLETED

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



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

## Turning off Air IDEAL 3P

---



- \* To turn off **Air IDEAL 3P**,
  - Press <ON/OFF>.
- or
- Wait 5 minutes.

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

- \* Factory programming memorizes the following 4 volumes in **Air IDEAL 3P**: 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:

RECORDED

- \* 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:

MENU 3:  
STORE IN MEMORY

- Wait 2 seconds.

The display indicates:

PROGRAM 1  
Volume : XL

- \* 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 of 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:

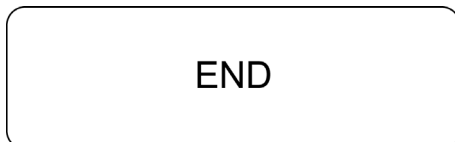
PROGRAM 4  
Volume : XL

- ★ 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.*

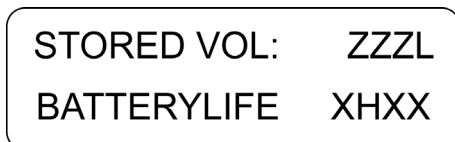
After a 2-second delay, the volume displayed is recorded.

The display indicates:



END

The screen then returns to the welcome message.



STORED VOL: ZZZL  
BATTERY LIFE XHXX

*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:

MENU 4: TIMED  
Ømin Øsec

- \* 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:

RECORDED

The screen returns to the welcome message.

STORED VOL ⌚ ZZZL  
BATTERYLIFE XHXX

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 and 2 (see pages 3-19 and 3-20).
  - 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 or else an error message appears.



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

The following message appears and the 1<sup>st</sup> line flashes:

MENU 5: SEQ NB X  
VOL ZZL 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 autonomy 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 or else an error message appears:

ERROR  
TIME > 5H

Then, the screen automatically returns to Menu 5.

At this time, parameters (number of sequences/duration of the interval) must be corrected in order to enable sampling.

**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 Air IDEAL 3P 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 (autonomy  $\geq$  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 autonomy:
  - Note the autonomy displayed when the instrument is turned on.
  - Using Menu 1, select a 1000 liter sample volume.
  - Go to Menu 6.
- Press the <START> button to run the battery discharge cycle.
- \* To select menu 6,
  - Press <MENU> 6 times.



The display indicates:

MENU 6: AUT. TEST  
BATTERY LIFE: XHXX

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

**CAUTION!** *If you wait more than 5 minutes, Air IDEAL 3P will turn off.*

## Starting sampling

---

**CAUTION!** Before starting, check that Air IDEAL 3P 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 **Air IDEAL 3P**, the following alarm message is displayed after several seconds and sampling stops automatically:

REMOVE  
PROTECTION COVER

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

- \* To start sampling,



- \* Turn on **Air IDEAL 3P**,
  - Press <ON/OFF>.

The display indicates:

STORED VOL: ZZL  
BATTERY LIFE: XHXX

- Press <START/STOP>.



- \* During sampling, the display indicates:

STORED VOL: ZZL  
SAMPLE VOL: XL

- 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

- \* 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 **Air IDEAL 3P** was turned off during sampling, the following message appears the next time the instrument is turned on:

LAST SAMPLING  
NOT COMPLETED

**CAUTION!** *In this case, the user will 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 under way 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.

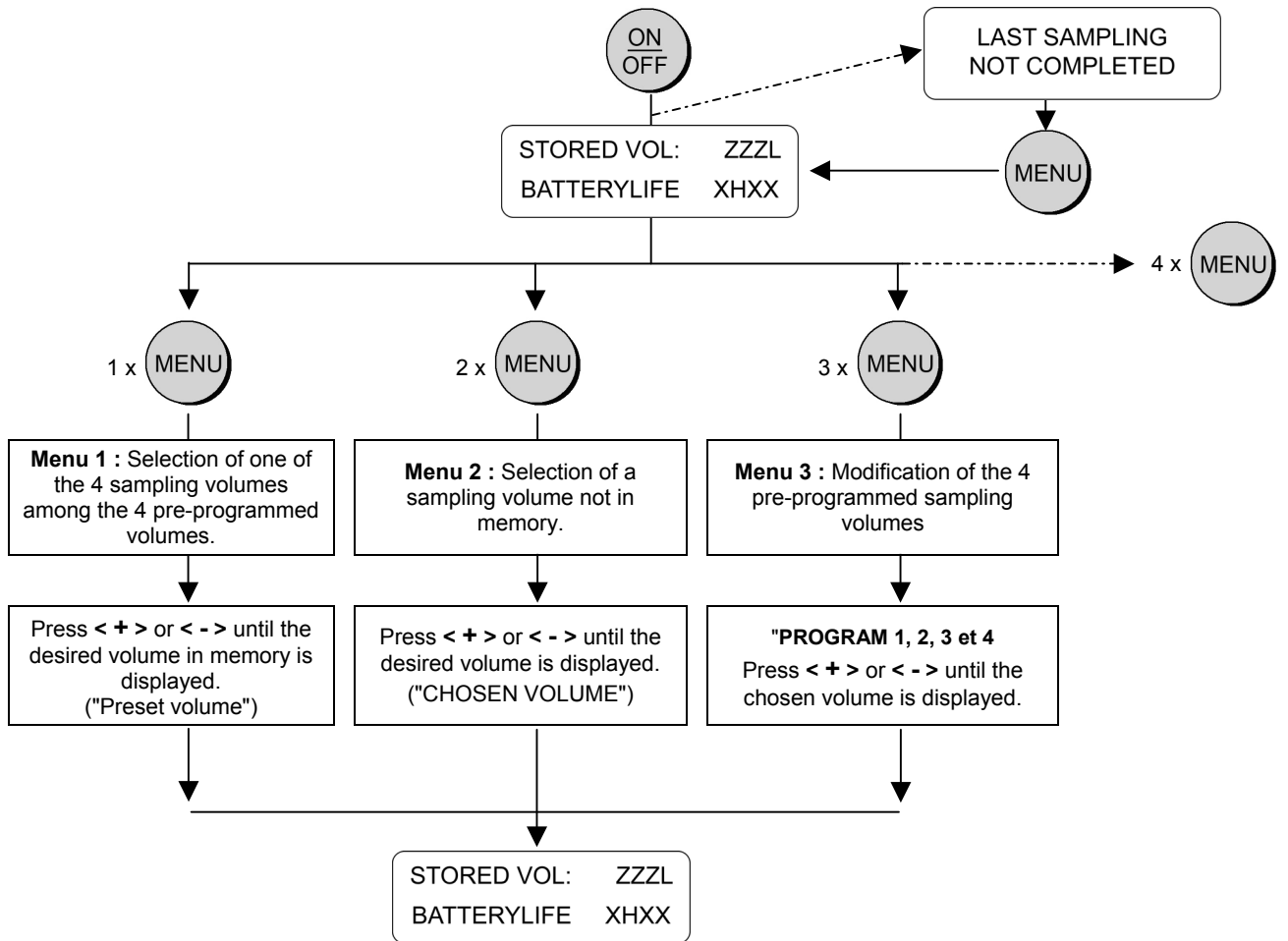
STORED VOL:	ZZZL
SAMPLE VOL:	XL

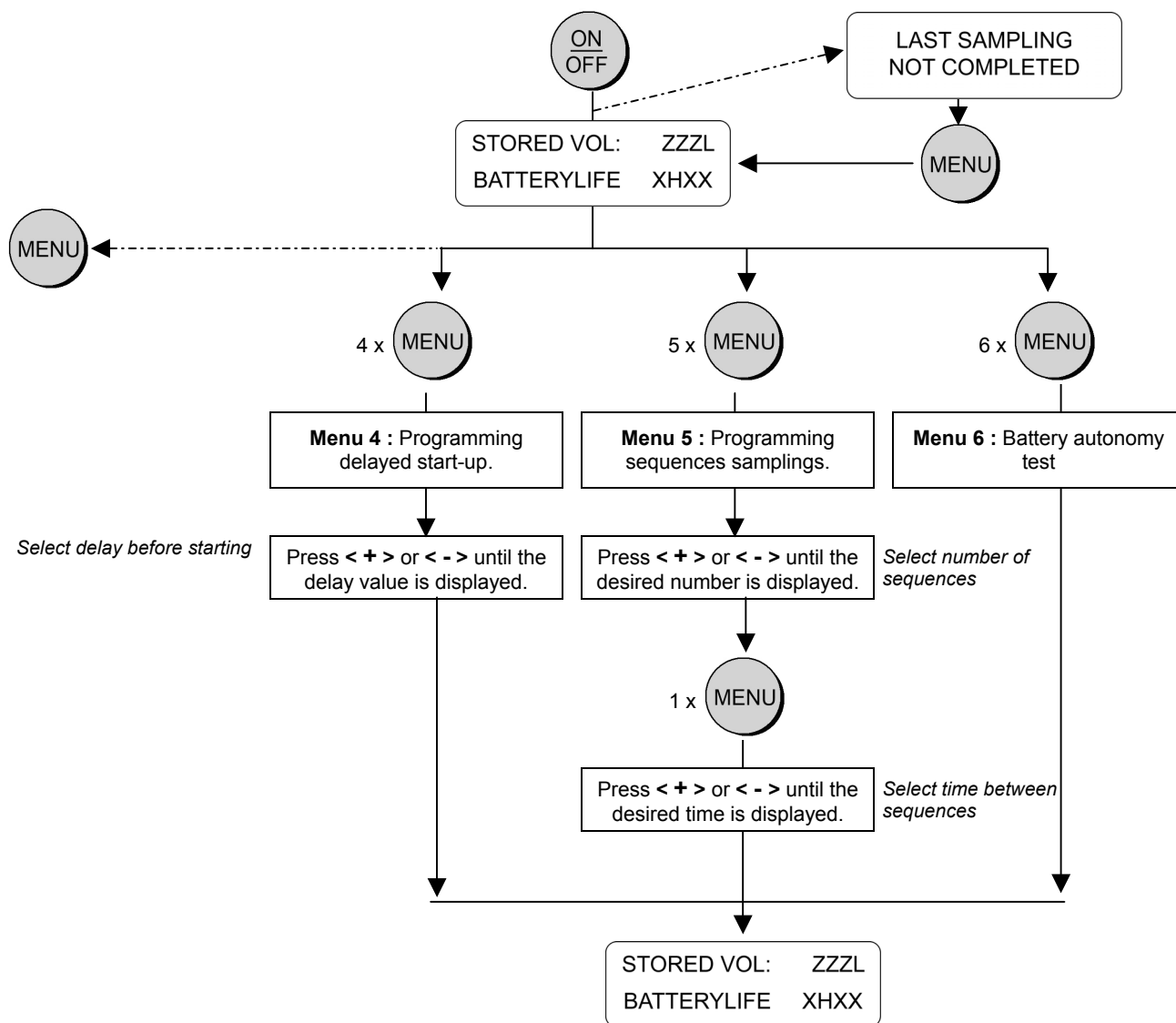
- ★ To resume sampling,
  - Press <START/STOP>.

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, **Air IDEAL 3P** will turn off.

**Setting Air IDEAL 3P parameters (summary diagram)**





## 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.
- Preparing a document for recording air sampling results.
- 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...).
- Protocol for disinfection of the air sampler.
- 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 microorganism 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

---

- Turn on the instrument.
- Check the remaining battery life.
- Place the instrument on a flat surface (work bench, table...) 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.
- 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 rapidly.
- The instrument indicates the end of sampling ( 6 buzzes).
- 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.
- Mark the date, time and sample location on the Petri dish.

### 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 C.F.U (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 microorganism(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...).

## 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),
- microorganism 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.**

**Dispose of the battery in a suitable container.**

### Routine servicing

---

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

- Battery recharging.
- Cleaning and disinfection.
- Sterilization of the sampling grid.

#### Cleaning and decontamination

---

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** 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 the external part

---

All the external parts of **Air IDEAL 3P** can be decontaminated with most usual disinfectants (70% isopropanol, hydrogen peroxide, 70% ethanol, quaternary ammonium).

#### Decontamination of the air circuit

---

bioMérieux has validated the bacteriological efficacy of air circuit decontamination with ClearKlens IPA® (Johnson Diversey).

#### Decontamination of the air circuit

---

Decontamination of the instrument according to this protocol with ClearKlens IPA (Johnson Diversey) has been validated. 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** was specially developed for use in production or control glove boxes. The suitability of **Air IDEAL 3P** for use in glove boxes was evaluated by the SKAN ag "Center of Competence for Isolator Technology".

- \* Two parameters were tested:
  - The capacity of **Air IDEAL 3P** 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 **Air IDEAL 3P**.

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 done by a qualified person who has all the necessary equipment to perform this task and to enter the data into the Air IDEAL 3P.*

## 6 Troubleshooting

Error message/signal	Possible cause	Recovery procedure
REMOVE PROTECTION COVER	The protection cover was not removed.	Install a grid.
ERROR TIME > 5 H	The total duration of sequences and intervals is too long.	Repeat programming.
MOTOR JAMMED	Mechanical incident that blocks the motor.	Inspect the black screen under the Petri dish attachment strip. Press <b>&lt;MENU&gt;</b> to return to the welcome message.



## 7 Appendix

### Using the reading table

---

The following reading tables indicate the most probable number of microorganisms 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 microorganisms collected per cubic meter**, the most probable number of microorganisms 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 =  $159 \times 1000 / 50 = 3188$

### 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		





A series of horizontal dotted lines spanning the width of the page, providing a guide for writing notes.

