TRIO.BAS™

BIOLOGICAL AIR SAMPLER

zeller GmbH
Labworld.at Laborgeräte - Glas - Reagenzien
Mikrobiologie - Hygienekontrolle
Industriestr. 1, 6845 Hohenems, Austria
Tel. +43 (0)5576 76705 Fax +43 (0)5576 76705 7
Email: office@labworld.at

THE MODERN MICROBIAL AIR MO NITORI NG

Biological Air Sampler

Index

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PATENT PENDING USA N° 15/178313

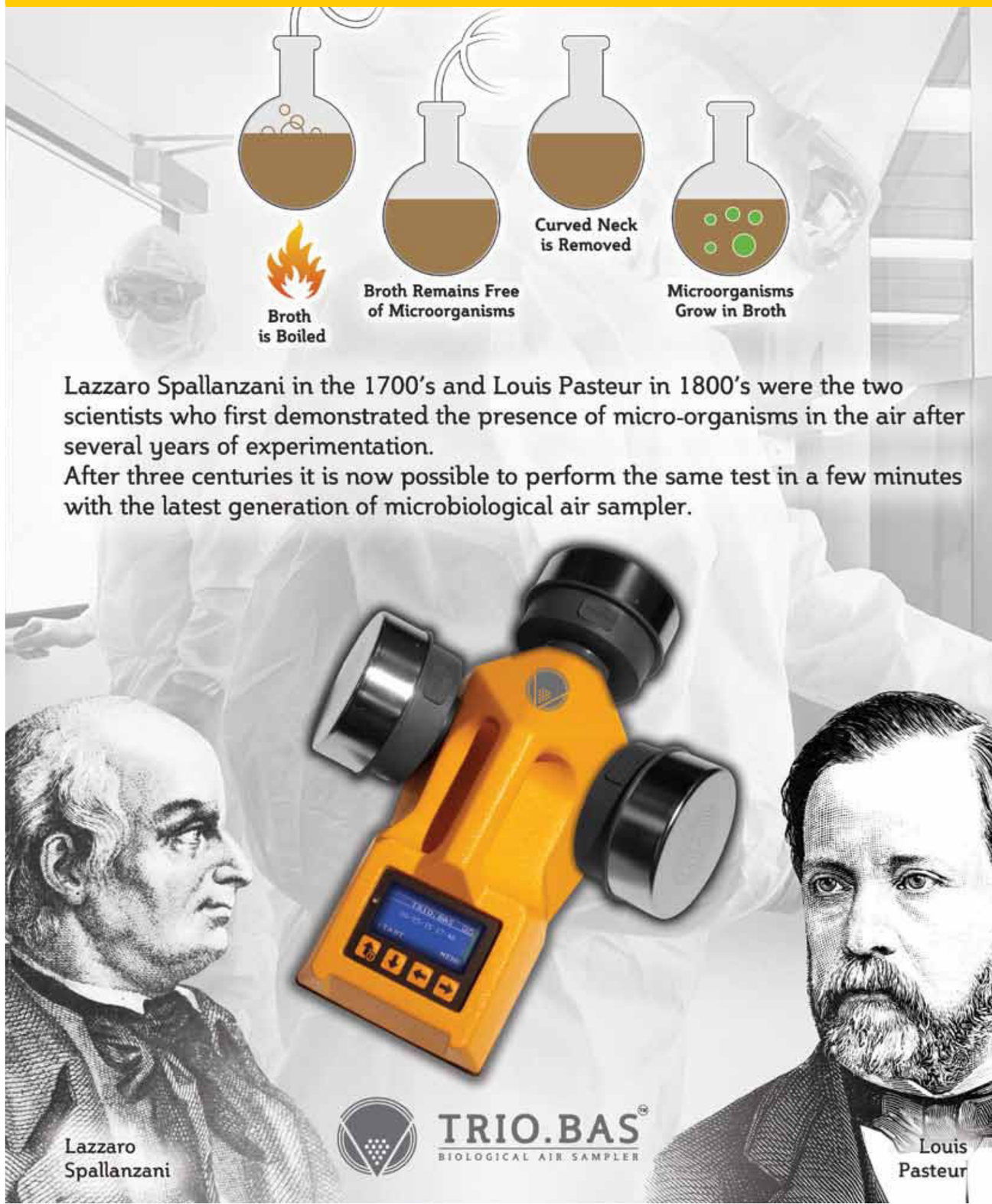
Summary

All instruments are produced in ISO 9001 certified premises

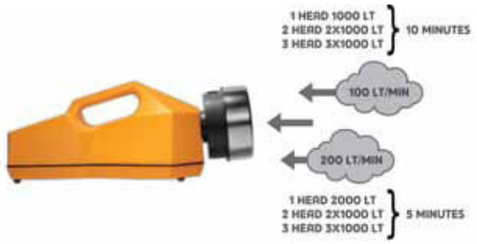
CERTIFICATE OF CONFORMITY

- ISO Standard 14698-1 – 2004 Guidance for Industry on Sterile Drug Products by Aseptic Processing – Current Good Manufacturing Practice
- FDA – 1987 Guideline on Sterile Drug Products by Aseptic Processing
- ACGIH – Guideline for Assessment of Bio-aerosol in the Indoor Environment
- ASTM – Draft Protocol – Committee D22.05.06
- USP Chapter <1116> Microbiological Evaluation of Clean Rooms and Controlled Environments
- EU Guide for GMP – Manufacture of Sterile Medicinal Products Control Medicines and Inspection
- CFR 21 USA Part 11 Compliance

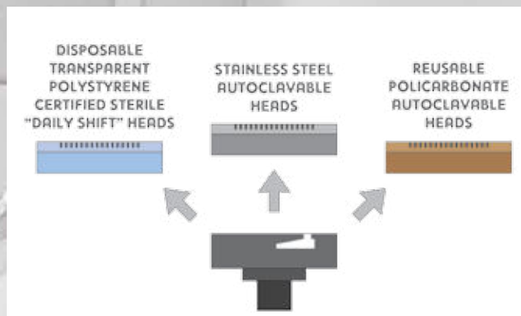
Test of Spontaneous Generation



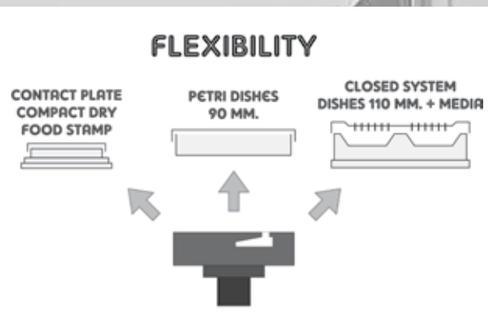
18 GOOD REASONS TO ADOPT A NEW GENERATION OF MICROBIOLOGICAL AIR SAMPLER



REDUCED SAMPLIG TIME: LESS
2 MINUTES FOR 1000 LITRES OF AIR (3 HEADS)



3 DIFFERENT BAYONET
ASPIRATING HEADS
TO FACILITATE COUPLING



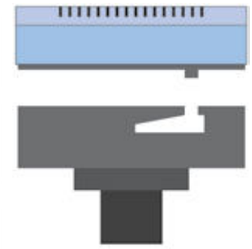
SUITABLE FOR 55 RODAC PLATES
90 PETRI DISHES OR 110 DISHES
STERILE CLOSED SYSTEM

BARCODE IDENTIFICATION 1D-2D OR
RADIO FREQUENCY IDENTIFICATION (RFID)
FOR INSTRUMENT, OPERATOR,
LOCATION, PLATE

EXPLOSION PROOF
STANDARD INSTRUMENT WITH COMPONENTS
AND PRODUCTION PROCESS EQUIVALENT
ATEX CERTIFICATION

PATENT PENDING

USA N° 15/178313



FAST CLOSING
BAYONET

SEQUENTIAL, INTERVAL,
SIMULTANEOUS SAMPLING

TECHNOPLASTIC SHOCKPROOF BODY
WITH ANTIBACTERIAL TREATMENT

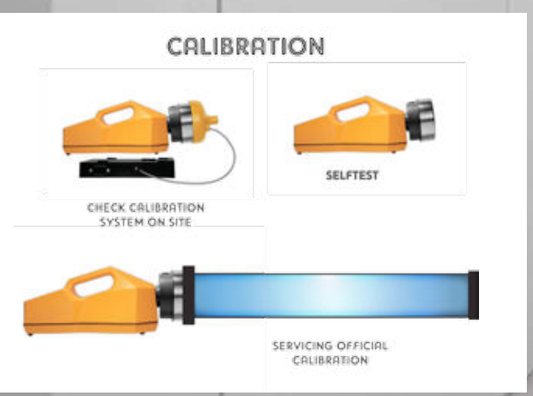
WATER & DUST
PROTECTION IP 65

BATTERY AUTONOMY
UP TO 100.000 LITRES OF AIR

CASCADE PASSWORDS

BASE STATION WITH BATTERY CHARGER
90/260V, AUTOMATIC VOLTAGE SELECTOR,
USB AND CHECK CALIBRATION SYSTEM (OPTIONAL)

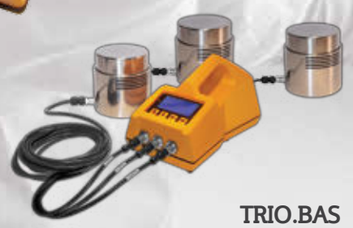
NO PLUG AND EXTERNAL CONNECTIONS



1 HEAD
TRIO.BAS

2 HEADS
TRIO.BAS

3 HEADS
TRIO.BAS



TRIO.BAS
ISOLATOR/MULTISTATION
SYSTEM WITH 3 SEPARATED
ASPIRATING HEADS AND
EXTERNAL COMMAND

TRIO.GAS

MADE IN ITALY

ALL INSTRUMENTS ARE PRODUCED IN ISO 9001 CERTIFIED PREMISES

MONO

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BLUETOOTH

Sterile "Daily Shift" aspirating head

S/S Aspiratin head individually numbered

Suitable for 55 mm contact or 90 mm Petri plates

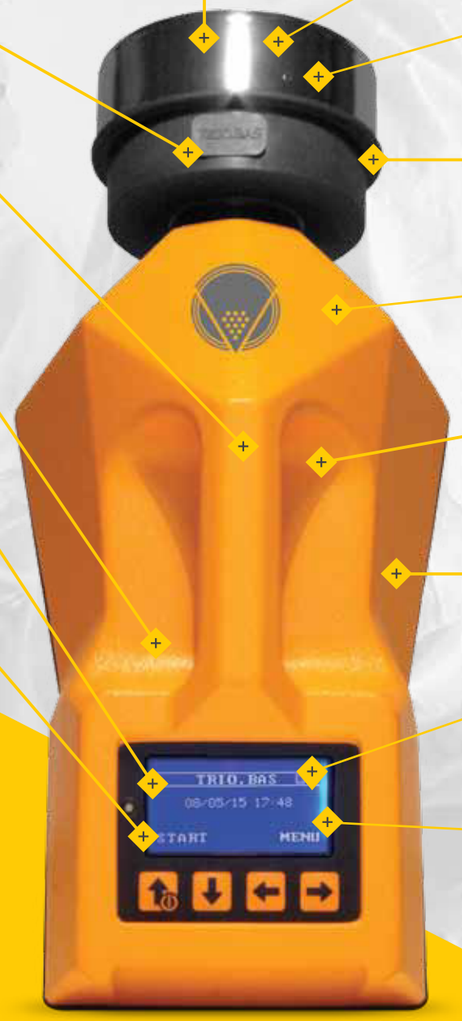
Aspirating head with bayonet closure

Ergonomic and balanced design to facilitate handling with gloved hands

100 or 200 litres per minute air flow rate

Delayed and remote start – simoultaneous or interval sampling

IP 65 protection from dust and water



Light weight

Operator – Administrator – Servicing cascade passwords

Antibacterial technopolymer shockproof body

Manual or automatic operations

Automatic calibration reminder

Bluetooth for data transferring

orum
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INNOVATIVE and ESTABLISHED PERFORMANCES

Induction battery charger (no external connections!)

SOP (Standard Operating Procedure) available from Application Notes

IQ, OQ, PQ documents available

Autocalibration

Registration up 1000 cycles

No plug or external connections

Prefixed sampling 14 volumes

Total traceability of data

Fully compliant according to EN/ISO14698 FDA

Stand up and tripod

Description

- This Air sampler is for customers who make a large number of controls, in different environments, with staff rotation and that comply with the quality standards and QM GLP / GMP.
- The registration of operator, sampling point and plates used for the sampling take place automatically with a Barcode module through the use of a scanner (Barcode Reader) with Bluetooth.
- The data collected by the Barcode Reader are transmitted directly to the instrument. This solution proves to be useful for those who already use culture plates with Barcode or two-dimensional Barcode (QR Quick Response Code).
- The 200 lts/min aspiration reduced operator time
- The subsequent transfer of the data collected is via Bluetooth between the sampler and a PC or Laptop equipped with Bluetooth. PC or Laptop should have a dedicated software (BAS.PC).
- Recharging the battery is done by induction without any cable connection between the instrument and the charger.
- The sampler is free of any external plug and is IP 65 certified.
- The most important customers are the pharmaceutical industries (and all those other industries that need to control microbiological air according to the GPL and GMP rules), cosmetics, medical devices, industries that package sterile products for third parties, hospitals, etc.

Code	**TRIO.BAS MONO** (Base station induction battery charger and aspirating head to be added to the order)
200	TRIO.BAS MONO BLUETOOTH Air sampler (100 lts/min) RODAC plate
201	TRIO.BAS MONO BLUETOOTH Air sampler (100 lts/min) Petri 90 plate
205	TRIO.BAS MONO BLUETOOTH Air sampler (200 lts/min) RODAC plate
206	TRIO.BAS MONO BLUETOOTH Air sampler (200 lts/min) Petri 90 plate

Essential items to add (see page 19-20-21)

DUO

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MADE IN ITALY

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BLUETOOTH

Aspirating head bayonet closure to facilitate coupling

Two Aspirating heads with bayonet closure

Sampling time saving by doubling the aspirated volume of air

Better investment of operator time

Two different culture media at the same time

Better statistical results by doubling sampling tests

Autocalibration

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Bacteria

Moulds

INNOVATIVE and ESTABLISHED PERFORMANCES

- Ergonomic and balanced design to facilitate handling with gloved hands
- Suitable for 55 mm contact or 90 mm Petri plates
- 100 or 200 litres per minute air flow rate
- Manual or automatic operations
- Antibacterial technopolymer shockproof body
- Induction battery charger (no external connections!)
- IP65 protection from dust and water
- Bluetooth for data transferring
- Light weight
- No plug or external connections
- Autocalibration
- Automatic calibration reminder
- Operator – Administrator – Servicing cascade passwords
- Vertical holder for cart on wheel transfer
- Delayed and remote start – Simoultaneous or interval sampling
- Prefixed sampling 14 volumes
- Total traceability of data Fully compliant according to EN/ISO14698 FDA
- IQ, OQ, PQ documents available
- SOP (Standard Operating Procedure) available from Application Notes
- Registration up 1000 cycles
- 100 locations registration

Description

- This Air sampler is for customers who make a large number of controls, in different environments, with staff rotation and that comply with the quality standards and QM GLP / GMP.
- The registration of operator, sampling point and plates used for the sampling take place automatically by a Barcode module through the use of a scanner (Barcode Reader) with Bluetooth. The data collected by the Barcode Reader are transmitted directly to the instrument.
- This solution proves to be useful for those who already use culture plates with Barcode or two-dimensional barcode (QR Quick Response Code).
- The subsequent transfer of the data collected is via Bluetooth between the sampler and a PC or Laptop equipped with Bluetooth. PC or Laptop should have a dedicated software (BAS.PC).
- Recharging the battery is done by induction without any cable connection between the instrument and the charger.
- The sampler is free of any external plugs and is IP65 certified.
- The 200 lts/min aspiration reduced operator time.

Code	**TRIO.BAS DUO** (Base station induction battery charger and aspirating head to be added to the order)
220	TRIO.BAS DUO BLUETOOTH Air sampler (100 lts/min) RODAC plate
221	TRIO.BAS DUO BLUETOOTH Air sampler (100 lts/min) Petri 90 plate
225	TRIO.BAS DUO BLUETOOTH Air sampler (200 lts/min) RODAC plate
226	TRIO.BAS DUO BLUETOOTH Air sampler (200 lts/min) Petri 90 plate

Essential items to add (see page 19-20-21)

TRIO

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MADE IN ITALY

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BLUETOOTH

Aspirating head bayonet closure to facilitate coupling

Three Aspirating heads with bayonet closure

Better investment of operator time

Three different culture media at the same time

Prefixed sampling 14 volumes

Sampling time saving by tripling the aspirated volume of air

Better statistical results by tripling sampling tests

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INNOVATIVE and ESTABLISHED PERFORMANCES

- Ergonomic and balanced design to facilitate handling with gloved hands
- Suitable for 55 mm contact or 90 mm Petri plates
- 100 or 200 litres per minute air flow rate
- Manual or automatic operations
- Antibacterial technopolymer shockproof body
- Induction battery charger (no external connections!)
- IP65 protection from dust and water
- Bluetooth for data transferring
- Light weight
- Automatic calibration reminder
- No plug or external connections
- Operator – Administrator – Servicing cascade passwords
- Vertical holder for cart on wheel transfer
- Delayed and remote start – Simoultaneous or interval sampling
- Autocalibration
- Total traceability of data Fully compliant according to EN/ISO14698 FDA
- IQ, OQ, PQ documents available
- SOP (Standard Operating Procedure) available from Application Notes
- Registration up 1000 cycles
- 100 locations registration

Description

- This Air sampler is for customers who make an average and high number of controls and that comply with the quality standards and QM GLP / GMP.
- The use of three heads allows to carry out at the same time 3 samples with different nutrient media.
- The registration of operator, sampling point and plates used for the sampling take place automatically by a Barcode module through the use of a scanner (Barcode Reader) with Bluetooth. The data collected by the Barcode Reader are transmitted directly to the instrument.
- This solution proves to be useful for those who already use culture plates with Barcode or two-dimensional barcode (QR Quick Response Code).
- The transfer data takes place via Bluetooth between the sampler and a PC or Laptop equipped with Bluetooth. PC or Laptop should you have a dedicated software (BAS.PC).
- Recharging the battery is done by induction without any cable connection between the instrument and the charger .
- The sampler is free of any external plug and is IP65 certified.
- The most important customers are the pharmaceutical industries (and all those other industries that need to control microbiological air according to the rules GPL and GMP), cosmetics, medical devices, industries that package sterile products for third parties, hospitals, etc.
- The 200 lts/min aspiration reduced operator time.

Code	**TRIO.BAS TRIO** (Base station induction battery charger and aspirating head to be added to the order)
240	TRIO.BAS TRIO BLUETOOTH Air sampler (100 lts/min) RODAC plate
241	TRIO.BAS TRIO BLUETOOTH Air sampler (100 lts/min) Petri 90 plate
242	TRIO.BAS TRIO BLUETOOTH Air sampler (200 lts/min) RODAC plate
243	TRIO.BAS TRIO BLUETOOTH Air sampler (200 lts/min) Petri 90 plate

Essential items to add (see page 19-20-21)

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MINI
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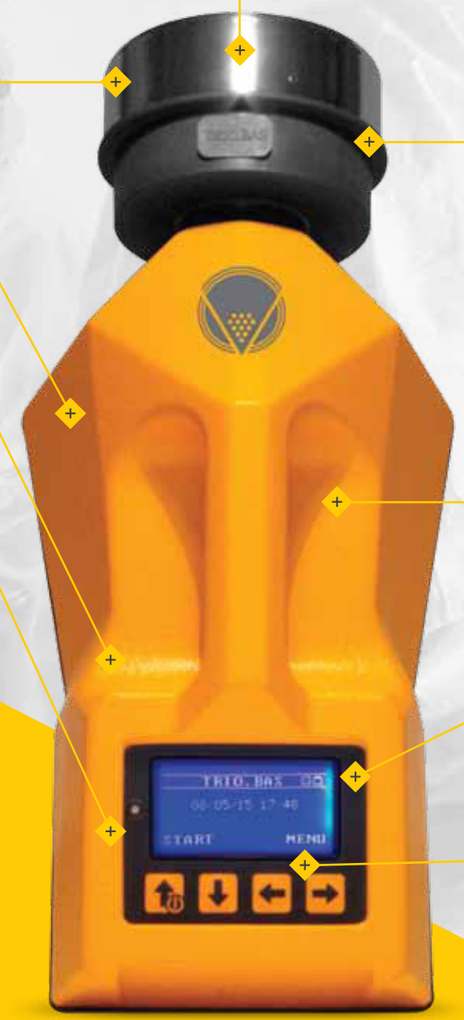
BLUETOOTH



Aspirating head bayonet closure to facilitate coupling

Suitable for 55 mm contact or 90 mm Petri plates

100 or 200 litres per minute air flow rate

Ergonomic and balanced design to facilitate handling with gloved hands

IP 65 protection from dust and water

Autocalibration

Antibacterial technopolymer shockproof body

Bluetooth for data transferring

Automatic calibration reminder

Traditional battery charger with cable

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Vertical holder to fix the sampler in vertical position to a carton weels

INNOVATIVE and ESTABLISHED PERFORMANCES

- Light weight
- Vertical holder
- Prefixed sampling 14 volumes
- IQ, OQ, PQ documents available
- SOP (Standard Operating Procedure available from Application Notes

Description

- This Air sampler is for customers who make few number of tests.
- The data transfer takes place via Bluetooth between the sampler and a smartphone or tablet (Android version) and transferred by them to a PC or Laptop.
- Recharging the battery is done via the power cable connected to the instrument.
- Customers are the food industry, cosmetics, medical devices, industries that package sterile products for third parties environmental laboratories, hospitals, etc...
- The 200 lts/min aspiration reduced operator time.

Code	**TRIO.BAS MINI** (Aspirating head to be addedto the order)
152	TRIO.BAS MINI BLUETOOTH Air sampler (100 lts/min) RODAC plate with Battery charger 100/240VCA 18VDC 859 mA - complete of cable with adapter for plug Eu/UK/USA
153	TRIO.BAS MINI BLUETOOTH Air sampler (100 lts/min) Petri 90 plate with Battery charger 100/240VCA 18VDC 859 mA - complete of cable with adapter for plug Eu/UK/USA
162	TRIO.BAS MINI BLUETOOTH Air sampler (200 lts/min) RODAC plate with Battery charger 100/240VCA 18VDC 859 mA - complete of cable with adapter for plug Eu/UK/USA
163	TRIO.BAS MINI BLUETOOTH Air sampler (200 lts/min) Petri 90 plate with Battery charger 100/240VCA 18VDC 859 mA - complete of cable with adapter for plug Eu/UK/USA

Essential items to add (see page 19-20-21)

ISOLATOR

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BLUETOOTH

MADE IN ITALY

Three Aspirating heads with bayonet closure

It is possible a sampling before, during, after activity

Three different culture media at the same time

Suitable for 55 mm contact or 90 mm Petri plates

100 or 200 litres per minute air flow rate

The use of "Daily Shift" sterile head reduces contamination risk

The connection comand unit-satellites by simple cables

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INNOVATIVE and ESTABLISHED PERFORMANCES

- Sampling time saving by tripling the aspirated volume of air
- Better investment of operator time
- Better statistical results by tripling sampling tests
- Ergonomic and balanced design to facilitate handling with gloved hands
- Manual or automatic operations
- Antibacterial technopolymer shockproof body
- Induction battery charger (no external connections!)
- IP 65 protection from dust and water
- Bluetooth for data trasferring
- Automatic calibration reminder
- No plug or external connections
- Operator – Administrator – Servicing cascade passwords
- Delayed and remote start – Simoultaneous or interval sampling
- Autocalibration
- Prefixed sampling 14 volumes
- Total traceability of data Fully compliant according to EN/ISO14698 FDA
- IQ, OQ, PQ documents available
- SOP (Standard Operating Procedure) available from
- Registration up 1000 cycles Application Notes

Description

- This Air sampler is for customers who make an average and high number of controls and that comply with the quality standards and QM GLP / GMP.
- The use of three heads allows to carry out at the same time 3 samples with different nutrient media.
- Recharging the battery is done by induction without any cable connection between the instrument and the charger.
- The registration of operator, sampling point and plates used for the sampling take place automatically with a Barcode module through the use of a scanner (Barcode Reader) with Bluetooth.
- The data collected by the Barcode Reader are transmitted directly to the instrument.
- This solution proves to be useful for those who already use culture plates with Barcode or two-dimensional barcode (QR Quick Response Code).
- The transfer takes place via Bluetooth between the sampler and a PC or Laptop equipped with Bluetooth. PC or Laptop should you have a dedicated software (BAS.PC).
- The sampler is free of any external plug and is IP65 certified.
- The most important customers are the pharmaceutical industries (and all those other industries that need to control microbiological air according to the rules GPL and GMP), cosmetics, medical devices, industries that package sterile products for third parties, hospitals, etc.
- The use of simple cables between the central comand unit and the satellites facilitate installation and operation.

Essential items to add (see page 19-20-21)

MULTISTATION

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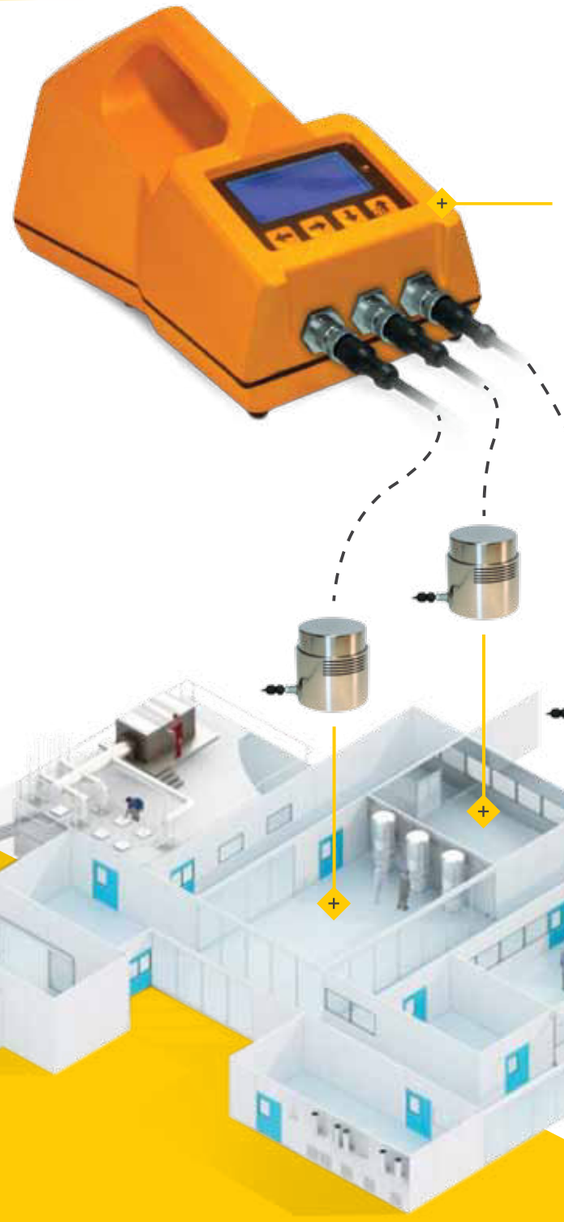
BLUETOOTH

MADE IN ITALY



Separated satellites in cleanroom with a central external comand unit

INNOVATIVE and ESTABLISHED PERFORMANCES

- No transfer of the instrument from an environment to another reduces the contamination risk
- The simple electrical cable facilitates the installation
- Fast sampling cycle because up to 1000 litres of air can be sampled in 5 minutes for each satellite
- The use of Daily Shift sterile aspirating head reduces the risk of contamination
- The sampling cycle can be programmed with continuous, interval, delay sampling
- Sampling data are transferred to printer or PC via Bluetooth
- Flexibility for 90 mm Petri dish or 55 mm Contact Plates
- Absolute flexibility just in case it is necessary to change sampling sites
- I.Q., O.Q., P.Q. documents available
- SOP (Standard Operating Procedure) available from Application Notes
- Autocalibration
- Automatic calibration reminder

Description

- The TRIO.BAS Multistation System microbial Air Sampler has also another useful application: the monitoring of separated Clean room. In fact the TRIO.BAS Multistation System can be used to monitor 3 separated environments with a single external comand unit.
- The risk of human contamination is reduced because the satellite units are permanently inside each Clean room together with the sterile "Daily Shits" Aspirating Heads.

Code	**TRIO.BAS MULTISTATION SYSTEM FOR ISOLATOR AND CLEANROOMS** (Base station induction battery charger, satellite, cable and aspirating head, to be added to the order)
250	TRIO.BAS MULTISTATION BLUETOOTH Air sampler (100 lts/min) RODAC plate
251	TRIO.BAS MULTISTATION BLUETOOTH Air sample (100 lts/min) Petri 90 plate
252	TRIO.BAS MULTISTATION BLUETOOTH Air sampler (200 lts/min) RODAC plate
253	TRIO.BAS MULTISTATION BLUETOOTH Air sample (200 lts/min) Petri 90 plate
Code	**SATELLITE UNIT for TRIO.BAS MULTISTATION** (Aspirating head and cable connection to be added to the order)
260	Satellite Multistation RODAC plate without aspirating head and cable (each)
261	Satellite Multistation Petri 90 plate without aspirating head and cable (each)

Essential items to add (see page 19-20-21)

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TRIO.BAS ATEX

MICROBIAL AIR SAMPLERS FOR POTENTIAL EXPLOSIVE ENVIRONMENTS

BLUETOOTH

MADE IN ITALY

ATEX

Description

- The same performances as TRIO.BAS MONO and DUO.
- TRIO.BAS ATEX microbial air samplers are used in Zone 2 Explosion Hazard areas, they are specifically and individually certified by an independent authority.
- The TRIO.BAS ATEX microbial air samplers (MONO, DUO, models) are built with components and production process equivalent to ATEX (explosion proof) certification.

Code	TRIO.BAS ATEX MONO with BLUETOOTH (BASE STATION INDUCTION BATTERY CHARGER AND ASPIRATING HEAD TO BE ADDED TO THE ORDER)
207	TRIO.BAS MONO BLUETOOTH ATEX (Explosion proof) Air sampler (100 lts/min) RODAC plate
208	TRIO.BAS MONO BLUETOOTH ATEX (Explosion proof) Air sampler (100 lts/min) Petri 90 plate
209	TRIO.BAS MONO BLUETOOTH ATEX (Explosion proof) Air sampler (200 lts/min) RODAC plate
210	TRIO.BAS MONO BLUETOOTH ATEX (Explosion proof) Air sampler (200 lts/min) Petri 90 plate

Code	TRIO.BAS ATEX DUO with BLUETOOTH (BASE STATION INDUCTION BATTERY CHARGER AND ASPIRATING HEAD TO BE ADDED TO THE ORDER)
227	TRIO.BAS DUO BLUETOOTH ATEX (Explosion proof) Air sampler (100 lts/min) RODAC plate
228	TRIO.BAS DUO BLUETOOTH ATEX (Explosion proof) Air sampler (100 lts/min) Petri 90 plate
229	TRIO.BAS DUO BLUETOOTH ATEX (Explosion proof) Air sampler (200 lts/min) RODAC plate
230	TRIO.BAS DUO BLUETOOTH ATEX (Explosion proof) Air sampler (200 lts/min) Petri 90 plate

Essential items to add (see page 19-20-21)

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Essential Items to Add

Battery Charger

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Base station induction battery charger

Description

- The batteries are charged when the sampler is in a rest position
- The main advantage of the induction battery charger is that there are not cable connection and the TRIO.BAS unit is IP65 certified
- Battery charging is done by induction without any cable connection between the instrument and the charger.
- The Air sampler is free of any external plugs.

Code	BASE STATION INDUCTION BATTERY CHARGER for TRIO.BAS MONO, DUO, TRIO and MULTISTATION
310	Base Station Induction battery charger 100/240VCA 50/60Hz 35W - Cable with plug connection Standard Schuko

Base station induction battery charger with user selftest calibration monitoring

Description

- The Base Station Induction Battery Charger with User Selftest is equipped with a system that allows, regardless of auto-calibration already present in the instrument, to be able to check the state of precision of the air flow. This verification is necessary to avoid possible invalidation of the tests between annual controls for official certification.

Code	BASE STATION INDUCTION BATTERY CHARGER with USER SELFTEST CALIBRATION MONITORING(Optional) for TRIO.BAS MONO, DUO , TRIO and MULTISTATION
351	Base Station induction battery charger with user Selftest calibration system. (100 lt/min) Petri 90 or RODAC Plate - Cable with plug connection Standard Schuko - (This Base is used in replacement of the Base Station cat. 310 when Selftest System is applied)
352	Base Station induction battery charger with use Selftest calibration system. (200 lt/min) Petri 90 or RODAC Plate - Cable with plug connection Standard Schuko - This Base is used in replacement of the Base Station cat. 310 when Selftest System is applied)

Accessories (see page 22-23)

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Essential Items to Add

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Aspirating Head

330

331

336

ESTABLISHED PERFORMANCES For Stainless Steel Aspirating Head

- The metal aspirating head are made in polished AISI 316 stainless steel. They are physically and individually tested and have an identification number according GLP and GMP.
- An important Characteristic is the light weight that give to the air sampler a good handling and easy manipulation for the operator.
- The bayonet type closure simplifies the application to the aspirating chamber of the sampler and avoids the production of particulates.
- The head has 221 calibrated holes - 1mm diameter.

Description

- Each microbial air sampling cycle, or group of sampling in the same controlled environment, with an active air sampler, requests the use of a sterile aspiration head.
- Each metal aspiration head should be therefore sterilized by autoclaving with subsequent filing of a sterilization document, as requested by regulatory inspectors.
- This process of sterilization should be avoided adopting the sterile "DAILY SHIFT" antistatic resin plastic head that are double packed and complete of official certificate of sterilization by irradiation.

ASPIRATING HEADS	
Code	**STAILESS STEEL ASPIRATING HEAD**
330	Stainless steel ASPI HEAD RODAC plate (alternative to Petri plate)
331	Stainless steel ASPI HEAD Petri plate (alternative to RODAC plate)
465	COVER HEAD stainless steel to protect ASPI HEAD
334	BLIND HEAD stainless steel to protect the Aspirating Chamber when not in use
Code	**THERMOPOLYMER ASPIRATING HEAD - autoclavable (Optional)**
336	Thermopolymer Aspi Head (AHTP-90) for Petri plate 90 (5xbox)

Accessories (see page 22-23)

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DAILY SHIFT HEAD

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340/341

Sterile aspirating head for TRIO.BAS microbial air samplers

- The Daily Shift Head (DSH) sterile aspirating heads avoid the sterilization of the S/S Aspirating Head of the air sampler.
- It saves time and it certifies the sterilization with an official document. This document is requested by regulatory authorities.
- The double irradiated sterile packaging allows you to have always available aspirating head ready for use.
- Particularly useful in case of autoclave servicing problems or supercharged activity.
- A single head is used during a complete daily working cycle in Clean Room.
- The transparancy of Daily shift head is useful to verify that the culture plate is inserted into the aspirating chamber.
- Reciclable plastic.

Description

- Sterile Single head double packed for use in CleanRoom.
- Head in anti-static material suitable for Clean Room.
- Each box contains the official certification of sterilization by irradiation.
- Suitable for all TRIO.BAS samplers (MINI, MONO, DUO, TRIO, ISOLATOR, GAS).
- Self life 6 years from the date of sterilization.

Code	STERILE ASPIRATING HEAD	Package
340	Daily Shift Sterile Aspirating Head (DSAH-55) RODAC plate Technopolymer	30xbox
341	Daily shift Sterile Aspirating Head (DSAH-90) Petri 90 plate Technopolymer	30xbox

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Accessories (see page 22-23)

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Accessories

MADE IN ITALY

Code: 370

Code: 380

Code: 391

Code: 390

Code: 395

Code: 397

Code: 421

Code: 502

Code: 503

Code: 505

Code: 506

Code: 507

Code: 508

Code: 509

Code: 520

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Accessories

MADE IN ITALY

Code	ACCESSORIES FOR TRIO.BAS
391	VERTICAL HOLDER - stainless steel - for MINI and MONO - 12x9x25h cm
370	STAND UP holder - technopolymer - for MONO, DUO, TRIO 15x11x9h cm.
371	CART WITH WHEELS complete with STAND UP holder size 350x350x70h mm - for MONO, DUO, TRIO
380	FLOOR TRIPOD with adapter (minimum extension 56 cm; max extention 153 cm)
390	Tissue SOFT carrying case - 37x16x22h cm - for MINI, MONO
395	Rigid ROBUSTUS carrying case - 48x38x17h cm. - for MINI, MONO, DUO, TRIO, ISOLATOR
396	Rigid ROBUSTUS SATELLITE carrying case - 48x38x17h cm. - for 3 SATELLITES ISOLATOR
397	Rigid ROBUSTUS MICRO carrying case - for 1 - 2 SATELLITES ISOLATOR
520	TRIO PRINTER BLUETOOTH - 11x8,5x4,5h cm.
421	Roll paper 57 mm (10xbox) for TRIO PRINTER BLUETOOTH
500	IQ , OQ documents for TRIO.BAS MINI
501	IQ , OQ documents for TRIO.BAS MONO
502	IQ , OQ documents for TRIO.BAS DUO, TRIO, ISOLATOR
509	IQ, OQ for TRIO.GAS
505	PQ documents for MINI
506	PQ documents for MONO
507	PQ documents for DUO, TRIO, ISOLATOR
508	PQ for TRIO.GAS
503	Certificate Calibration service TRIO.BAS MINI
504	Certificate Calibration service TRIO.BAS MONO,DUO,TRIO,ISOLATOR

- The IQ, OQ, PQ documents can be filled in by the operator or by the technician of the producer.
- The Robustus carrying cases are indicated for the delivery of air sampler to the producer/distributor for the annual calibration.

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GAS SYSTEM

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MADE IN ITALY

Method of sampling according Standard ISO 8573-7 and ISO 14698

IP65 for instrument and for case

I.Q., O.Q. P.Q. documentations

Microbial impaction sampler to test the microbiological quality of compressed air or gas used in Cleanroom

Collection of viable particles onto 90 mm Petri or 55 mm contact plates

Calibrated regulator guarantees a 100 litres per minute air flow rate

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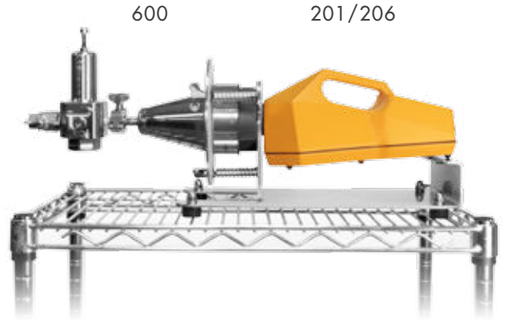
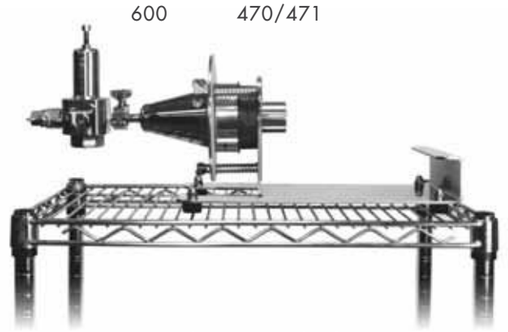
600 201/206



S/S cart on wheels

600 470/471



S/S cart on wheels

INNOVATIVE and ESTABLISHED PERFORMANCES

- All the sampling data are transferred via Bluetooth to PC according GMP and GLP
- The sampler is easily aseptically connected to the output of the compressed gas
- SOP (Standard Operating Procedure) available from Application Notesw
- Totally AISI 316 built
- It is used in combination with TRIO.BAS MONO or ASPI. GAS CHAMBER

Description

- The TRIO.GAS microbial compressed air sampler is important to ensure that product contact air is contamination free within sterile or aseptic manufacturing facilities (e.g. Cleanroom).
- The system is according ISO Standard 8573-7 and ISO 14698.
- The air flow from the compressed supply is regulated throught an autoclavable flow meter before passing throught a TRIO.BAS sampling head.
- All the sampling data are transferred via Bluetooth (using TRIO.BAS MONO BLUETOOTH) to a tablet o smartphone or via Bluetooth (usingTRIO.BAS MONO BLUETOOTH) to a PC with downloaded a dedicated software. (BAS.PC), according to GMP and GLP.
- If the TRIO.GAS is used in combination with MONO the time is regulated by software of TRIO.BAS instrument.
- If the TRIO.GAS is used in combination with ASPI.GAS CHAMBER, the test is manual and the time is calculated by a timer.

Code	TRIO.GAS SYSTEM
600	TRIO.GAS SYSTEM complete of stainless steel electrovalve , gas connection, stailess steel fixing system for air sampler and carrying case. The TRIO.BAS MONO Bluetooth air sampler or ASPI GAS CHAMBER are not included and should be separately ordered.
201/206+331	TRIO.BAS MONO BLUETOOTH Air sampler (100 lts/min) Petri 90 plate/RODAC 55 plate
470	ASPI GAS CHAMBER - Rodac plate for TRIO.GAS SYSTEM
471	ASPI GAS CHAMBER - Petri 90 plate for TRIO.GAS SYSTEM

471

WIND SYSTEM

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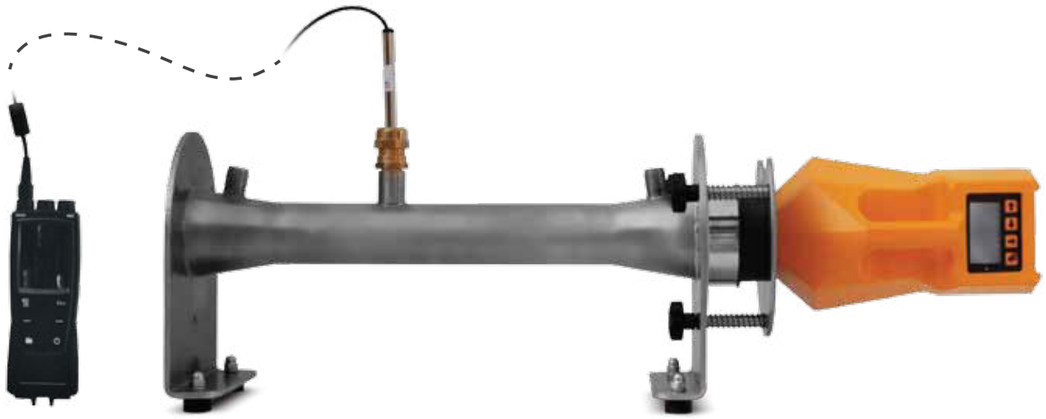

ESTABLISHED PERFORMANCES

Benchtop wind tunnel air volume calibration system for TRIO.BAS microbial air samplers.The TRIO.WIND system is used for official annual calibration of the volume of aspirated air by the TRIO.BAS samplers as requested by the control authorities.

Code	TRIO.WIND TABLE TOP CALIBRATION SYSTEM
360	TRIO.WIND TABLE TOP CALIBRATION SYSTEM complete of stainless steel tunnel, stainless steel fixing system for air sampler, flow velocity measuring instrument, certified probe and carrying case for transport.

Preventative maintenance, qualification, calibration, repair service

This service is provided at production facilities or can be arranged on site.

Orum International and the distributors provide calibration, qualification, maintenance.

Optional

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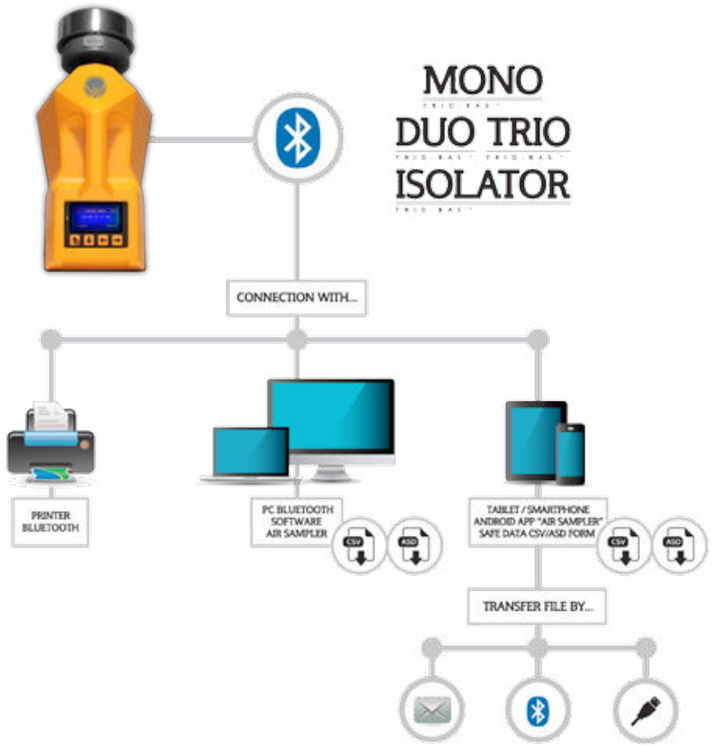
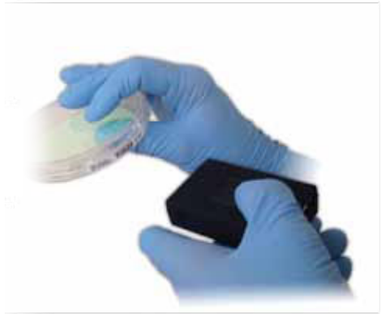
BLUETOOTH

MADE IN ITALY

TRANSFER DATA TRIO.BAS ™



Code	TRANSFER DATA VIA BLUETOOTH (Optional)
300	APP Android "ASAPP" - transfer data from instrument to Smartphone/Tablet by Bluetooth
295	CD Software "ASPC" - transfer data from instrument or smartphone/Tablet to PC by Bluetooth
420	Key Bluetooth for PC without Bluetooth connection



Code	BARCODE READER BLUETOOTH (Optional) - APPLICATION FOR GMP/GLP (Optional)
294	Barcode Reader Bluetooth Module 1D - 2D
291	Location preset Barcode/RFID tag (10xbox)
292	User preset Barcode/RFID tag (10xbox)

Code	RFID RADIO FREQUENCY BLUETOOTH (Optional) - APPLICATION FOR GMP/GLP (Optional)
290	RFID reader module with antenna
291	Location preset Barcode/RFID tag (10xbox)
292	User preset Barcode/RFID tag (10xbox)
293	RFIF self-adhesive label for plate (100xbox)

RFID

ADDENDUM TO CATALOG

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Summary

APPLICATION NOTES

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BARCODE 1D, 2D USE for TRIO.BAS microbial air samplers

The use of barcode ID in microbiological air monitoring procedures can help to save time, to better control the activity of the operator and to achieve a complete traceability of the test.

- **The microbial air sampler preparation**

  The air sampling instrument should be completed with a Bluetooth barcode reader and users and places should be identified by barcode tag / labels. Instrument itself is identified by a s/n written into the microcontroller memory.

- **The Bar-code system preparation**

  Three different points should be identified with barcode labels:
  (a) The culture plates with the sterile medium complete of manufacturer barcode label (55 mm Contact Plates or 90 mm Petri dishes) to be involved before sampling and after plate incubation
  (b) The operator (the tag could be fixed on the lab coat of the operator)
  (c) The location of the sampling (the tag / label could be fixed on the door of the location or on the wall close to the samplingpoint).

- **The Sampling protocol using Barcode ID**

  The description here reported is only an example because different locations or premises may have different needs.
  (1) The operator switches on the air sampler, select "auto" mode and identifies himself pointing the bar-code reader on his identifying tag.
  (2) The operator identifies the plate pointing the bar-code reader on the plate tag / label.
  (3) The operator identifies the location pointing the bar-code reader on the door or wall or surface tag.
  (4) The operator transfers the sterile 55 mm Contact Plate or 90 mm Petri dish into the aspiration chamber of the air sampler, removes the plate lid and applies the sterile aspiration head.
  (5) The operator presses GO / START on the air sampler to collect the expected volume of air.
  It is suggested to adopt the same volume of air for the same type of environment and condition, to avoid the operator having to change the volumes. If it is necessary to have different volumes, it's suggested to plan different sessions of sampling for each different volume.
  (6) The operator opens the aspiration chamber of the sampler, applies the plate lid and collects the culture plate to be transferred to the laboratory. The culture plates must be delivered to the incubator of the laboratory in short time and protected during transit at 4°C.

- **Data Sampling Collection by Barcode**

  All the sampling data are collected and transferred via Bluetooth from the air sampler (identification instrument number, date, hour, location, operator, plate, volume of air) to tablet / PC (with availability of APP and/or dedicated software).
  At the end of incubation time of the culture plate, the CFU are counted, a Barcode reader can be used for searching the plate id and the number of CFU are registered on its summary table. All these data cannot be modified according to the specific protocol requested by the regulatory authorities

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N.01 Principle of microbial air sampler by impact method on agar plate

Air containing microbe-carrying particles is aspirated and accelerate through a hole and direct towards a nutrient agar surface of a plate. As the air turns away from the agar surface, the microbe-carrying particles that cannot follow the flow are impacted. The plate containing nutrient agar is then incubate at a suitable time and temperature, and the resulting Colony Forming Units (CFU) are counted to evaluate the number of microbe-containing particles collected from a specific volume of air.
How the microbe-carrying particles impact on agar surface
The aspirated air passes through an intake orifice of the sampler head at a velocity of "U" and, as it approaches the agar surface, it turns. The arc of the turning circle has a radius of "r" which is assumed to be the same as the radius of the intake nozzle. The velocity round the curve is assumed to be "U".
The microbe-carrying particle travels along the streamline and experiences a centrifugal force that causes it to move toward the agar surface of the plate.

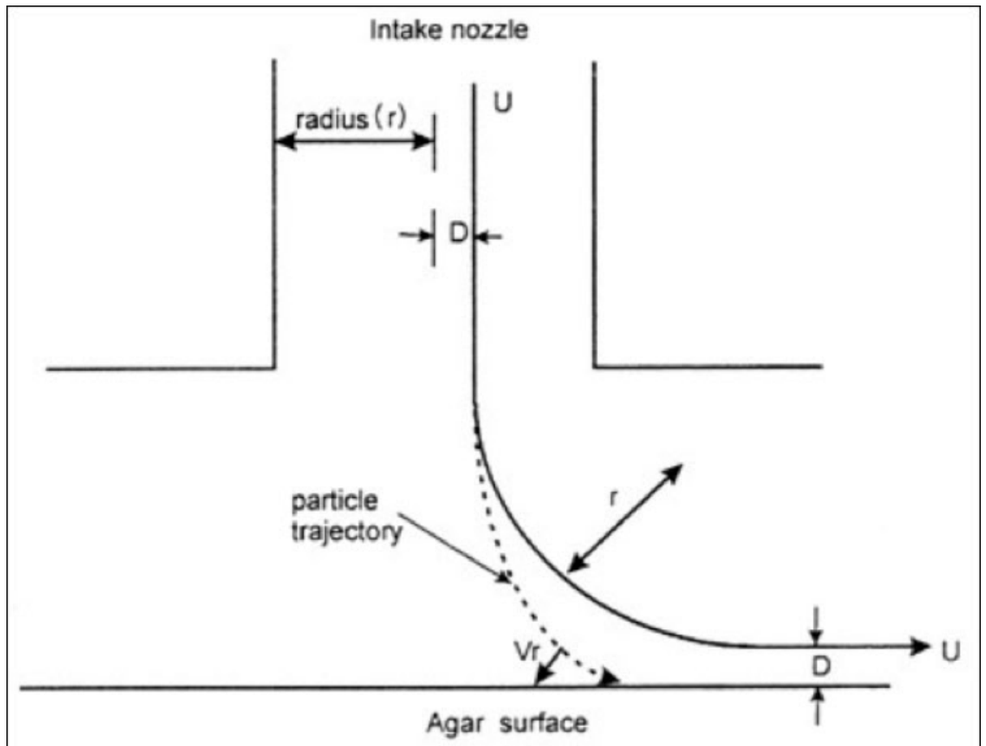

Fig. 1. Impaction of a particle on a surface after exiting a nozzle.

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N.06 Sampling Plan

Introduction

The air sampling plan in check-list format aids both the operator's supervisor and the operator in remembering all the points required for correct microbiological air sampling.

1. STAGE OF SAMPLING PLAN	ACTIONS AND COMMENTS
Date of sampling	
Reason for sampling	
Air Sampler Type	
Accessories	
table tripod	
floor tripod	
remote switch	
additional sterilized heads	
aerosol disinfectant	
Sampling form	
Sampling area	
Sampling location	
Operator's name	
Sample file	
Time of sampling (0-24 hours)	
Sampling interval	
Volume of air	
Replicate sampling	
Sample identification number	
Type of plate	

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1. STAGE OF SAMPLING PLAN	ACTIONS AND COMMENTS
Number of people during sampling	
Type of media	
Micro-organisms to be counted	
Micro-organisms to be identified	
HVAC switch on or off	
Temperature of environment	
Indoor	
outdoor	
Atmospheric humidity	
In situ head sterilization	

2. CONTACT PLATES OPANING/RE PACKING	ACTIONS AND COMMENTS
Container used	
Container code	
Disinfectant	
Sterile gloves (clean room)	

3. TRANSPORT TO THE LABORATORY	ACTIONS AND COMMENTS
Address of laboratory	
Working hours of the laboratory	
Dead-line for sample transport	
Transport case	
Refrigerated case	
Method of transport	
Person responsible	
Means of transport	

4.SAMPLE PREPARATION IN LABORATORY	ACTIONS AND COMMENTS
Is immediate analysis needed?	
Which data are recorded and how?	
Incubation temperature	
Incubation time	
Sample report form details	

Reference

IES-RP-CC023.1-Microorganisms in clean rooms- Institute of Environmental Sciences

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N.09 Fungal Spore Control Ventilation (FSCV) in Hospital

Introduction

The breathing of ambient concentration of airborne fungi for a normal person has no adverse effect on his health. The effects are adverse for the hospitalized patient with immune suppression: he is in fact susceptible to infections caused by naturally occurring airborne fungi that may grow at body temperature. The incidence of infections caused by fungi that were a few years ago considered only saprophytic has risen dramatically during the last decade.
The increased use of antibiotics and chemotherapy has contributed to this trend.

The most common genus of fungi responsible for opportunistic infection

Aspergillus, Acremonium, Chrysosporium, Fusarium, Mucor, Penicillium, Scopulariopsis, Trichoderma are the most common genera of fungi that produce infections.

Fungal Spore Control Ventilation (FSCV)

Immuno-suppressed patients should be maintained in a controlled environment (FSCV) to prevent the contraction of serious opportunistic infections. This goal is reached by increasing air changes, positive pressurized wards, highly filtered air.
A typical Fungal Spore Control Ventilation system will provide greater than 95% filtration efficiency and more than 10 air changes per hour.
The FSCV is also applied to operating theatres.

Programmed fungi-aerosol monitoring

The Fungal Spore Control Ventilation system should be maintained under strict control by a regular monitoring of the fungi present into the aerosol of the considered environment.

SAMPLING INSTRUMENTATION

– Portable, battery operated bioaerosol sampler
– Rodac Plates with Sabouraud Dextrose Agar
– Rodac Plates with Potato Dextrose Agar
– Rodac Plates with Rose Bengal Agar
– Spray disinfectant.

INSTRUMENTATION SETTING

Refer to the air sampler Instruction Manual

SAMPLING PROTOCOL

Three samples should be collected for each run to obtain an average result. The head of the sampler should be disinfected by isopropyl alcohol between each use.

A blank unexposed Rodac Plate should be tested with each sampling event as a negative control.
A. Indoor samples should be collected from the FSCV rooms.
B. Indoor control samples should be collected from non-FSCV rooms.
C. Outdoor control samples should be collected outside but close to the building.

Result Interpretation

The fungal levels of FSCV area, non- FSCV indoor area, outdoor should be plotted on paper for a general comparison.
FSCV areas should contain fungi levels a full order of magnitude lower than levels on outdoor areas.
The reason for incorrect presence of airborne fungi may be due to malfunction of filtration devices, interruption in positive pressure, leaks to the outdoors or localized fungal sources.

Suggested limits

Total Fungi at 37°C Less than 2 cfu/m3
Total Fungi at 20°C Less than 15 cfu/m3
Opportunistic Fungal Pathogens Less than 1 cfu/m3

Reference

Aerotech – Kalmar Laboratories – IAQ Microbiology – Reference Guide – Fungal Spore Control Ventilation in Hospitals – pages 7-1/7-2 – 1998.

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N.14 Standard Operative Procedure for Microbial Air Sampling in Clean Room

It is important to organize a correct and clear sampling plan when several clean rooms or controlled contamination areas are to be monitored at the same time for microbial bioburden.
To reach this goal it is necessary to have a suitable set of air samplers and a specific SOP that gives to the operators all the information to avoid mistakes and / or misunderstanding.
The reported Standard Operating Procedure (SOP) can be used as a guide to be adopted to each individual case.

STANDARD OPERATING PROCEDURE

SUBJECT

Microbial air sampling of multi Clean Room premises

OBJECTIVE

To obtain reliable and consistent microbial air monitoring of the Clean Room

RESPONSIBILITY

Clean Room Manager in close co-operation with Microbiology Laboratory Manager

TERMINOLOGY

Agar, Air Sampler, Aseptic, Bioaerosol, Bioburden, Clean Room, Contact Plate, Contamination, Delay Time, Disinfection, Incubation Time, Incubation Temperature, Interval time, Irradiation, Microbiology Medium, Micro-organisms Captured by impact, Numbers of run, Poured Contact Plates, Sampling Site, Single Run Volume, Sterilization.

MATERIAL

Microbiology air sampler
Battery charger
Clean Room transfer case
Tripod for air sampler
Poured Contact Plates (Plate Count Agar) tripled bagged and irradiated
Disinfectant spray (70% ethanol) tripled bagged, filtered and irradiated

PROTOCOL

Introduction of the air sampler into the Clean Room
Follow the Good Aseptic Practice

Introduction of poured Contact Plates into the Clean Room
Use the irradiated triple bagged Contact Plates

Introduction of disinfectant spray into the Clean Room
Use the irradiated triple bagged disinfectant spray

Identification of Contact Plates
Each plate must be identified by sampling site (XXXX), date (XX / XX / XX), hour (XX.XX)

Disinfection of air sampler
Follow the Good Disinfection Practice.

Use of air sampler
Follow the instruction manual.

Air sampler positioning inside the Clean Room
The microbiology air sampler can be positioned:
a) directly on the surface, close to the considered most critical area
b) fixed on tripod, at the height considered most critical
c) fixed on the wall, using the wall arm

Air sampler programming
The volume of air to be sampled and the sampling program are a choice of the Clean Room Manager. The suggested amount of air per each plate in a Clean Room should be 1000 / 1800 litres of air.

Sampling data downloading
Each sampler should be connected to the printer for sampling data downloading (date, operator identification, sampler identification, sampling site, volume of air).

Transfer of Contact Plate to incubation
At the end of sampling operation, each identified Contact Plate must be protected by its sterile bag and sent to the lab for incubation.

NON CONFORMITY

Contaminated Contact Plates	Do not use them
Expired Contact Plates	Do not use them
Torn plastic bag	Do not use them
Low Battery warning signal	Charge the air sampler

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N.15 Trouble shooting in environmental monitoring

The major routes of contamination can be broadly classified as surfaces, water, people and air.
Each time that "ALERT LEVEL" and "ACTION LEVEL" are reached, the person responsible for environmental monitoring should know what action must be taken.

The reported troubleshooting guide taken from the Document Guide Line No.20 – Effective Microbiological Sampling of Food Processing Environments – by C. & C. gives some useful hints.

Troubleshooting

- Is the problem real? How much confidence do you have in the microbiological evidence and the detection techniques used?
- What is the scale of the problem? Has more than one sample been taken, is the problem within a batch, between batches or across a product range?
- Has the process or recipe been changed? What is it written in the protocol?
- Has the problem occurred before and was it solved? Any evidence in the available protocol?
- Are any single raw material implicated?
- Are environmental microbiological reduction processes in control? Were HVAC System, air filtration, boot-washing, hand-washing, sanitation program recently monitored?
- Where is product contamination first encountered? Once a product becomes contaminated, the product itself will spread the contamination downstream
- When during the production batch is product first contaminated? Contamination at the beginning of production is related to raw materials, failures of microbiological control process or gross environmental contamination levels. Contamination arising late in the production batch is usually related to inadequate sanitation program, leaving residues on surfaces. This may also indicate that production runs are too long in terms of product safety and quality
- If sampling indicates that an equipment surface is the contamination source, is the equipment dismantled for inspection? A close co-operation is necessary between the Production Manager and the Bacteriology Laboratory Manager
- Is the causative organism unusual?

References

GuideLine No.20 – Effective Microbiological Sampling of Food Processing Environments
Troubleshooting – C&C – 1999.

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N.21 Air Sampling Standard

The FDA Process Analytical Technology (PAT) requires a more efficient and reliable microbiological air monitoring system. The ability to check and to identify possible microbial contamination during the production and process enables companies to take more quick appropriate and immediate measures to avoid economic losses. The new generation of microbiological air samplers and new monitoring procedures improve the efficiency of the measurement of the microbial air quality in clean rooms and controlled areas.

The International Standards

The ISO 14698-1 "Cleanrooms and associated controlled environments – Bio-contamination control" and ISO 14698-2 "Evaluation and interpretation of bio-contamination data" are the latest international standards specific for Clean Room and controlled area.
They both provide the techniques:
(a) for the detection and monitoring of airborne bio-contamination
(b) for the evaluation and qualification of the efficiency of microbiological air samplers

The risk assessment

The HACCP (Hazard Analysis Critical Control Point), FTA (Fault Tree Analysis), FMEA (Failure Mode and Effect Analysis) are used to evaluate the areas at risk, to identify appropriate mechanisms of control, and to establish initial control levels.

The environmental monitoring program

The ISO 14698-1 gives several recommendations:
(a) type and size of viable particles to be collected
(b) sensitivity of the viable particles in function of the sampling procedure
(c) expected concentration of viable particles
(d) capability to detect low or high levels of micro-organisms
(e) type of nutrient media
(f) duration of sampling
(g) positioning of samplers
(h) possible disturbance of the unidirectional air flow of the tested environment by the samplers
(i) the outlet air from the sampler should not contaminate the environment or be re-aspirated by the sampler itself.

The impaction air sampler

Adopting the "impact sampler", where the air impacts on the agar surface of a plate, the volume of air should be selected appropriately to obtain a clear colony separation and to facilitate the result reading and interpretation. The air flow should not determine the dehydration of the media and the possible stressing of the micro-organisms. The stress of micro-organisms should be considered with attention because it can determine the slow growth or even the death, with consequent false results ad interpretation of the contamination of the involved area.
The calculation should be reported to 1000 litres of air.

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A new generation of impaction air sampler and accessories

The air sampler

The news about the portable, battery operated impaction air sampler is the fact that the stainless steel aspiration chamber is totally separated from the body of the unit.
The two or three parts are connected by a cable up to 25 metres long.
It is therefore possible to reach several goals:
(a) to collect the sample inside an isolator, Clean Room or controlled environment with separated external commands to reduce contamination risk and save important space
(b) to guarantee the sterilization of the aspirating chamber of the instrument with the more updated physical or chemical agents like VHP
(c) to connect several air samplers that can be positioned in more critical points of the same area or in different separated environments.
(d) to produce more continuous monitoring to have under control the critical actions of pharmaceutical and biotechnology production like improper aseptic techniques and / or inadequate cleaning agents
(e) to facilitate the sample data collection and recording from a single unit
(f) to connect the unit to a device for the evaluation of the quality of the compressed air
The accessories
(g) The aspirating head of the air sampler may be a source of contamination and its sterility in Clean Room and Isolator must be certified. The "-Head" (International pbi) aspirating head is a disposable head with certified sterility document.
(h) The transfer of the plate (Contact Plate or Petri dish) inside the aspiration chamber of the air sampler may be source of contamination by production staff people. The complete chamber may be pre assembled by a trained microbiologist in aseptic conditions;
(i) The sterility of compressed air and gases used in Clean Room should be monitored by a specific device mounted on the air sampler.

Conclusions

The ISO 14698 standard provides techniques to help the Clean Room and Isolator operator for the detection of airborne bio contamination.

References

ISO 14698-1:2003 "Clean Room and associated controlled environments – Bio contamination control".
ISO 14698-2:2003 "Evaluation and interpretation of bio contamination data".

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N.24 Record of results

The dispersion and diffusion of micro-organisms in indoor air is very irregular and influenced by several factors like the presence of air currents, number of people present in the environment, movement of people in the area, electrostatic charges, humidity, temperature, etc.
It is clear the correct sampling technique is important. It is imperative to make several tests in the same place, at same time to produce a statistical result that takes an accurate picture of the microbiological conditions of the considered environment.
To obtain a statistical result, it is imperative to have a correct record of all data of the sampling cycles.

The material

The portable microbiological impaction air sampler should be reliable, calibrated, fully charged and suitable to produce twin contemporaneous samples. The sampler should be positioned in defined and programmed places (e .g.: 1 metre high, 1 metre from the wall, close to the air conditioning outlet, etc.) using the support or tripod.
The aspirating head at the beginning of the sampling cycle must be sterile (e. g.: metal autoclaved or sterile plastic).
The Contact plate (RODAC) or the Petri dish with agar media should be freshly prepared and with the correct amount of medium to guarantee a regular growth of the micro-organisms.
The operators should be very well trained about the sampling techniques and equipped with disposable gloves, and sterile spray disinfectants.
A specific Standard Operating Procedure (SOP) for the sampling protocol should be available for all the staff involved in the sampling activity.
Record of the sampling data
All data of the sampling cycles should be registered on a specific form to be sure the next results are correctly compared for interpretation and discussion.
Example of registration form for indoor air sampling cycle

Date/Hour	Operator Name	Instrument Identification	Volume Aspirated Air	Sampling Identification	Sampling Point Location	Plate Identification

Culture Medium	Incubation Time/ Temperature	PCA/CFU Plate Min-Max-Average	PCA/CFU 1000 LTS Air Average	PCA/CFU Plate Min-Max-Average	PCA/CFU 1000 LTS Air Average
		Min Max Average		Min Max Average	

Note

It is useful for a correct interpretation, to note all the available information like:
(a) the total number of people present in the area (or no people present in the area)
(b) if the sampling was performed “at rest” or “in operation”
(c) the temperature of the environment
(d) the humidity of the environment
(e) the type of HVAC
(f) a map with all the sampling points

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N.26 Maintenance and Calibration of air sampler according GMP and GLP – EN 14042

Chapter 12 “Quality Assurance” of the European Standard EN 14042 – “Workplace atmosphere – Guide for the application and use of procedures for the assessment of exposure to chemical and biological agents”.

“It is good practice to set up a Quality Assurance scheme for the maintenance and calibration of the samplers. This includes:

a) the establishment of a Standard Operating Procedure (SOP);
b) for re-usable device, a log of usage;
c) keeping a record of the traceability of the calibration;
d) retaining the raw data as required by the quality or other system;
e) using a unique and durable sampler numbering system for the re-usable devices;
f) depending on the measurement task, taking an appropriate number of field blank and replicate samples (e.g.: 10%);
g) an appropriate level of internal and external Quality Assurance”.

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N.27 Mapping for the Microbiological Environmental condition monitoring in food production

It has been recommended that food processing plants adopt air monitoring programs to detect possible contamination sources in their regular HACCP program.
Juice, ready-to-eat foods, pasta, meat, dairy and other food processing facilities have been advised to establish a system for weekly air monitoring. Air sampling of various areas (finished product, protein, fresh produce areas, etc.) yield information as to possible microbial contamination. That is to say, knowing the microbial population, number of colony forming units per cubic meter of air (CFU/m3) of a given area can be predictive of possible food contamination possibilities, e.g., yeast, molds, and pathogens.

• **Areas of risk**
First identify location of areas of risk in both raw and finished product sites. Second, using the "TRIO.BAS" air sampler, monitor these risk areas weekly to determine if the risk is real. These risk areas could be any place where air may come from heat or air conditioning or where people move in and out.

• **Spatial maps**
The use of spatial mapping aids in the interpretation of these data and is a visual tool easily showing increases or decreases in CFU/m3. Air handling is critical to these areas, however, without adequate monitoring of the air, there is no way to assure that the air treatment is indeed effective.
Also, without this somewhat simple testing, companies are not even aware that there are contamination issues, until a customer calls with a quality complaint, a notable loss in product shelf life or possible Product Recall. The following air sampling regime is suggested:
- Ten (10) foot diameter samples should be taken from a given area.
- Sample from 50 to 500 liters of air over a specific media, e.g., PDA for molds, SMA for general microbial population.
- Incubate appropriately then read each plate and record the results.
- Map these results, as stated earlier spatial mapping is the ideal way to display these results.
- Compare the before and after air treatment result, as well as ongoing sampling (weekly or monthly).
- When counts >300 CFU/m3 are found a described corrective action should be implemented and then the resample the air in the storage area.
- The above is an approved validation for any USDA/FDA HACCP Program.

• **References**
U.S. Department of Labor, OSHA, Safety and Health Topics, Sampling & Analytical Methods, Evaluation Guidelines for Surface Sampling Methods. Falkenberg, R. L. "Spatial Analysis of Food Facilities." Geospatial Solutions. Pg 14, July 2004. Devico, Norma Jean. Gotta See It To Believe It. Food Quality. July/August 2002. Kirsch, Lee." Fundamentals of an Environmental Monitoring Program." PDA Journal of Pharmaceutical Science and Technology. Vol. 55 No. 5 September/October 2001. Wester, R.; Hui, X.: Landry, T.; Maibach, H. "In Vivo Evaluation of MDI Skin Decontamination Procedures," Department of Dermatology, UCSF; Health and Environmental Research Laboratory, The Dow Chemical Co., Presented at Polyurethanes Expo. 1998.

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N.28 USP Regulation 797

Issued by the non-profit US Pharmacopoeia (USP) and endorsed by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), "USP Regulation 797" is the first enforceable standard for sterile com¬pounding. Originally enacted on January 1, 2004, the latest version became official on June 1, 2008.
"USP 797" is a broad regulation that covers a variety of pharmacy policies and procedures. It is designed to reduce the number of patient infections due to contaminated pharmaceutical preparations.
"USP 797" contains specific requirement for ongoing air and surface evaluation to ensure product sterility and safety for compounded sterile preparations (CSPs).
"USP 797" applies to all staff and environments involved in the preparation of CSPs: pharmacies, hospitals, clinics, medical doctor offices. Less formal procedures are applied in these sectors for sterility safeguard in comparison with drug manufactured that are under strict control of FDA.
• Risk level
"USP 797" classifies the compounding in 3 different levels: Low-Risk level CSPs, Medium-Risk level CSPs, High- Risk Level CSPs.
• Recommended Action Levels for microbial contamination
– Viable Air Sampling

CLASSIFICATION	CFU / 1000 LITRES OF AIR
ISO Class 5	>1
ISO Class 7	>10
ISO Class 8 or worse	>100
Surface Sampling	
CLASSIFICATION	CFU / RODAC plates
ISO Class 5	>3
ISO Class 7	>5
ISO Class 8 or worse	>100

If air or surface microbial contamination action levels are reached, taking immediate action will help to quickly eradicate threats and mitigate risks to patients health.
It may be necessary to consult a microbiologist/infectivologist or industrial hygienist to identify and correct the source of contamination.

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N.33 Correct aseptic sampling during air sampling monitoring

The correct sampling is fundamental to avoid a microbial contamination with possible wrong results at the end of the analytical process.
It is for this reason that all the staff involved in the sampling process should be trained.
We are reporting some Guide Lines that should be distributed and explained to all involved personnel.

- Guide Lines

WHAT NOT TO DO

- Contaminate the plate touching the inside surfaces
- Contaminate the inside edge of the lid of the container
- Lean the lid of the plate on a contaminated surface during the sampling operation
- Collect a unrepresentative sample
- Use damaged or contaminated containers

WHAT TO DO

- Wash the hands and / or wear clean and sterile gloves
- Label / identify the plate before to start the sampling operation
- Eliminate the gloves and wash the hands at the end of sampling operation
- The plate should be removed from its protective bag only for labelling and sampling.

- Sample Identification

The plate should be identified before to start the sampling process with the following data:

- reference number or letter
- operator's name
- name or type of sample
- site of sampling
- exact point of sampling
- date and hour of sampling
- sample temperature at time of sampling
- expected temperature during transit
- store the sample at the correct temperature as indicated in the sampling plan document (e.g.: 4°C).

- Sampling delivery

The container with the sample should be stored in dark, insulated box and delivered to the analytical laboratory not later than 4-6 hours.
-Temperature during transit
The samples for microbiological tests should be stored at 4°C to avoid the multiplication of the microbial population, with the purpose to avoid wrong analytical results.
This goal is reached using portable, battery operated refrigerators.

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N.42 Suggested Frequency and Microbial Recovery rate of Sampling for Aseptic Processing Areas

The USP 38 – The United States Pharmacopeial Document – Official from May 1, 2015 – presents on page 1197, Table 2 the "Suggested Frequency of Sampling for Aseptic Processing Areas".

FREQUENCY OF SAMPLING

SAMPLING AREA LOCATION	FREQUENCY OF SAMPLING
Clean Room / RABS	
Critical Zones (ISO 5 or better)	
Active Air Sampling	Each operational shift
Surface Monitoring	At the end of operation
Aseptic area adjacent critical zone	
All sampling	Each operating shift
Other nonadjacent aseptic area	
All sampling	Once a day
Isolators	
Critical Zones (ISO 5 or better)	
Active Air Sampling	Once a day
Surface Monitoring	At the end of the campaign
Nonaseptic areas surrounding the Isolator	
All sampling	Once per month

All operators are aseptically gowned in these environments (with the exception of background environments for isolators). These recommendations do not apply to production areas for nonsterile products or other classified environments in which fully aseptic gowns are not donned.

The USP 38 – The United States Pharmacopeial Document – Official from May 1, 2015 – presents on page 1199, Table 3 the "Suggested Initial Contamination Recovery Rates in Aseptic Environments".

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SUGGESTED INITIAL CONTAMINATION RECOVERY IN ASEPTIC ENVIRONMENTS

Room classification	Active Air Sample (%)	Settle Plate (9 cm) 4H Exposure (%)	Contact Plate or Swab (%)	Glove or Garment (%)
Isolator/Closed RABS (ISO 5 or better)	<0.1	<0.1	<0.1	<0.1
ISO 5	<1	<1	<1	<1
ISO 6	<3	<3	<3	<3
ISO 7	<5	<5	<5	<5
ISO 8	<10	<10	<10	<10

All operators are aseptically gowned in these environments (with the exception of background environments for isolators). These recommendations do not apply to production areas for nonsterile products or other classified environments in which fully aseptic gowns are not donned.

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N.51 Training of personnel in Cleanroom, Isolator, RABS according USP 38 – The United States Pharmacopeial – Document (1116) Aseptic Processing Environments – Page 1195

- The personnel performances

Good personnel performance plays an essential role in the control of contamination, proper training and supervision are central to contamination control. Aseptic processing is the most critical activity conducted in Microbiological Controlled Environments, and manufacturers must pay close attention to details in all aspects of the endeavor. Rigorous discipline and strict supervision of personnel are essential in order to ensure a level of Environmental quality appropriate for aseptic processing.

Training of all personnel working in controlled environments is critical.

This training is equally important for personnel for the microbial monitoring program, because contamination of the Clean working area could inadvertently occur during microbial sampling. In highly automated operations, monitoring personnel may be the employees who have the most direct contact with the critical surfaces and zones within the processing area.

Microbiological sampling has the potential to contribute to microbial contamination caused by inappropriate sampling techniques or by placing personnel in or near the critical zone. A formal training is required to minimize this risk. This training should be documented for all personnel who enter controlled environments. Intervention should always be minimized, including those required for monitoring activities, but when interventions cannot be avoided they must be conducted with aseptic technique that approaches perfection as closely as possible.

- The management of the facility

Management of the facility must ensure that personnel involved in operations in Clean Rooms and advanced aseptic processing environments are well versed in relevant microbiological principles. The training should include instructions about the BASIC principles of aseptic techniques and should emphasize the relationship of manufacturing and handling procedures to potential sources of product contamination. Those supervising, auditing, or inspecting Microbiological Control and Monitoring activities should be knowledgeable about the BASIC principles of microbiology, microbial physiology, disinfection and sanitation, media selection and preparation, taxonomy, and sterilization. The staff responsible for supervision and testing should have academic training in medical or Environmental Microbiology.

Sampling personnel as well as individual working in Clean Room should be knowledgeable about their responsibilities in minimizing the release of microbial contamination.

Personnel involved in microbial identification require specialized training about required laboratory methods. Addition training about the management of collected data must be provided. Knowledgeable and understanding of applicable standard operating procedures are critical, especially those procedures relating to corrective measure taken when environmental conditions required.

Understanding of contamination control principles and each individual's responsibilities with respect to GMP should be an integral part of the training program, along with training in conducting investigations and in analyzing data.

- The significant sources of contamination

The only significant sources of microbial contamination in aseptic environments are the personnel. Because operators disperse contamination and because the ultimate objective in aseptic processing is to reduce end-user risk, only healthcare individuals should be permitted access to controlled environments. Individuals who are ill must not allowed to enter an Aseptic Processing Environment, even one that employs advanced aseptic technologies such as isolators, blow/fill/seal or closed RABS.

- The importance of Good Personal Hygiene

The importance of Good personal hygiene and a careful attention to details in aseptic gowning cannot be overemphasized.
Gowning requirements differ depending on the use of the controlled environment and the specifics of the gowning system itself.
Aseptic processing environments require the use of sterilized gowns with the best available filtration properties.
The fullest possible skinhead coverage is desirable, and sleeve covers or tape should be considered to minimize leaks at the critical glovebox-sleeve junction.
Exposed skinhead should never be visible in conventional Clean Room under any conditions. The personnel and gowning considerations for RABS are essentially identical to those for conventional Clean Room.
Once employees are properly gowned, they must be careful to maintain the integrity of their gloves, masks, and other gowns materials at all times.
Operators who work with isolator systems are not required to wear sterilized Clean Room gowns, but inadequate aseptic techniques and employees borne contamination are the principal hazards to safe aseptic operations in isolators, as well as RABS, and in conventional Clean Rooms. Glove and sleeve assemblies can develop leaks that can allow the mechanical transfer of microorganisms to the product. A second glove, worn under or over the primary Isolator / RABS glove, can provide an additional level of safety against glove leaks or can act as a hygienic measure.

- Conclusions

Also, operators must understand that aseptic technique is an absolute requirement for all manipulation performed with gloves within RABS and Isolator systems. The Environmental Monitoring program, by itself, cannot detect all events in aseptic processing that might compromise the microbiological quality of the environment. Therefore, periodic media fill or process simulation studies are necessary, as is thorough ongoing supervision, to ensure that appropriate operating control and training are effectively maintained.

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N.52 Short course of microbiology for environmentalist

Text from "The Society for General Microbiology U.K."

BASIC MICROBIOLOGY

Microbe	An organism that can only be seen clearly under a microscopy
Eukariote	An organism made of cells which contain membrane-bound organelles such as nuclei
Prokariote	An organism made of a cell which lacks membrane-bound organelles such as nuclei, e,g. bacteria and archea
Bacterium	A unicellular prokaryote with a cell wall made from peptidoglycan; bacteria (plural) make up one of the 3 domain life
Archean	A unicellular prokaryote similar to bacteria; archea (plural) make up one of the 3 domains of life
Eukarya	One of the 3 domain of life; contains all eukaryotes, including plants, animals, fungi and other organisms that were previously classified as Protoctista in 5 kingdom system
Kingdom	The highest rank in the hierarchy of the 5 kingdom system are Prokariotae, Animalia, Plantae, Fungi and Protoctista
Domain	A category of organisms; all organisms can be classified in one of 3 domains Eukarya, Prokarya and Archaea
Classification	The arrangement of organisms into groups
Taxonomy	The process of naming and classifying organisms
Phenetic classification	A method of arranging organisms based on properties such as anatomy or morphology (i.e. the 5 kingdom system)
Phylognetic classification	A method of arranging organism based on evolutionary relationship between organisms (i.e. the 3 domain system)
Chromosome	An organized structure of DNA (and often) protein); contains genes
Plasmid	A circular piece of DNA separate from the chromosome of a bacterium
Conjugation	The transfer of DNA from one cell to another via direct cell to cell contact
Asexual	A type of reproduction that does not depend on sex cells or sex organs
Binary fission	A type of asexual reproduction in which a single-celled organism divides to produce two daughter cells of the same size
Budding	A type of asexual reproduction in which a new cell or appendage is formed from an outgrowth of a cell; occurs in microbes such as yeast and some plants and animals

Capsule	A protein or polysaccharide layer external to the cell wall; found in some prokaryotic cells
Endospore	A dormant non-reproductive structure formed inside some bacterial cells, often in response to environmental conditions; many are able to survive extreme temperatures, radiation and desiccation and will develop into bacterial cells when conditions become more favourable
Flagellum	A long filament sticking out of a cell that enables movement; in bacteria it moves with a cork screw motion due to the rotation of a flagellar motor anchored in the cell membrane
Pilus	A protein filament protruding from the surface of some bacterial cells (similar to a fimbria); some are involved in conjugation
Fimbria	A protein filament protruding from the surface of some bacterial cells (similar to a pilus)
Ribosome	A structure made of protein and RNA, that is the site of protein synthesis
Peptidoglycan	A polymer found in the cell walls of bacteria
Gram Stain	A method that stains bacteria differentially according to their cell wall structure
Gram-negative	Bacteria with cell walls made of 10% peptidoglycan plus an additional lipopolysaccharide layer; they stain pink or red with Gram's reagent
Gram-positive	Bacteria with cell walls made of 90% peptidoglycan; they stain purple with Gram's reagent
Glycocalyx	Slim or gummy material secreted on the outside of some bacterial cells, e.g. a slime layer or capsule
Slime layer	A gummy layer external to the cell wall that is found in some prokaryotic cells; unlike a capsule it is diffuse and easily removed
Fungus	A eukaryotic organism with a cell wall made from chitin; can be unicellular (e.g. yeast) or multicellular (e.g. moulds)
Yeast	A unicellular fungus; used widely in biotechnology
Hypha	A thread-like fungal filament which forms branching networks called mycelia
Mycelium	A mass of fungal filaments (hyphae)
Spore (fungal)	A single-celled or multicellular structure produced for dispersal, as a result of sexual or asexual reproduction or in response to adverse conditions
Fruiting body	A structure made by filamentous fungi in order to produce and release spores; they are commonly known as mushrooms and toadstool
Virus	An acellular infectious agent consisting of a protein coat and nucleic acid core
Virion	A virus particle consisting of a protein coat called a capsid and a core (containing a nucleic acid) called the nucleocapsid
Envelop (viral)	A phospholipid bilayer on the outside of certain viruses
Capsid	The protein coat that surrounds the nucleic acid genome of a virus
Nucleocapsid	The core of a virus; contains the RNA or DNA genome
Lytic cycle	The life cycle of a virus during which it replicates continually, destroying the host and releasing virl particles

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N.57 SOP Microbial Compressed Air / Gas Sampling according ISO 8573-7

The purpose of this document is to describe the procedure for compressed air / gas sampling, and reporting of the viable airborne particulates as part of environmental program, using TRIO.BAS GAS Microbial Air Sampler.

PURPOSE

This procedure applies for sampling and evaluation of compressed air quality for viable particulates using a Microbiological Air Sampler in Clean Room. The purpose is to certify the absence of microorganisms in 1.000 litres of compressed gas/air.

GLOSSARY

Agar, Autoclave, Contact Plate, Cleanroom, CFU: Colony Forming Units, Disinfection, Impact, Medium, Petri dish, RABS, SDA: Sabouraud Dextrose Agar, Sterilization, Total Bacterial Count, Tsa: Tryptic Soy Aga

Principle of impact using a Microbiological Air Sampler
Air is aspirated at a fixed speed for a variable time through a cover with small holes. The resulted flow of air is directed on to the agar surface of the contact plate (Petri dish) placed inside the sampler, under the cover with holes. When the preset sample time is completed, the culture plate is removed and incubated for a pre-determined amount of time, and the colony forming units are counted and recorded as CFUs per the volume of measured air.

REFERENCE

– ISO 8573-7:2003 Compressed Air – Part 7 – Test method for viable microbiological contaminant content
Abstract ISO 8573-7:2003 specifies a test method for distinguishing viable, colony-forming, microbiological organisms (e.g. yeast, bacteria, endotoxins) from other solid particles which may be present in compressed air. One of a series of standards aimed at harmonizing air contamination measurements, it provides a means of sampling, incubating and determining the number of microbiological particles.
– TRIO.BAS Air Sampler User's Manual

RESPONSIBILITIES

It is the responsibility of Quality Control Staff to ensure proper operation, maintenance and calibration of Air Sampler per this procedure. It is the responsibility of Quality Control/Quality Assurance to ensure that all personnel performing this procedure is properly trained. It is the responsibility of Quality Control Personnel to update and revise this procedure as appropriate.

SAFETY

The safety rules are controlled by the company safety officer.

MATERIALS/CULTURE PLATES
• BAS GAS MICROBIAL AIR SAMPLER

• BAS MINI MICROBIAL AIR SAMPLER
• 90 mm Petri dish or 55 mm Contact plates for Total Bacterial Count

PROTOCOL

PREPARATION

1. Verify the TRIO.BAS GAS and TRIO.BAS MINI air sampler are available and ready to be used. Verify that the paper document for cycle registration is available.
2. Verify the pressure of the compressed air gas at the output of the gas to analyze is correct according to the TRIO.BAS instruction manual specification.
3. The aspirating volume of the TRIO.BAS GAS and TRIO.BAS MINI is 100 lts/air per minute and therefore program it for 1.000 litres (10 minutes are necessary for 1.000 litres of air).
4. The correct adapter must be available to connect the TRIO.BAS GAS to the compressed air/gas output.
5. Before to start any activity, clean, wash and disinfect with sprayed sterile alcohol the hands. Dress the suitable protective gowns and gloves. All the operations should be aseptically performed applying the GAP (Good Aseptic Procedure).
6. Prepare the adapter for connection by treating them with sterile alcohol. Make attention to avoid particulates of the Teflon tape are inside the gas tubing.
7. Verify that the culture plates (Petri or Contact) are correct according to the producer specification (date, quality, etc). Identify each culture plate.
8. Prepare the surface on which the air sampler will be positioned: 8.1. Cleaned and disinfected surface. 8.2. Sterile dress and gloves. 8.3. Cart on wheel to facilitate the movement of the air sampler inside the Cleanroom.
9. Position the TRIO.BAS GAS and TRIO.BAS MINI on the cleaned surface, treat all the parts with spray sterile alcohol and complete the assembly. Connect the TRIO.BAS GAS to the gas output.
10. Clean and disinfect all the surfaces of the air samplers between several sampling cycles.

BLIND TEST

11. Insert a culture plate inside the aspiration chamber of the TRIO.BAS MINI. Take out the lid and transfer it on a clean and disinfected surface. Apply the TRIO.BAS MINI to the TRIO.BAS GAS unit.
12. According to the protocol of the ISO Standard 8573-7, it is necessary to perform a blind test before and after the air sampling (with the air sampler in off condition) to verify that the operator was working in the correct way. The handling of the culture plate is performed as for the real test, but without the compressed gas. The culture plate should be inside the aspiration chamber for 30 seconds. The plate is then transferred for incubation.

TEST

13. Insert a culture plate inside the aspiration chamber of the TRIO.BAS MINI. Take out the lid and transfer it on a clean and disinfected surface. Apply the TRIO.BAS MINI to the TRIO.BAS GAS unit.
14. Open the valve of the compressed air / gas and, at the same time, switch on the TRIO.BAS MINI. At the end of 1.000 litres of air close the valve and switch off the TRIO.BAS MINI.
15. Disconnect the TRIO.BAS MINI air sampler, apply the lid to the culture plate and transfer it to incubation.
16. Transfer the data of the cycles to P.C. by the Bluetooth of the air sampler.

NON CONFORMITY

17. 17.1. The culture plates are contaminated before the use. 17.2. The expiration date of the culture plates is over. 17.3. The certificate of the microbial air sampler is expired.

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N.73 Air sampler disinfection

Cleaning and disinfection of microbial active air samplers in Clean Room

INTRODUCTION
All the materials that are used with a microbial air sampler (protective aspirating head, aspirating head, body of the air sampler, bags, etc) should be cleaned and disinfected before the sampling cycles.

CLEANING
The external part of the air sampler should be treated with mild non corrosive detergent.
• Clean the body of the instrument with a soft cloth
• Do not use abrasive liquid
• Do not submerge in water!
• Do not pour water directly on the instrument
• Do not use solvent (e.g. acetone) for cleaning
• The holes of the aspirating head must be periodically treated with compressed air to remove possible dust that clogs the orifices.

DINSINFECTION AND STERILIZATION
Aspirating head – The s/s aspirating head complete of its protective cover may be wrapped in aluminum sheet and transferred to an autoclave and treated at 121°C for 20 minutes.
The s/s aspirating head can be also sanitized by treating the inside and outside part with sterile isopropilic alcohol (swab or spray).
Aspirating chamber of the plate – The aspirating chamber of the air sampler, complete of the aspirating head, may be sanitized using sterile isopropilic alcohol sprayed about 30 cm from the head with the air in aspiration. Approx. 30 seconds are sufficient to fully disinfect the air path. The alcohol will evaporate in a few seconds. This operation should ideally executed under laminar flow.

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N.76 SOP – Standard Operating Procedure for use, maintenance, calibration of "TRIO.BAS" microbiological air samplers

OBJECT

The purpose of this document is to describe the procedure for sampling, and reporting of the viable airborne particulates as part of environmental program, using TRIO.BAS Microbiological Air Sampler.

PURPOSE

This procedure applies to particulate sampling and evaluation of air quality for viable particulates using a Microbiological Air Sampler

GLOSSARY

Agar, Autoclave, Bacteria, Bioburden, Calibration, CleanRoom, Contact Plate, Cleanroom, CFU: Colony Forming Units, Culture plate, Disinfection, Impact, Yeast, Medium, Petri dish, Microorganism, Mould, RABS, RODAC, SDA: Sabouraud Dextrose Agar, Sterilization, Total Bacterial Count, TSA: Tryptic Soy Agar

Principle of impact using a Microbiological Air Sampler

Air is aspirated at a fixed speed for a variable time through a cover with small holes. The resulted flow of air is directed on to the agar surface of the contact plate (Petri dish) placed inside the sampler, under the cover with holes. When the preset sample time is complete, the plate is removed and incubated for a pre-determined amount of time, and the colony forming units are counted and recorded as CFUs per the volume of measured air.

REFERENCE

– ISO14698
– Air Sampler User's Manual

RESPONSIBILITIES

It is the responsibility of Quality Control Staff to ensure proper operation, maintenance and calibration of Air Sampler per this procedure.
It is the responsibility of Quality Control/Quality Assurance to ensure that all personnel performing this procedure is properly trained.
It is the responsibility of Quality Control Personnel to update and revise this procedure as appropriate.

MATERIALS/REAGENTS

A1.1 Active Microbial Air Sampler
A1.2 Battery Charger
A1.3 70% Isopropyl Alcohol.
A1.4 TSA plates with lecithin and polysorbate 80
A1.5 SDA plates with lecithin and polysorbate 80
A1.6 Incubator 32 ± 2.5 ° C and 22 ± 2.5 ° C.

PROTOCOL

B1 Programming Quantity of Air to be measured
Switch on the ON switch.
B1.1. To select or change the volume of air to be measured, use the arrows to select 1000L or one of the 14 volumes.
B1.2 Press enter to confirm the selection.
B1.3 Push start (GO) to take samples with selected volume each time.

C1 Display Records
C1.1 TRIO.BAS are capable of storing 1000 records in the software file.
C1.2 Each sample is identified in chronological date order and shows the date, time, operator, site and volume of air.

D1 Print Records Using Bluetooth Printer
D1.1 Connect the air sampler to the printer.
D1.2 Turn on the sampler and the printer.
D1.3 The data will be printed in a chronological order: progressive sample number, day, month, year, hour, operator's name, site, litres of aspirated air.

NON CONFORMITY

E1.1 The correct calibration time of the air sampler must be confirmed in the Calibration Certificate.
E1.2 The culture plates must be with the correct expiration date.

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N.80 Glossary according USP 38

Glossary for Microbiological Air Environmental Monitoring

Microbiology according USP 38 – The United States Pharmacopeial – Document (1116) Aseptic Processing Environments -Page 1201, 1202.

- Airborne Particulate Count – The total number of particles of a given size per unit volume of air.
- Airborne Viable Particulate Count – The recovered number of CFU per unit volume of air.
- Air Changes – The frequency per unit of time that the air within a controlled environment is replaced. The air can be recirculated or totally replaced.
- Air Sampler – Device or equipment used to sample a measured amount of air in a specified time to quantitate the particulate or microbiological status of air in the controlled environment.
- Aseptic – Technically, the absence of microorganisms, but in aseptic processing this refers to methods and operations that minimize microbial contamination in environment where sterilized products and components are filled and / or assembled.
- Aseptic Processing – An operation in which a products assembled or filled into the primary package in an ISO5 or better environment and under conditions that minimize the risk of microbial contamination. The ultimate goal is to produce products that are as free as possible of microbial contamination.
- Barrier System – Physical barriers installed within an aseptic processing room to provide partial separation between aseptically gowned personnel and critical areas subject to considerable contamination risk. Personnel access in the critical zone is largely unrestricted. It is subject to a high level disinfection.
- Bioburden – Total number and identity of the predominant microorganisms detected in or on an article.
- Clean Room – A room in which the concentration of airborne particles is controlled to meet a specified particulate cleanliness Class. In addition, the concentration of microorganisms in the environment is monitored; each cleanliness Class defined is also assigned a microbial level for air, and personnel gear.
- Commissioning of a Controlled Environment – Certification by engineering and quality control that the environment has been built according to the specifications of the desired cleanliness Class and that, under conditions likely to be encountered under normal operating conditions (or worst case conditions), it is capable of delivering an aseptic process. Commissioning includes media-fill runs and results of the environmental monitoring program.
- Contamination Recovery Rate –T he contamination recovery rate is the rate at which environmental samples are found to contain any level of contamination. For example, an accident rate of 1% would mean that only 1% of the samples taken have any contamination regardless of colony number.
- Controlled environment – Any area in an aseptic process system for which airborne particulate and microorganism levels are controlled to specific levels, appropriate to the activities conducted within that environment.
- Corrective action – Action to be performed that are according to standard operating procedures and that are triggered when certain conditions are exceeded.
- Critical Zone –Typically the entire area where products and the containers and closures are exposed in aseptic processing.
- Detection frequency –The frequency with which contamination is observed in an environment. Typically expressed as a percentage of samples in which contamination is observed per unit of time.
- Environmental isolates – Microorganisms that have been isolated from the environmental monitoring program.
- Environmental Monitoring Program – Documented program implemented via standard operating procedures that describes in details the methods and acceptance criteria for monitoring particulates and microorganisms in controlled environments (air, surface, personnel gear). The program includes sampling sites, frequency of sampling, and investigative and corrective actions.

- Equipment Layout – Graphical representation of an aseptic processing system that denotes the relationship between and among equipment and personnel. This layout is used in the Risk Assessment Analysis to determine sampling site and frequency of sampling based on potential for microbiological contamination of the product/container/closure Systems. Changes must be assessed by responsible managers, since unauthorized changes in the layout for equipment or personnel stations could result in increase in the potential for the contamination of the product/container/closure system.
- Isolator for Aseptic Processing – An aseptic isolator is an enclosure that is over-pressurized with HEPA filtered air and is decontaminated using an automated system. When operated as a closed system, it uses only decontaminated interfaces or rapid transfer points for material transfer. After decontamination they can be operated in an open manner with the ingress and/or egress of material through defined openings that have been designed and validated to preclude the transfer of contamination. It can be used for aseptic processing activities or for asepsis and containment simultaneously.
- Material Flow – The flow of material and personnel entering controlled environments should follow a specific and documented pathway that has been chosen to reduce or minimize the potential for microbial contamination of the product/container/closure system. Deviation from the described flow could result in increase in the potential for microbial contamination. Material/personnel flow can be changed, but the consequences of the change from a microbiological point of view should be assessed by responsible managers and must be authorized and documented.
- Media fill – Microbiological simulation of an aseptic process by the use of growth media processed in a manner similar to the processing of the product and with the same container/closure system being used.
- Media Growth Promotion – Procedure that references Growth Promotion Test of Aerobes, Anaerobes and Fungi in Sterility Tests to demonstrate that media used in the microbiological environmental monitoring program, or in media fill runs, are capable of supporting growth of indicator microorganism and of environmental isolates from samples obtained through the monitoring program on their corresponding ATTC strains.
- Product Contact Areas – Areas and surface in a controlled environment that are in direct contact with products, containers, or closures and the microbiological status of which can result in potential microbial contamination of the product/container/closure system.
- Restricted Access Barrier System (RABS) – An enclosure that relies on HEPA filtered air over-spill to maintain separation between aseptically gowned personnel and the operating environment. It is subject to a high level of disinfection prior to use in aseptic process. It uses decontaminated (where necessary) interfaces or RTPs for materials transfer. It allows for the ingress and or egress of materials trough defined openings that have between designed and validated to preclude the transfer of contamination. If opened subsequent decontamination, its performance capability is adversely impacted.
- Risk Assessment Analysis –Analysis of the identification of contamination potential in controlled environments that establish priorities in terms of severity and frequency and that will develop methods and procedures that will eliminate, reduce, minimize, or mitigate their potential for microbial contamination of the product/container/closure system.
- Sampling Plan – A documented plan that describes the procedures and methods for sampling a controlled environment; identifies the sampling sites, the sampling frequency, and number of samples; and describes the method of analysis and how to interpret the results.
- Sampling Sites – Documented geographical location, within a controlled environment, where sampling for microbiological evaluation is taken. In general, sampling sites are selected because of their potential for product/container/closure contacts.

REFERENCE

USP 38 – The United States Pharmacopeial – Document (1116) Aseptic Processing Environments -Page 1201, 1202

APPLICATION NOTES

By AROUND LAB NEWS

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N.82 Sampling viable organisms by microbial active air samplers

Importance of the impaction on agar surface.

Effect of jet velocity, nozzle size, nozzle distance from the agar surface, quality of medium, volume of medium inside the culture, expiration date of the plate, moisture content and sterility of the medium, temperature should be considered to obtain the optimization of these variables. These facts are determinative to obtain an efficient design of a microbial air sampler.
ISO-14698 standard mentions that impaction velocity should be less than 20 metres per second.
No air sampling device is perfect for all particles of different dimensions. Different organisms may be more robust than others and sizes vary widely so any design of sampling head can be no more than the best possible compromise.
An important aspect of the impaction on the agar surface is total number and the diameter of the holes in the aspirating head.
All these variables were considered in the development and production of the microbial air sampler TRIO.BAS.

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www.triobas.com

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zeller GmbH

Labworld.at Laborgeräte - Glas - Reagenzien
Mikrobiologie - Hygienekontrolle
Industriestr. 1, 6845 Hohenems, Austria
Tel. +43 (0)5576 76705 Fax +43 (0)5576 76705 7
Email: office@labworld.at