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PROTOCOL

Protocol No.	600
Subject	PARTICLE COUNT PROTOCOL
Effective Date	08-13-2021

INTRODUCTION

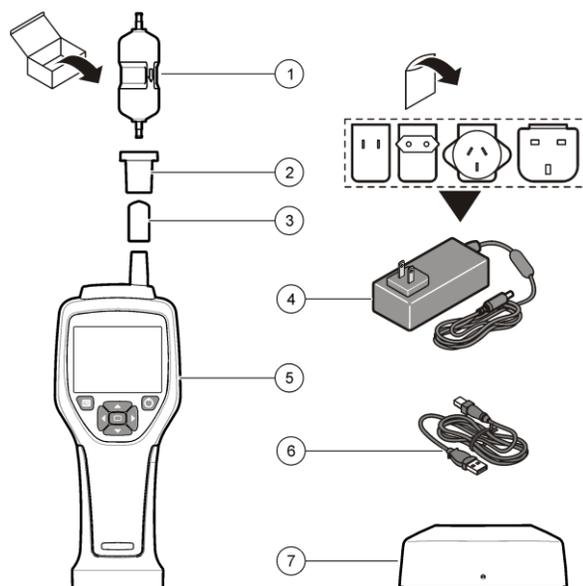
Microbiological contamination of the air in the operating room is considered one of the most common risk factors for surgical site infections since microorganisms are transferred through airborne particles, so the assessment of air quality in the operating or procedure room should be performed routinely using quantitative particle counter to determine if the air filtration process from the HEPA units is adequate, and to ensure that the risk of infection at the surgical site is minimal from the airborne pathogens point of view.

This protocol will be developed using the MET ONE HHPC 2 as an example, which must be operated as shown below. However, please refer to your handheld device specific operating manual if you happen to use a different machine.

MET ONE HHPC 2

This will be the prototype unit that will be discussed in this protocol. Accessories could vary per manufacturer.

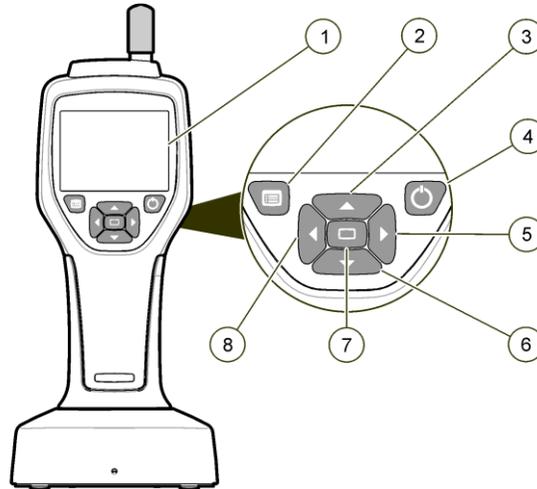
1. Zero-count filter
2. Filter adapter (optional)
3. Sample inlet protective cap
4. AC adapter
5. Handheld instrument
6. USB cable
7. Cradle accessory



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1. LCD display screen
2. Menu button
3. UP arrow button
4. Power button
5. RIGHT arrow button
6. DOWN arrow button
7. Select button (also Start/Stop sample)
8. LEFT arrow button



How to Start up MET ONE PARTICLE COUNTER

Press down the POWER button to turn on or turn off the instrument.

Menu icons

- Icons in the Navigation Menu are shown horizontally. The icon in the middle of the screen is shown highlighted. Arrows above and below an icon indicate that sub-menus exist



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Menu Sample→

To go to the Navigation Menu and select a menu option:

1. Push the Menu button.
2. Push the right or left arrow buttons to highlight an icon. Push the Up or Down arrow buttons to Move through sub-menu options.
3. Push the Select button to accept the highlighted icon. The menu or screen for the selected option appears.
4. View data or edit and configure fields as necessary.
5. Fields and controls in a screen may include radio buttons, text and numeric fields, and checkboxes and drop-down menus. An onscreen keyboard appears when the cursor is in a text field. Use the Keyboard to input data in the field.

Sample setup

Refer to the help screen for more information. Change the settings for how the instrument runs a sampling process in the Sample Setup menu.

Sub-menus include options for Location, Alarms and Data display setups. To update or change the

Sample Setup settings:

1. Push the Menu button.
2. Navigate to the Sample Setup icon, then push the Select key.
3. Change the settings for the options. Default values are shown in parentheses.
4. Configure the options for Location, Data display, Communications, Data export and Alarm Setup as necessary.

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Option Description

- **Method** (Time): The instrument gets a sample for the amount of time in the Time field. The recommendation is 5 minutes in total, or 3 separate 1 minute and 20 seconds samplings.
- **Volume**: The instrument gets a sample equal to the value in the Volume field.
- **Time**: The instrument gets a sample for the amount of time that is put in this field. Range: 00:00:01 to 23:59:59 00:01:00. In the Time-based sampling method, this value plus the hold time equals one Cycle.
- **Volume**: The instrument gets a sample equal to the volume put in this field. In the Volume based sampling Method, this value plus the hold time equals one cycle and the sample time remaining is an Estimated value.
- **Hold**: The amount of time between samples. Range: 00:00:00 to 23:59:59.
- **Delay**: The period of time before the first sample starts after the Start key is pushed. Range: 00:00:03 to 23:59:59
- **Cycles** The total number of sample and hold intervals. Range: 0 to 999. When in Automatic mode, the Instrument stops after the last cycle is complete. A value of 0 makes the unit run continuously until the user pushes the Select button.

Mode Automatic:

The instrument gets samples according to the stored parameters.

- Manual: the instrument gets one sample and stops.
- Beep: the instrument uses Automatic mode settings but ignores the count alarm settings. The unit Gives an audible beep for each particle counted.

System functions

- Instrument diagnostics



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- Communications setup 
- System setup 
- Sign on 

Common functions

- Trend data view 
- Sample screen 
- Buffered data view 

Setup functions

- Location setup 
- Sample setup 
- Alarm setup 
- Display setup 

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Verify Instrument Operation:

NOTE: “Electrical noise, sensor leakage or other interference can cause the instrument to give incorrect data.”

To make sure the instrument operates correctly:

1. Attach the Zero-Count Filter. An attachment item the form of a cylinder to be added to the sampling spout inlet of the device.
2. Press the menu button, In the Data Display Setup screen select Sample setup in main menu and press Enter.
3. In the Sample Setup screen, set the sample time to 5 minutes, the hold time to 00:00:00, the Delay time to 00:00:03, the MODE to Automatic and the number of CYCLES to 3.
4. Press the menu button, and press LEFT/RIGHT button to go to the Sample Screen icon and press Enter.
5. Start the Product sampling and let it complete the x3 (5-minute samples).
6. Examine the particle counts in the last sample. Counts must align with these specifications for Instrument operation to be verified: No more than 0 particle > 0.5 μm in each 5-minute tests.

Purging the instrument:

Remove unwanted materials from the instrument before it is used in a cleanroom or clean-manufacturing environment. Also do this procedure after each high sampling count to help keep the Internal sensor clean.

1. Install the zero-count filter.
2. Set the instrument to sample continuously.
3. Start the count process. Continue until there are no new counts.
4. Remove the zero-count filter for normal operation.

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Start a (TEST) Sample Process with Normal View:

Remove the protective cap from the inlet and attach the correct probe (if necessary) before starting a sample process.

1. Navigate to the Sample screen icon.
2. Push the Select button to start the sample process.
 - The instrument begins the sample process with the default or stored Sample Setup values.
 - While the instrument takes samples, the display shows the sample status, current sample number and the sample time that remains.
 - **Note:** *If the Sample Mode is set to Volume, the value for the sample time that remains is an estimated value Based on the Volume in Sample Setup.*
3. Let the instrument complete the sample process. To cancel the sample process, push the Select button again.
 - The instrument logs data to the data buffer. A status field shows errors (if any) that occurred in the sample process.
 - **Note:** *If the sample is manually terminated prior to completion, the data will not be saved.*

Read Buffered Data, (TEST PREVIOUSLY PROCESSED)

1. Press the Menu button.
2. Navigate to Buffered data screen.
3. Press Enter/Select button
4. The Data will show for each test ran, press UP/DOWN to view different test performed
5. TO DELETE FILES- Press Left/Right button to Highlight icon w/ X and press Select & select again to confirm

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The measurement process should be done in the three recommended locations: ANTEROOM (entrance), BUFFER-ROOM (synthetic hood) and CHAMBER (chair). Subsequently, the reading must be saved in an Excel document to have an adequate record of the data, as shown in the following example.

OPERATING ROOM 4		
ANTE	BUFFER	CHAMBER
(OR Entrance)	Synthetic Hood	(OR Chair)
✓ 7627.1	✓ 3178	✓ 2966.1
✓ 1483.1	✓ 1271.2	✓ 423.7
✓ 2966.1	✓ 211.9	✓ 211.9

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