ENGLISH

M Air T

Millipore Air Tester

Operation and Maintenance Instructions

CONTENTS

INTRODUCTION

Congratulations on choosing the **M Air T**, one of the most innovative concepts for airborne microbial monitoring.

The Tester consists of easy to handle equipment designed to test airborne contamination from Clean Room Class 100,000 (SI: M6.5) down to Clean Room Class 100 (SI: M3.5).

This is the first truly portable Tester providing recoveries that are comparable with the Slit-To-Agar Method upon which the United States Pharmacopoeia's Guidelines for clean rooms are based (Eighth Supplement, USP-NF, p. 4429).

It uses a unique agar cassette design* ensuring consistent nutrition capability of the agar surface.

The cassette consists of a dark body to enhance contrast, and an integrated grid to partition the large surface into smaller areas for easier enumeration of colonies.

The sieve of the Tester contains close to 1,000 micro-perforations. This minimizes colony overlapping.

During incubation, a dynamic process re-hydrates the impacted agar surface, providing faster results and higher recoveries.

The M Air T is ideal for performing environmental surveys in a variety of applications.

*Patent pending.

APPLICATIONS

Pharmaceuticals

- Determine microbiological quality of laminar flow hoods.
- Trend analysis of aseptic filling areas.
- Assess decontamination procedures.

Food and Beverages

- Evaluate airborne contamination, critical in HACCP.

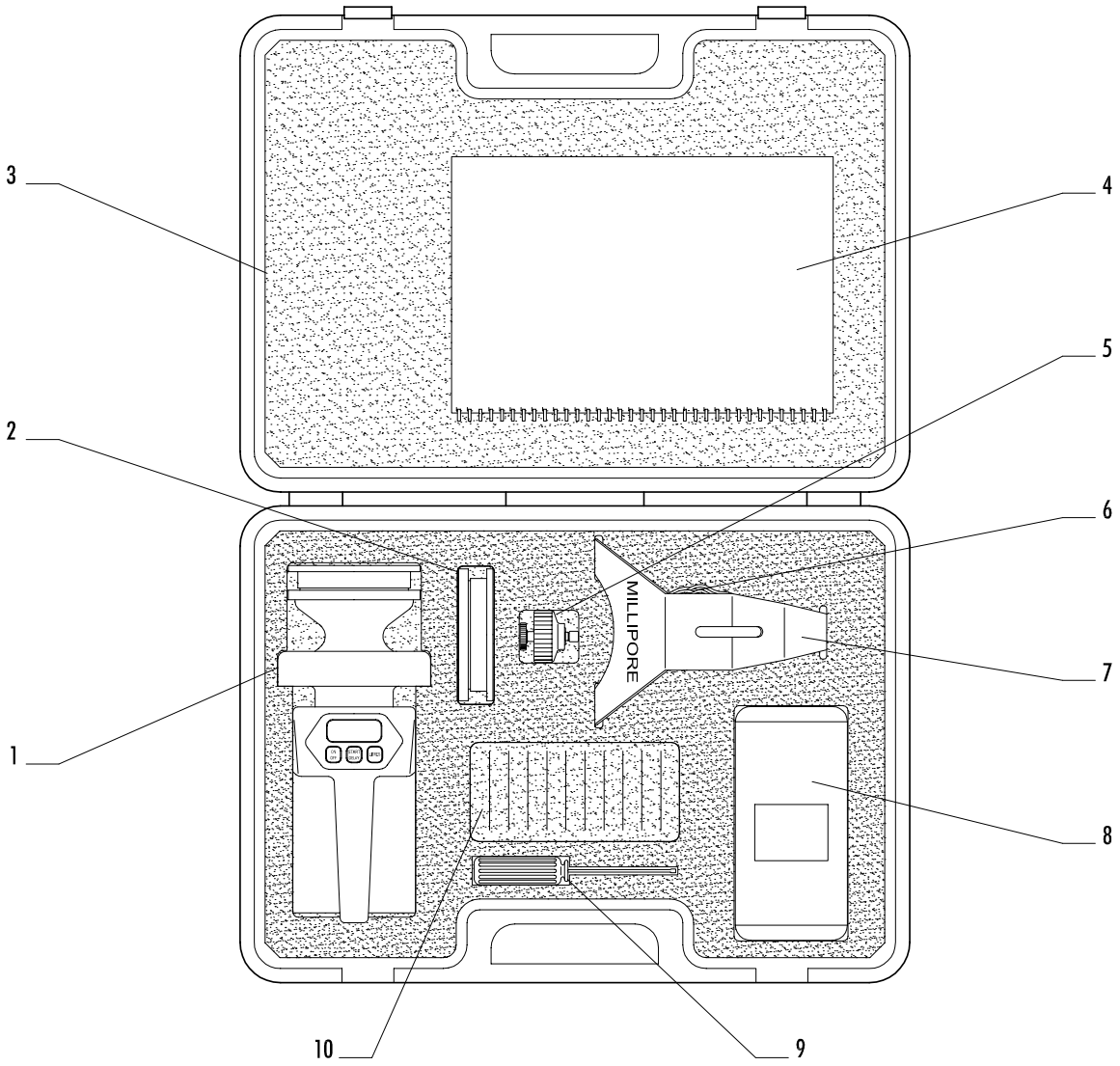
Hospitals

- Detect airborne pathogenic microorganisms in the pharmacy, surgical suites, or other critical patient care areas.

Electronic Industry

- Differentiate between particulate and microbial contamination in clean rooms.

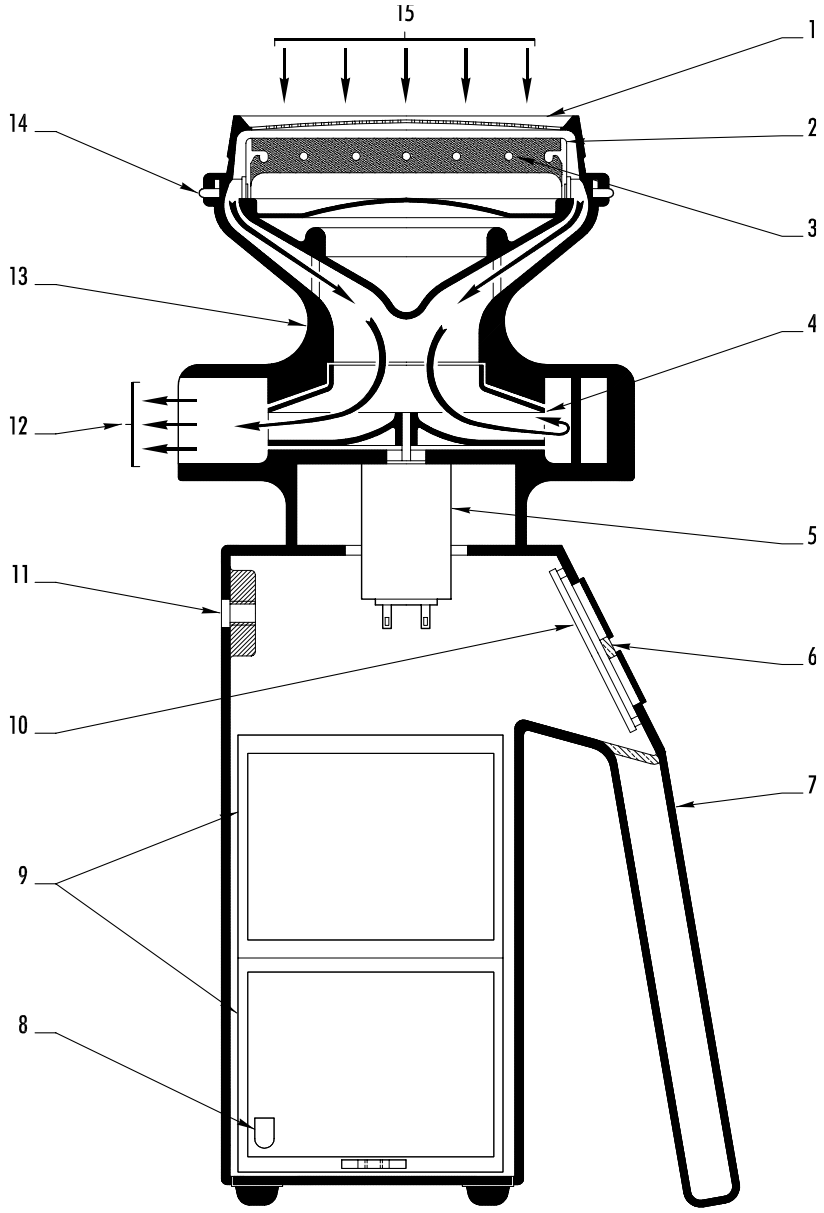
COMPONENTS



Each M Air T Kit includes:

1	M Air T Apparatus	**6**	Battery Charger
2	Spare Micro-perforated Sieve with Cover	**7**	Tripod
3	Carrying Case	**8**	Box of Sanitization Wipes
4	Operation and Maintenance Instructions Manual	**9**	Allen Key
5	Tripod fixation Screw	**10**	Free space

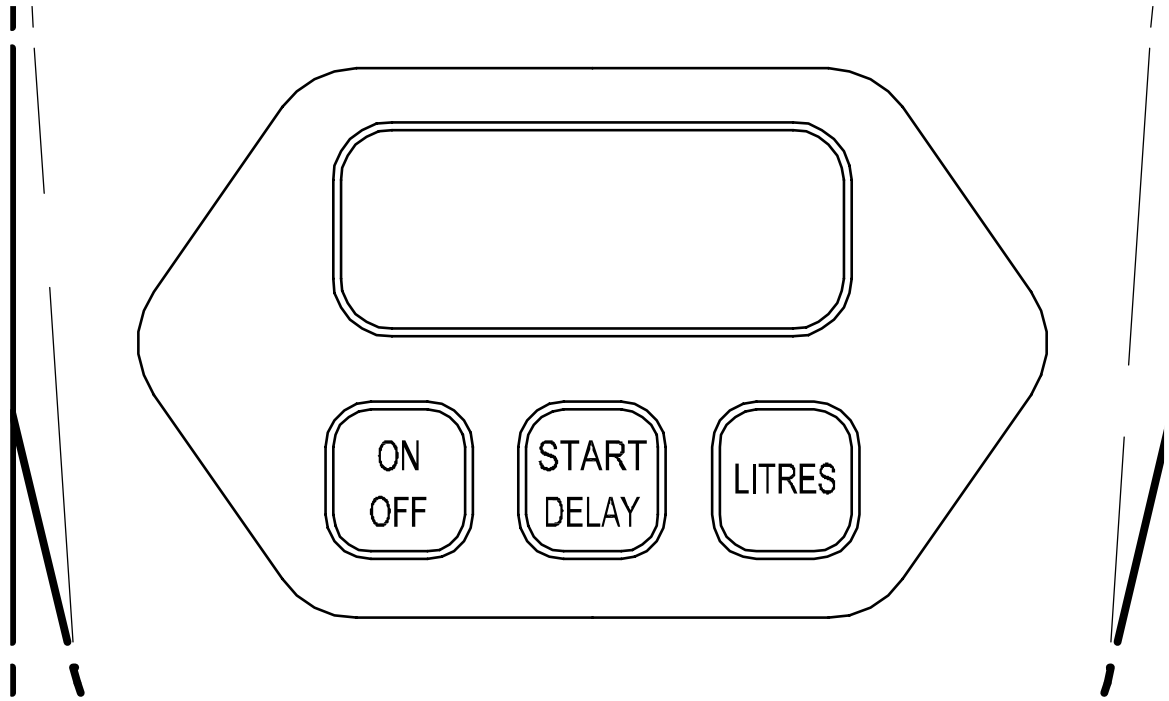
COMPONENTS



Glossary

1	Micro-perforated Sieve
2	M Air T Cassette
3	Agar Medium
4	Aspiration Turbine
5	Motor
6	LCD Display
7	Handle
8	Charger plug for Batteries
9	Batteries
10	Electronic Circuits
11	Tripod fixation Hole
12	Air Outlet
13	Aerodynamic Sleeve
14	Bayonet Lock
15	Air Inlet

SETTING PARAMETERS



Switching the Tester ON:

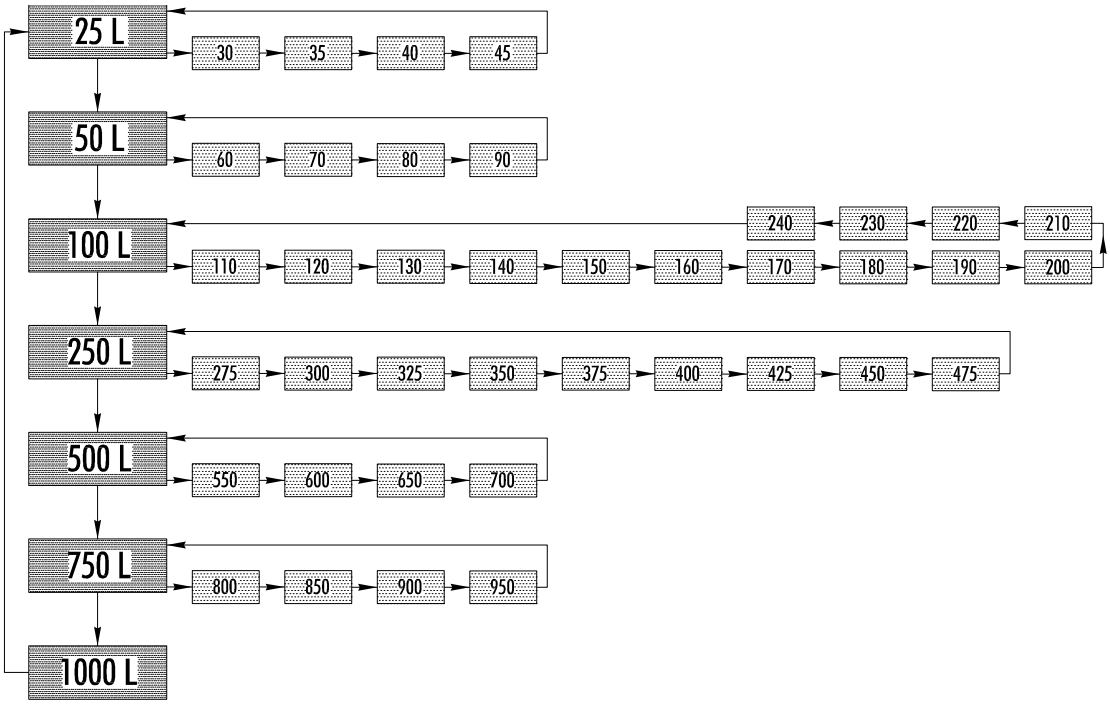
1. **Push the ON / OFF button.**
   Previously selected air sample volume retained in memory appears on the display to make successive sampling easier.
2. **Press the START / DELAY button quickly twice.**
   The display flashes, Tester starts and counts down the volume of air that remains to be processed.
   At the end of the process the display indicates EOC (End Of Cycle).

Adjusting the volume to be processed:

1. **Push the LITRES button.**
   The previously selected volume appears on the display.
2. **To access other preset volumes:**
   Press the Litres button once.
   Preset volumes are**:**
   25 L, 50 L, 100 L, 250 L, 500 L, 750 L, 1000 L.
   (See Cubic Feet Conversion Chart.)
3. **To change the volume setting:**
   Select the preset volume that is just below the volume you want to process.
   Then hold the Litres button down until the Tester display indicates the desired sampling volume.

SETTING PARAMETERS

Preset sampling volumes available are:



Start sampling by pressing the START / DELAY button twice.

Conversion Chart: Litres vs. Cubic Feet

Litres	Cubic Feet	Litres	Cubic Feet	Litres	Cubic Feet	Litres	Cubic Feet
25	**0.88**	120	**4.24**	240	**8.47**	550	**19.4**
30	**1.06**	130	**4.59**	250	**8.83**	600	**21.2**
35	**1.24**	140	**4.94**	275	**9.71**	650	**22.9**
40	**1.41**	150	**5.30**	300	**10.6**	700	**24.7**
45	**1.59**	160	**5.65**	325	**11.5**	750	**26.5**
50	**1.77**	170	**6.00**	350	**12.3**	800	**28.2**
60	**2.12**	180	**6.35**	375	**13.2**	850	**30.0**
70	**2.47**	190	**6.71**	400	**14.1**	900	**31.8**
80	**2.82**	200	**7.06**	425	**15.0**	950	**33.5**
90	**3.18**	210	**7.41**	450	**15.9**	1000	**35.3**
100	**3.53**	220	**7.77**	475	**16.8**		
110	**3.88**	230	**8.12**	500	**17.7**		

SETTING PARAMETERS

Adjusting the Timer:

1. To modify the time setting, hold down the START / DELAY button. The display shows previously selected value and starts to count down the time. (LCD display flashes.)

   Time can be changed in increments of 5 minutes up to one hour.

2. To validate and start the count down, press down on the START / DELAY button again.

3. To stop, press the ON / OFF button.

INSTALLING A CASSETTE AND TESTING

Define the location of the Tester according to GMP requirements.

The Tester works in the upright position or, by using a tripod, in the horizontal or inclined position.

For testing above bench level, the Tester may be supported by a commercial tripod.

Ensure pre-filled cassettes are at room temperature before starting the test.

Running the Tester:

1. Unlock and remove the micro-perforated sieve from the Tester (Fig.1).

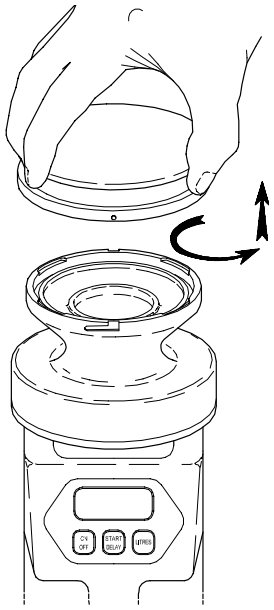
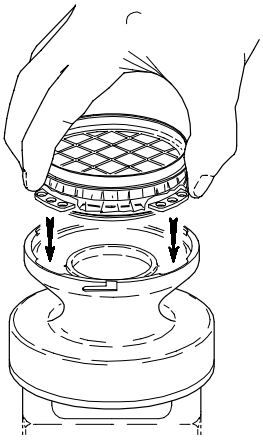
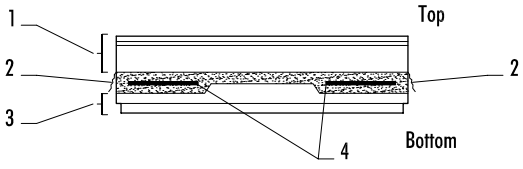


Fig. 1

2. Remove the cover from the sieve. Autoclave the sieve for 30 minutes at 121 ℃ and sanitize the external surfaces of the Tester with alcohol.

3. Position the wings of the cassette into the recessed area of the Tester head (Fig. 2).





Schematic of a Cassette

1 Lid
2 Inert Film
3 Bottom Cover
4 Wings

Fig. 2

INSTALLING A CASSETTE AND TESTING

4. Retain the cassette in position by holding on to its wings. Remove the lid and place it on the bench, internal face down. Peel off the inert film from the agar surface (Fig. 3).

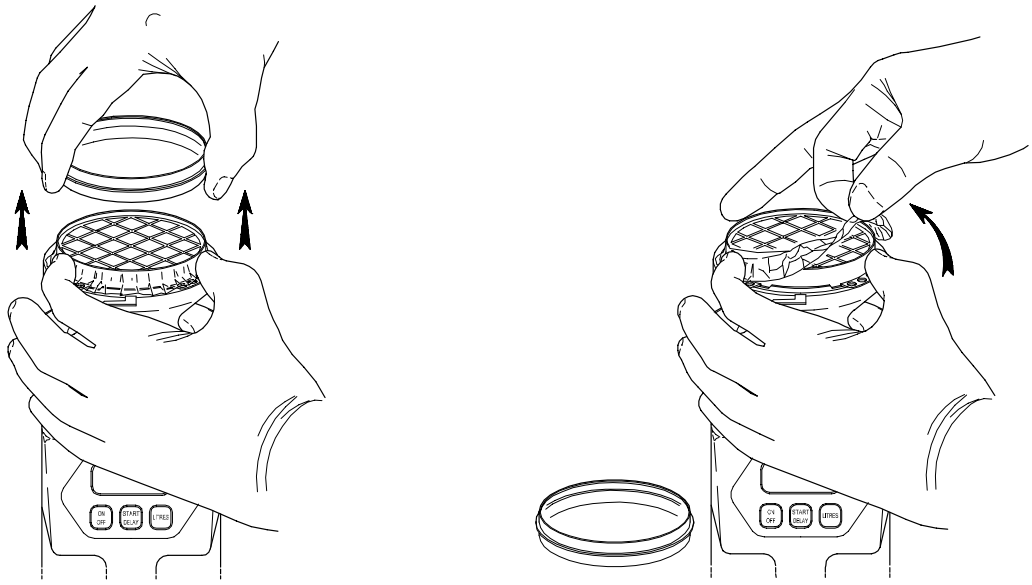


Fig. 3

5. Lock the micro-perforated sieve into position.

6. Press the ON / OFF button. Set the sampling parameters, then quickly press the START / DELAY button twice (Fig. 4).

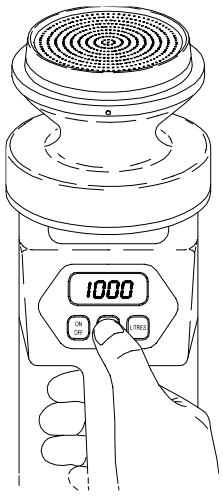


Fig. 4

7. When the display indicates EOC, unlock the sieve, remove it, and put the lid back on the cassette (Fig. 5).

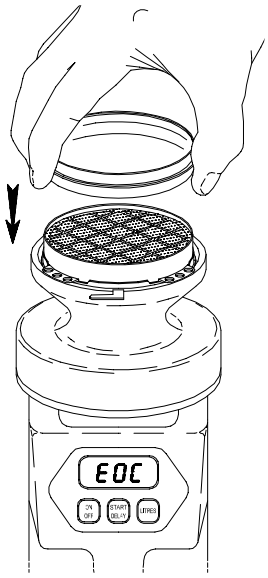


Fig. 5

8. To remove the cassette from the Tester head, lift the cassette while firmly holding the edge (Fig. 6).

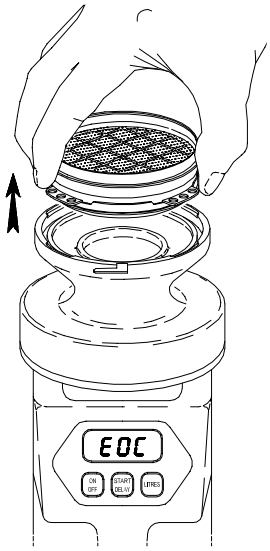


Fig. 6

9. Label and incubate the cassette in the upside down position.

Using the Tester in horizontal or inclined position:

The tripod enables to use the Tester in two different positions:
horizontally or at 30° from the horizontal position.
Fix the tripod onto the Tester by screwing it into the Tester fixing hole.
Run the Tester.

MAINTAINING THE SYSTEM

The micro-perforated sieve can be cleaned with mild detergent, decontaminated with 70° alcohol or autoclaved.

Do not use bleach solution.

The surface of the Tester is compatible with mild detergent and can be decontaminated with alcohol, quaternary ammonium or 250 ppm bleach.

Precautions

- Do not use oxidizing agents such as hydrogen peroxide or peracetic acid.
- Avoid spraying liquids into the Tester.
- Do not autoclave or flame the entire Tester. The stainless steel micro-perforated sieve can be autoclaved without its cover.
- Do not open the Tester head.

REPLACING BATTERIES

The Tester is supplied with a charger specifically designed for use in critical areas.

When the icon "  " starts to flash on the LCD display, the batteries should be charged. Once the flashing starts, the system still has enough power left to process approximately 15 more sampling cycles.

When the charger is plugged into the Tester, the LCD display shows :**"AC**" (ACTIVE CHARGE).

The battery icon remains visible on the LCD display until the batteries are completely charged.

An electronic device operates during the Charge / Discharge cycle of the Tester to maximize the life of the batteries.

Replacement batteries: Model R 14 (1.2 V – 2.2 Ah).

You may also use non rechargeable batteries instead of Cadmium / Nickel batteries.

Caution:

- Using other battery types than the one specified may reduce the number of possible tests once the battery icon appears.
- After an extended period without use, the battery icon may flash before processing a test. Recharge the batteries immediately.
- **Do not use the charger with non rechargeable batteries, to avoid damage.**

REPLACING BATTERIES

To replace batteries:

1. Switch OFF the Tester.
2. Remove the two Allen screws under the Tester using the key provided.
3. Remove the used batteries.
4. Replace the used batteries with new ones (Model R14).
5. Tighten the two Allen screws.
6. Charge the new batteries until the battery icon disappears from the LCD display.
7. When switching ON the Tester after replacing the batteries, the LCD display indicates the software version (e.g.:U.01).
8. Press the ON / OFF button to remove this indicator.
9. The Tester is now ready for use.

CALIBRATING THE SYSTEM

Calibration is done by adjusting the voltage supplied to the electric motor.

Millipore provides a Certificate of Calibration with each Tester.

Tests are done in a laboratory certified by an official body of control and measurement.

Millipore recommends you return the Tester to the nearest Millipore subsidiary at least once a year for re-calibration.

For in-house control of the flow rate of the Tester, using the calibration unit, contact your Millipore subsidiary.

SYSTEM SPECIFICATIONS

Dimensions

255 mm height; 105 mm depth; 125 mm length (10" x 4"x 5").

Weight

Weight (including batteries): 1.9 kg (4 lb).

Materials

Micro-perforated Sieve: Stainless Steel 316.
Tester Head: Anodized aluminum.
Tester Body: Epoxy-coated aluminum.

Air Flow Rate

140 L/min for the first 500 litres, then 180 L/min.

Maximum Sample Volume

1000 litres in less than 7 minutes.

Battery Capacity

Up to 7 hours of successive tests.

Calibration Certificate

Included in each Tester box.

Regulatory

CE marked.

TROUBLESHOOTING

If the Tester is not functioning correctly, refer to the following table.
If this is not sufficient, contact your local Millipore Support Office.
See the list of addresses on the rear cover of this manual.

PROBLEM	CAUSE	REMEDIAL ACTION
Display indicates ER 1	Battery charge level too low	Charge batteries
Display indicates ER 2	Something interferes with the turbine	Contact Millipore
Tester doesn't start **Display fixed** **No action pressing any button**	Electronic interference in the software of the Tester	Reset the Tester. Unscrew the rear panel of the Tester. Remove it for a second, then screw it back
Tester doesn't start **Display doesn't give indication**	Battery charge level too low Batteries completely discharged Electronic problem	Connect the Tester through the charger to an external power source. Check if the Tester starts. **Yes:** Batteries discharged **No:** Contact Millipore
Tester doesn't charge the batteries	Batteries too old Electronic problem	Change batteries Contact Millipore
Tester has a short battery life	Check if batteries are well positioned Check if batteries are not too old Electronic control	Open the rear panel of the Tester and check the polarity of the batteries Change the batteries Contact Millipore

Caution: To avoid damage to the turbine, do not open the Tester head.

ORDERING INFORMATION

Description	Qty/Pk	Catalogue No.
Equipment		
M Air T Kit, 230 V/50 Hz, complete with carrying case, including:	**1**	**ATAS 220 01**
M Air T Apparatus	1	ATAS PLR 01
Battery Charger, 230 V/50 Hz	1	ATAC 220 01
Micro-perforated Sieve with Cover	1	ATAH EAD 01
Allen Key	1	ATAK EY0 01
Tripod, including Fixation Screw	1	ATAS UP0 01
Box of Sanitization Wipes	1	–
Operation and Maintenance Instructions Manual	1	–
M Air T Kit, 115 V/60 Hz, complete with carrying case, including:	**1**	**ATAS 115 01**
M Air T Apparatus	1	ATAS PLR 01
Battery Charger, 115 V/60 Hz	1	ATAC 115 01
Micro-perforated Sieve with Cover	1	ATAH EAD 01
Allen Key	1	ATAK EY0 01
Tripod, including Fixation Screw	1	ATAS UP0 01
Box of Sanitization Wipes	1	–
Operation and Maintenance Instructions Manual	1	–
Accessory		
Calibration Unit	1	ATAC AL0 01
Cassettes		
M Air T Cassette, pre-filled with TSA*, double sleeve-packaged in 6 bags of 8 cassettes, sterile, for use in Clean Room areas	48	ATMC TTD 48

* For cassettes containing other media, contact your nearest Millipore subsidiary.

WARRANTY

Millipore warrants its products against defects in manufacturing and workmanship for a period of one (1) year from the date of delivery, provided that they have been used under the conditions described in this manual.

Millipore offers no other warranty neither explicit nor implicit, in particular no warranty of merchantability or fitness for a particular purpose. The terms of this warranty, as well as information, characteristics and descriptions of Millipore products shown on brochures and catalogues published by the Company may not be modified without express authorization signed by a duly qualified Millipore representative. Any written or oral interpretation not in accordance with this warranty or to the said publications shall be considered null and void.

In case of non-respect of the terms of the above-mentioned warranty, Millipore's sole obligation shall be to repair or replace, at its discretion, all or part of a product found to be defective during the period of warranty, due to defects in workmanship or manufacturing, on condition that the customer notifies the fault immediately.

The present service obligation cannot be considered as not having been fulfilled if Millipore has demonstrated its good faith in repairing or replacing any defective Millipore product or part.

Millipore cannot be held responsible for prejudice due to non-operation or damage to property where its products could have been the cause, nor consequently be required to award indirect damages.

The terms of this warranty do not affect the buyer's statutory rights.