TRIO.BAS™

BIOLOGICAL AIR SAMPLER

The most complete line of impact microbial air sampling instruments available

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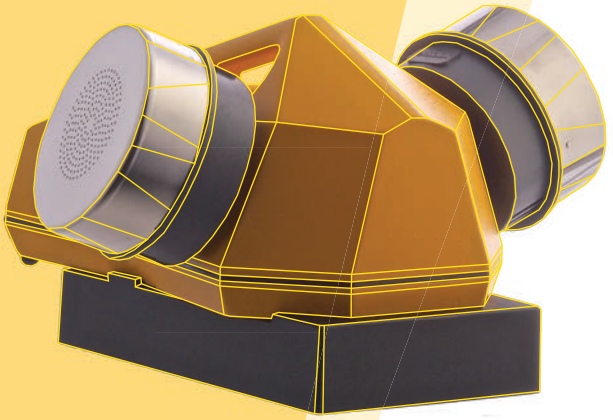
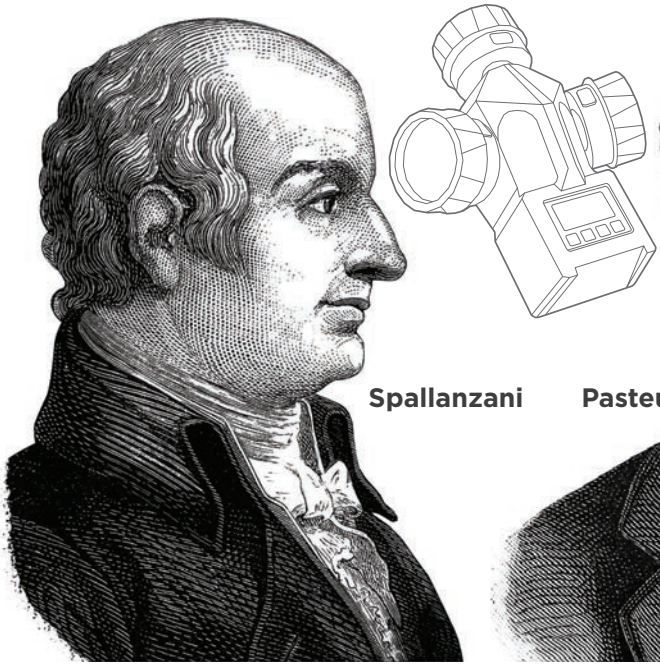


Applicable Industries:

- Pharmaceutical/ Biotechnology
- Compounding Pharmacy
- Medical Device Manufacturer
- Sterile Product Packager
- Hospital/Surgical
- Tissue Lab
- Food/Beverage/Dairy
- Cannabis
- Aerospace
- Cosmetics/Personal Care

THE DISCOVERY OF AIRBORNE ORGANISMS

Lazzaro Spallanzani in the 1700's, and Louis Pasteur in the 1800's, were the two scientists who first demonstrated the presence of microorganisms in the air after several years of experimentation. After three centuries, it is now possible to perform the same test in a few minutes. Presenting the new generation of microbial air samplers, by the original engineers of the first portable air samplers introduced over 40 years ago.



Spallanzani

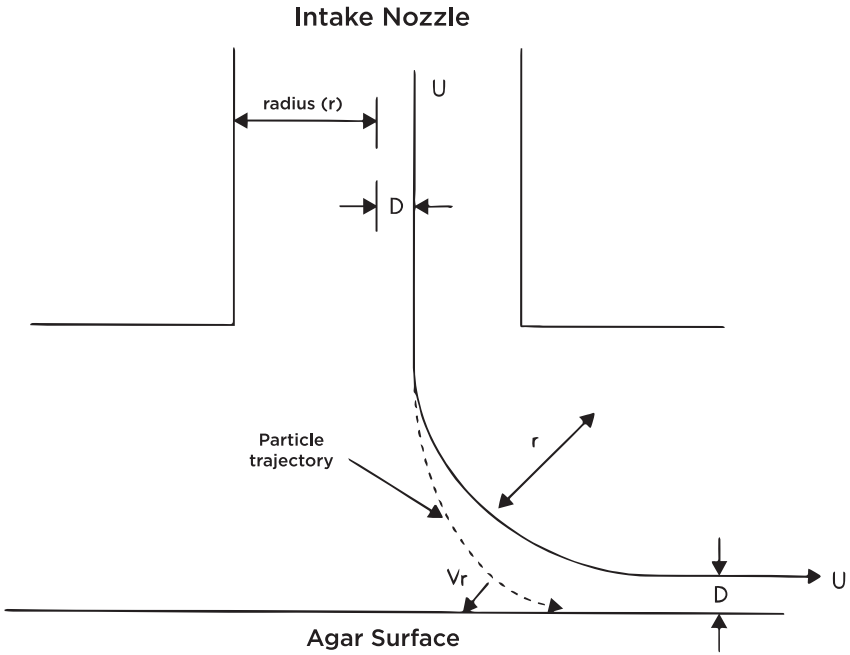
Pasteur

Principle of microbial air sampling by impact method on agar plate

Air, containing microbe-carrying particles, is aspirated and accelerated through an intake and directly towards the 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 agar is then incubated for the appropriate time and at the proper temperature. 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 an agar surface:
The aspirated air passes through an intake 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 around 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

REGULATIONS

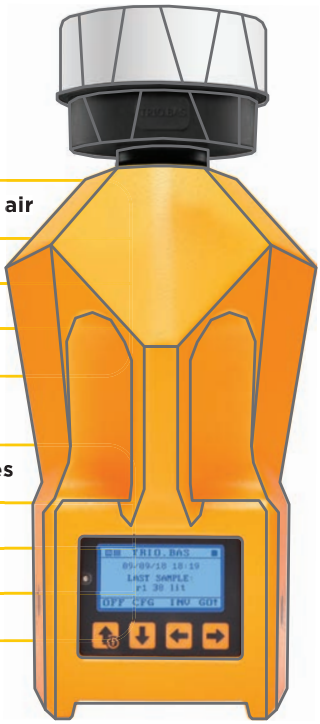
USP Regulation <797>

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 compounding. Originally enacted on January 1, 2004, the latest version becomes official in December, 2019.

USP <797> is a broad regulation covering a variety of pharmacy policies and procedures; designed to reduce the number of patient infections due to contaminated pharmaceutical preparations.

USP <797> contains specific requirements for ongoing air and surface evaluation to ensure product sterility and safety for compounded sterile preparations (CSPs).

Recommended Action Levels for microbial contamination:



Viable Air Sampling

Classification	CFU/1000 liters of air
ISO Class 5	>1
ISO Class 7	>10
ISO Class 8 or worse	>100

Surface Sampling

Classification	CFU/Contact 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 patient health.

Suggested frequency and microbial recovery rates for aseptic processing areas

The USP <1116> - The United States Pharmacopeial Document

Table 2: Suggested Frequency of Sampling for Aseptic Processing Areas

Clean Room/RABS	
Sampling Area/Location	**Frequency of Sampling**
Clean Room/RABS	
Critical zone (ISO 5 or better)	
Active air sampling	Each operational shift
Surface monitoring	At the end of the operation
Aseptic area adjacent critical zone	
All sampling	Each operating shift
Other nonadjacent aseptic areas	
All sampling	Once per day
Isolators	
Critical zone (ISO 5 or better)	
Active Air Sampling:	Once a day
Surface Monitoring:	At the end of the campaign
Non-aseptic areas surrounding the isolator	
All sampling	Once per month

The USP <1116> – The United States Pharmacopeial Document

Table 3: Suggested Initial Contamination Recovery Rates in Aseptic Environments

Room Classification	Active Air Sample (%)	Settle Plate (9cm) 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

MINI

Ideal for use in less critical environments

Each kit includes:

- TRIO.BAS MINI Bluetooth air sampler
- Battery charger and cable
- Aspirating head
- Cover head
- LIGHT carrying case
- Calibration certificate

Features:

- Aspirating head with quick bayonet closure system for easy manipulation
- Light weight: Significantly lighter than industry counterparts
- Rechargeable via external port using standard wall charger
- Note: Sampling data must be manually recorded with the MINI

	VWR Cat. no.
MINI Kit, 100 liters/min., contact plate	76076–694
MINI Kit, 100 liters/min., Petri plate	76169–638
MINI Kit, 200 liters/min., contact plate	76076–696
MINI Kit, 200 liters/min., Petri plate	76169–640

MONO induction

Ideal for cleanroom use

Each kit includes:

- TRIO.BAS MONO air sampler
- Induction battery charger and cable
- Aspirating head
- Cover head
- ROBUSTUS carrying case
- Calibration certificate
- IQ, OQ, PQ fillable document

Features:

- No plugs or external connections
- Delayed interval sampling and remote start capabilities
- Data transfer capability via Bluetooth.
  (*Separate purchase required.* ***See page 15***)
- MONO certified to ATEX standards also available

	VWR Cat. no.
MONO Kit, 100 liters/min., contact plate	76076–704
MONO Kit, 100 liters/min., Petri plate	76169–642
MONO Kit, 200 liters/min., contact plate	76076–706
MONO Kit, 200 liters/min., Petri plate	76169–644

DUO induction

Achieve faster sampling times and better statistical results with the DUO!

Ideal for cleanroom use

Each kit includes:

- TRIO.BAS DUO air sampler
- Induction battery charger and cable
- Aspirating heads
- Cover heads
- ROBUSTUS carrying case
- Calibration certificate
- IQ, OQ, PQ fillable document

Features:

- No plugs or external connections
- Two aspirating heads for sampling on separate plates to determine bacterial and yeast/mold counts
- Programmable for simultaneous or interval aspirating times
- Data transfer capability via Bluetooth. (*Separate purchase required.* ***See page 15***)
- Ask about DUO certified to ATEX standards

	VWR Cat. no.
DUO Kit, 100 liters/min., contact plate	76076–708
DUO Kit, 100 liters/min., Petri plate	76169–646
DUO Kit, 200 liters/min., contact plate	76076–710
DUO Kit, 200 liters/min., Petri plate	76169–648

TRIO

Ideal for cleanroom use

The only active microbial air sampler currently on the market with three sampling heads. Achieve faster sampling times and better statistical results with the TRIO!

Each kit includes:

- TRIO.BAS TRIO air sampler
- Induction battery charger and cable
- Aspirating heads
- Cover heads
- ROBUSTUS carrying case
- Calibration certificate
- IQ, OQ, PQ fillable document

Features:

- Three aspirating heads with ability to sample before, during and after operations
- Able to collect samples on three different culture media plates or sample on separate plates of same medium to obtain statistically significant results according to GMP
- No plugs or external connections
- Data transfer capability via Bluetooth.
  (*Separate purchase required.* ***See page 15***)

	VWR Cat. no.
TRIO Kit, 100 liters/min., contact plate	76169–650
TRIO Kit, 100 liters/min., Petri plate	76169–654
TRIO Kit, 200 liters/min., contact plate	76169–656
TRIO Kit, 200 liters/min., Petri plate	76169–658

MONO & DUO cable

WITH SAMPLING DATA TRANSFER CABLE

A solution to capturing data for facilities concerned with data transmissions, or that do not permit wireless transfer of information. Data from the instrument memory can be transferred to a PC via the included transfer cable and dedicated software (see VWR Cat. no. 75804-738, required for data download to another device).

TRIO.BAS MONO with Sampling Data Transfer Cable

Each kit includes:

- Instrument
- Stainless steel aspirating head
- Protective cover head
- Charging and Transfer cables
- ROBUSTUS carrying case
- IQ, OQ, PQ fillable document

	VWR Cat. no.
MONO Kit, 100 liters/min., contact plate	76288–236
MONO Kit, 100 liters/min., Petri plate	76288–238
MONO Kit, 200 liters/min., contact plate	76288–240
MONO Kit, 200 liters/min., Petri plate	76288–242

TRIO.BAS DUO with Sampling Data Transfer Cable

Each kit includes:

- Instrument
- Two stainless steel aspirating heads
- Two protective cover heads
- Charging and Transfer cables
- ROBUSTUS carrying case
- IQ, OQ, PQ fillable document

	VWR Cat. no.
MONO Kit, 100 liters/min., contact plate	76288–244
MONO Kit, 100 liters/min., Petri plate	76288–250
MONO Kit, 200 liters/min., contact plate	76288–246
MONO Kit, 200 liters/min., Petri plate	76288–248

RABS ISOLATOR

AIR SAMPLER FOR USE IN ISOLATORS AND RABS

An external command unit and one satellite. AISI 316 stainless steel construction.

Each kit includes:

- Instrument
- Satellite aspirating head
- Stainless steel head cover
- Five meter long satellite attachment cable
- Charging and Data transfer cables
- Robustus carrying case
- Calibration certificate
- IQ OQ PQ fillable documents

Features:

- Option to add two additional satellites (see satellite kit information below)
- Use separate media at the same time to determine bacterial and fungal counts
- 100 or 200 liter per minute formats, contact plate or Petri plate formats
- Charges via cable; Sample up to 70,000 liters on a single battery charge
- Can monitor separate cleanrooms with a single external command unit
- Bluetooth data transfer capability *(requires an additional purchase.* ***See page 15****)*

	VWR Cat. no.
RABS ISOLATOR 1 Satellite Pack, 100 liters/min., contact plate	76377–520
RABS ISOLATOR 1 Satellite Pack, 100 liters/min., Petri plate	76377–522
RABS ISOLATOR 1 Satellite Pack, 200 liters/min., contact plate	76377–524
RABS ISOLATOR 1 Satellite Pack, 200 liters/min., Petri plate	76377–526

Satellite Kits with Cables

Each kit includes:

- Satellite air sampling chamber
- Stainless steel aspirating head
- Stainless steel head cover
- Five meter long satellite attachment cable
- LIGHT carrying case

Contact..... 76169–668
Petri..... 76169–670

MULTIFLEX 1+2

One external command unit with fixed air sampling chamber plus two independent sampling satellites. AISI 316 Stainless Steel construction.

Each kit includes:

- Instrument
- Two stainless steel aspirating heads
- Two stainless steel head covers
- Two, five meter long satellite attachment cable
- Charging and Data transfer cables
- Robustus carrying case
- Calibration certificate
- IQ OQ PQ fillable documents
- Monitor separate cleanrooms with a single external command unit and two satellites connected to five meter long cables
- Use separate culture media at the same time to determine bacterial and fungal counts
- 100 or 200 liter per minute formats
- Contact plate or mono Petri plate formats
- Charges via cable: Sample up to 70,000 liters on a single battery charge
- Bluetooth data transfer capability *(requires an additional purchase.* ***See page 15****)*

	VWR Cat. no.
MULTIFLEX 1+2, 100 liters/min., contact plate	76377–528
MULTIFLEX 1+2, 100 liters/min., Petri plate	76377–530
MULTIFLEX 1+2, 200 liters/min., contact plate	76377–532
MULTIFLEX 1+2, 200 liters/min., Petri plate	76377–534

TRIO.GAS

Designed to test the presence of microorganisms in compressed air or gas lines.

- Calibrated regulator guarantees 100 liters per minute flow rate
- Autoclavable with no disassembly required
- Automated to end sample after programmed volume is reached*
- Signal lets operator know sample is complete*
- Sampling data is retrievable for download via proprietary printer or dedicated software (MONO) or to record manually (MINI).
- No glass valves or meters to crack or break

**When used with MONO or MINI instrument*

Each kit includes:

- Stainless steel electro-valve
- Gas connection
- Stainless steel fixing system for air sampler
- MINI or MONO unit
- Induction battery charger and cable
- Aspirating head
- Cover head
- LIGHT carrying case
- Two IQ, OQ, PQ fillable documents

	VWR Cat. no.
TRIO.GAS System + MONO air sampler, 100 liters/min., contact plate	76196–430
TRIO.GAS System + MONO air sampler, 100 liters/min., Petri plate	76196–432
TRIO.GAS System + MINI air sampler, 100 liters/min., contact plate	76196–438
TRIO.GAS System + MINI air sampler, 100 liters/min., Petri plate	76196–440

TRIO.GAS System Aspirating Chamber Kit

Each kit includes:

- Stainless steel electro-valve
- Gas connection
- Stainless steel fixing system for air sampler
- Aspirating head
- Cover head
- Carrying case
- IQ, OQ, PQ fillable documents
- MONO or MINI NOT included

Important Note:

If ***manually*** timed samples and hand recorded sampling data is acceptable, the MINI or MONO instrument is not necessary. Purchase the GAS system 76196-434 or 76196-436, which includes aspirating gas chambers. Choose kit based on preferred plate size.

	VWR Cat. no.
TRIO.GAS System Aspirating chamber kit, contact plate	76196–434
TRIO.GAS System Aspirating chamber kit, Petri plate	76196–436

AIRBIO DUO cable

Work surface stability with two aspirating heads. Save sampling time by doubling the aspirated volume of air!

Picture shows the instrument with optional Daily Shift Heads in use (see page 16).

Each kit includes:

- Instrument
- Two stainless steel aspirating heads
- Two stainless steel head covers
- Charging and Data transfer cables
- Robustus carrying case
- Calibration certificate
- IQ OQ PQ fillable documents

- Use separate culture media at the same time to determine bacterial and fungal counts
- 100 or 200 liter per minute formats
- Contact plate or mono Petri plate formats
- Charges via cable: Sample up to 70,000 liters on a single battery charge
- Programmable options include up to 100 place IDs and 100 Operator IDs
- Bluetooth data transfer capability *(requires an additional purchase.* ***See page 15****)*

	VWR Cat. no.
AIRBIO DUO cable, 100 liters/min., contact plate	76377–536
AIRBIO DUO cable, 100 liters/min., Petri plate	76377–538
AIRBIO DUO cable, 200 liters/min., contact plate	76377–540
AIRBIO DUO cable, 200 liters/min., Petri plate	76377–542

MINI for CompactDry™

TRIO.BAS MINI designed specifically for CompactDry™ media.

Each kit includes:

- TRIO.BAS MINI air sampler
- Charging cable
- Stainless steel aspirating head
- Protective cover head
- Carrying case
- CompactDry™ plates sold separately

	VWR Cat. no.
CompactDry Kit, 100 liters/minute	76308–448

DATA TRANSFER

DATA INTEGRITY VERIFIED

For TRIO.BAS instruments with Bluetooth or cable Data Transfer Capability, choose the preferred data download method. A separate purchase is required.

Tablet Device*

(for data transfer)
Portable tablet for remote control of instrument(s), data download storage and transfer capabilities.
**Requires CD software* 75804–738*

Each 76169–672

CD Software*

Enables data transfer capability from instrument or smart phone/tablet to PC by Bluetooth.
**For Bluetooth capable Windows systems*

Each 75804–738

Bluetooth Printer

Small footprint. Pair with instrument for immediate printout of sampling data, or choose to store data and print out sampling history at a later date.

Bluetooth printer, 11 x 8 x 5 75994–470
Paper rolls (57mm, 10/bx) 75804–704

Bluetooth Key*

For transferring sampling data to a PC that does not include built-in Bluetooth feature.
**Requires CD software* 75804–738

Each 75804–702

DAILY SHIFT HEADS

Individually packaged, sterile by irradiation, and includes a certificate of sterility assurance. For use on the MINI, MONO, DUO, TRIO and MULTISTATION units. Technopolymer aspirating heads are ready for immediate cleanroom use.

Benefits of Daily Shift Heads:

- A daily certificate of sterilization assurance is requested by regulatory authorities as part of the usual auditing process. Use of DAILY SHIFT aspirating heads eliminates the cost of sterilization after each sample cycle and the consequent task of preparing the certificate of sterility
- DAILY SHIFT heads offer convenience and time savings during periods of unusually heavy workloads
- DAILY SHIFT heads offer peace of mind in case of autoclave breakage or unavailability
- DAILY SHIFT heads can be used on the same day, on the same shift, inside the same cleanroom
- Semi-transparent to confirm agar plate has been properly inserted
- Six year shelf life from date of sterilization

	VWR Cat. no.
DAILY SHIFT HEAD, contact plate, 27/bx	75804–756
DAILY SHIFT HEAD, Petri plate, 27/bx	75804–758

ACCESSORIES

Technopolymer Standup Holder
for MINI
Each 75804–694

Stainless Steel Wall Holder
for wall mount or table
Each.....75994–450

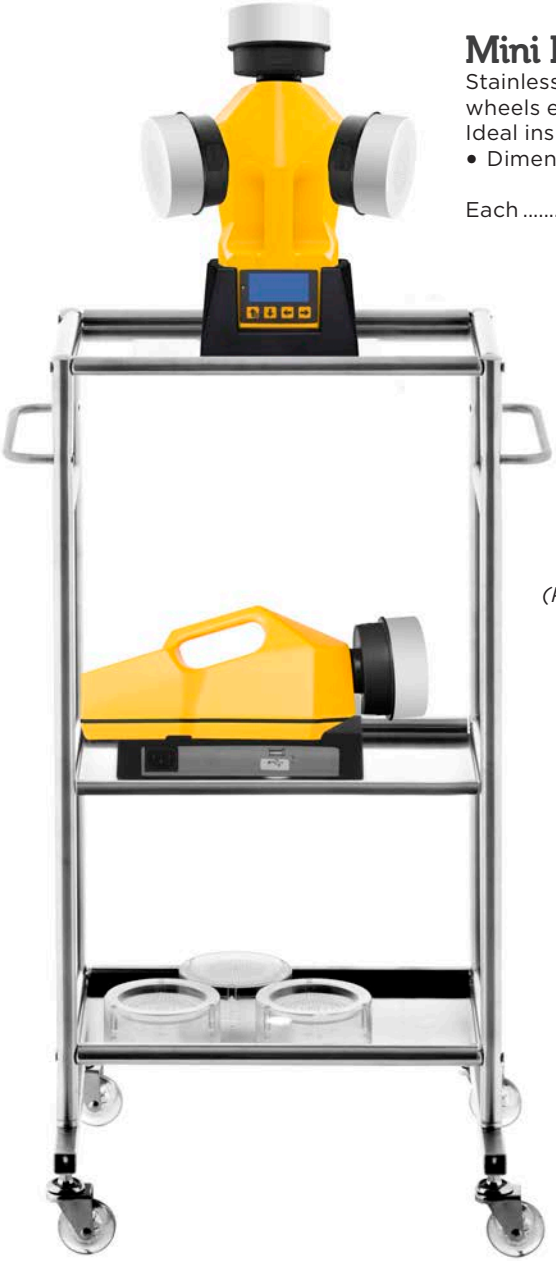
Soft Carrying Case
for MINI and MONO
Each.....75804–698

Aluminum Tripod
56cm to 153cm.
Device not included.
Each 75804–696

Stainless Steel AISI 316 Tripod
150cm to 200cm. Ideal for cleanroom use.
Device not included.
Each 75994–454

Stainless Steel Vertical Hook and Knob
Each 75994–446

MULTI HOLDER CARTS



Mini Multi Holder Cart

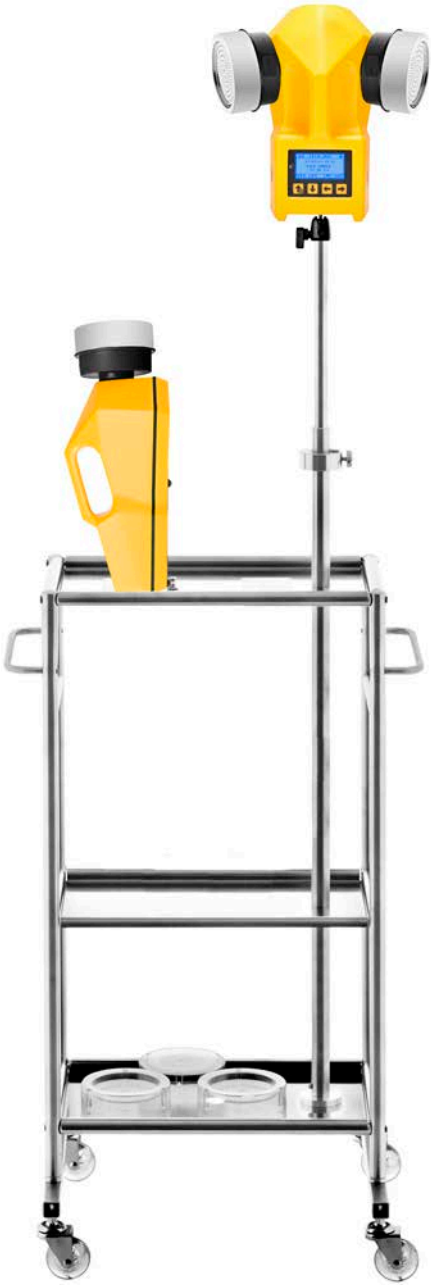
Stainless steel AISI 316 cart on wheels equipped with three shelves. Ideal inside cleanroom.

- Dimensions: 25x35x70cm

Each 75994–452

(Pictured with TRIO, MONO and stand, not included)

MULTI HOLDER CARTS



Maxi Multi Holder Cart

Stainless steel AISI 316 cart on wheels with fixed vertical hook holder and adjustable vertical extension post. Ideal inside cleanroom.

- Dimensions: 25x35x70cm
- Extension post adjustable height: 100cm to 210cm

Each 76288–234

(Pictured with DUO and MONO, not included)

CALIBRATION CONTROL EQUIPMENT

Proper calibration of air sampling devices is a requirement per the USP. Hardy Diagnostics' ISO 17025 certified lab is the factory trained and sole North American calibration service center for TRIO.BAS air sampling instruments. *For detailed information, please see the **TRIO.BAS Instrument Services** tab located under **Product Support** on our website:* ***HardyDiagnostics.com/air-sampler-calibration/***

Self Test

A manual verification instrument to check the precision of air flow rate. **For control purposes only**; not to take the place of annual, official calibrations. 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, the ability to check the state of precision of the air flow. **Only compatible with induction battery charging system instrument formats**.

Calibration System includes:

- Calibration bell
- Connector cable and charger with outlet plug

Instrument not included

For 100 liter/min. flow instrument..... 75804–760

For 200 liter/min. flow instrument..... 75804–762

VERITEST

A manual verification instrument to check the precision of air flow rate. **For control purposes only**; not to take the place of annual, official calibrations. Ideal for verifying calibration on instruments with direct data transfer cables including the following: *76288-248, 76288-246, 76288-244, 76288-250, 76288-236, 76288-238, 76288-240, 76288-242.*

Each.....76288–232

PREPARED CULTURE MEDIA and CompactDry™

Mono Plates

Malt Extract Agar
For the cultivation and enumeration of yeasts and molds. 15x100mm plate, 10/pk..... 89407–712

TSA (Tryptic Soy Agar), SterEM™, USP
General growth medium for the detection and enumeration of microorganisms. Irradiated, 15x100mm plate, triple bagged, 10/pk 76200–294

TSA (Tryptic Soy Agar), USP
General growth medium for the detection and enumeration of microorganisms. 15x100mm plate, 26ml fill, 10/pk..... 89408–004

SabDex (Sabouraud Dextrose) Agar, SterEM™, USP
For the cultivation of fungi. Irradiated, 15x100mm plate, triple bagged, 10/pk 10324–404

SabDex (Sabouraud Dextrose) Agar
For the cultivation of fungi. 15x100mm plate, 10/pk..... 89407–894

Contact Plates

TSA (Tryptic Soy Agar)
With Lecithin and Tween® 80, USP, contact plate with Lok-Tight™ friction lid, 10/pk..... 89408–026

SabDex (Sabouraud Dextrose) Agar
With Lok-Tight™ friction lid, for surface testing, 10/pk..... 89407–878

Malt Extract Agar
With Lecithin and Tween® with Lok-Tight™ friction lid, 10/pk..... 89407–708

TSA with Lecithin and Tween® 80, USP
For the cultivation and enumeration of microorganisms with Lok-Tight™ lid. Irradiated, triple bagged, 10/pk..... 76200–280

SabDex Agar with Lecithin & Tween® 80, USP
For the cultivation of fungi. With Lok-Tight™ lid. Irradiated, triple bagged, 10/pk..... 76200–284

CompactDry™ Media

Total Plate Count
CompactDry™ TC, Total Plate Count, 100/box.....10145–968

Yeast & Mold
CompactDry™ YM, Yeast and Mold, 100/box.....10145–972

Yeast & Mold Rapid
CompactDry™ YMR, Yeast Mold Rapid, 100/box.....76076–714

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0120 Lit. No. 080006WREV2

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