V100 Controller and Air Sampler

Users Manual

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Table of Contents

Section 1 Specifications

V100 Air Sampler Controller	
Motor Type	Blower Motor
Display	Color ¼ VGA TFT LCD touch screen
Interface	Windows CE®-based
Sample Time/Volume	Variable (User Defined), Maximums: 60-minutes/1700 Liters* @ 28.3 LPM, 40-min/2000L @ 50 LPM, and 20-min/2000L @ 100 LPM (*software allows for 240-min/6800L)
Delay/Hold Times	Variable (User Defined)
Sample Flow Rates	28.3, 50, or 100 liters per minute LPM (1, 1.766, or 3.531 cubic feet per minute [CFM])
Flow Rate Control	Electronic, Closed-Loop, Mass-Flow Control
Maximum Tube Length	Single Sampler: 75’ @ 28.3 LPM, 60’ @ 50 LPM, 15’ @100 LPM Dual Sampler: 50’ @ 28.3 LPM, 30’ @ 50 LPM
Printer	Thermal
Memory	1 GB flash RAM
Unit ID	User Defined/Selectable
Site ID	User Defined/Selectable
Sample ID	Unique System Generated (Unit Serial # + 5 digit string)
Input/Output	USB Client 1.1, Ethernet 10BaseT-/100-BaseT
Audible Alarm	Internal
Alarm Limits	High and Low Flow Rates (User Defined)
Enclosure Dimensions	H-W-D: 7 x 8 x 10 inches (17.8 x 20.3 x 25.4 cm)
Enclosure Materials	Chassis: 316 Stainless Steel: Cover: Kydex™ with Microban™ Handle: Aluminum and Nylon
Weight	12 Pounds
Power Ratings	Auto switching: 100-240 VAC, 50/60 Hz, 3.6 / 1.8A
Operating Range	5-40º C, 10-80% RH, non-condensing; Indoor Use; Max Altitude 6560 feet (2000 meters)
Calibration	Flow Rate (with each specific sampler/ hose length)
Calibration Frequency	User Defined (Recommended every 6-months)
Verification	Turntable Rotation / Timer
Verification Frequency	User Defined (Recommended every 6-months)
Gas Compatibility	Air and inert gases such as carbon dioxide and, nitrogen
Installation Category	Category 2
Pollution Degree	1 and 2

Air Samplers	
Remote-Slit-Sampler (R2S)	Size: 5” (127mm) OD, 5.75” (146mm) H; Weight: 2lbs 12oz (1247g); Materials: Base/Turntable: Epoxy/Polyester Coated Aluminum, 316SS/Aluminum Components; Inlet Dome: Clear Polycarbonate; Seal: Blue Fluorosilicone; Drive Motor: Stepper; Electrical Connector: 4-Pin
Remote Compressed Gas/Confined Space Sampler (RCG)	Size: 5” (127mm) OD, 6.75” (171mm) H; Weight: 3lbs 2oz (1417g); Materials: Base/Turntable: Epoxy/Polyester Coated Aluminum, 316SS/Aluminum Components; Inlet Dome: Clear Polycarbonate with aluminum/316 SS inlet/throat; Seal: Blue Fluorosilicone; Drive Motor: Stepper; Electrical Connector: 4-Pin
Remote Autoclavable Sampler (RAS)	Base/Inlet Cover/Barb: 316 Stainless Steel or Aluminum; Seals: Blue Fluorosilicone; Dimensions: 4.125” (105mm) OD x 1.5” (38mm) H; Weight: 3lbs 5oz 1503g (316SS)

Section 2 General Information

2.1 Document Description

Document EMTEK.V100.001v01 (Second Edition). February 2011.
This document remains the official reference source for all revisions/releases of this product until rescinded by an update, including current and updated versions of the operating firmware and software.

2.2 Patents

- The R2S sampling technology is patented. U.S. Patent No. 5831182.
- V100 Controller Patent Pending.

2.3 Copyright

2.4 Disclaimer

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2.6 V100 Technical Description

The V100 (EMTEK, LLC Versatile 100) is an air sampler controller that operates the EMTEK line of microbial air samplers. It is an extremely versatile air sampling system that operates on AC power. Its enclosure is comprised of a top cover that is made of Kydex™ that lies over a 316 Stainless Steel chassis. The Kydex™ cover contains Microban™, an antimicrobial agent that minimizes and/or reduces the growth of microbial contaminants that may come in contact with the Kydex™ cover. The user interfaces with the V100 through a color LCD touch screen for entering user defined sample parameters and for the initiation and termination of sample runs. During operation the LCD displays key sample information, as well as a visual sample progress indicator.

The V100 offers three (3) sample flow rates: 28.3, 50 and 100 Liters Per Minute (LPM). The highest flow rate, 100 LPM, allows for the collection of a cubic meter of air in 10-minutes. The flow is controlled through a proprietary control system, which offers automatic flow control of the three defined flow rates. Flow rates are calibrated and set against traceable standards through the use of an external software program and may not be altered through the user interface on the unit. Sample rates and total volume sampled maybe displayed and output in Cubic Feet, Liters, or Cubic Meters. Alarm settings are available for the flow rates, which will produce both an audible and visual alarm during operation and will then be output to the printer upon completion/termination of the sample period. Alarm occurrences are maintained within the systems internal memory with the associated sample parameter information until the memory buffer is cleared. Additionally, a blower alarm is also present, which will produce both an audible and visual alarm if the appropriate blower speed is not maintained during operation.

The V100 operates the current line of EMTEK microbial air sampling heads including the R2S (a slit-to-agar sampler), RAS (a sieve impaction sampler), and RCG (a compressed air/gas and confined space sampler). Each of the air samplers may be employed for testing with standard 90mm (100mm) agar based microbial test plates (e.g., Trypticase Soy Agar (TSA)). The V100 may operate a single air sampling head at any of the three flow rates, or two air sampling heads at the same time at either the 28.3 LPM, or 50 LPM flow rates. During single head operation, an air sampler may be operated from the V100 at a distance of up to 75-feet, when using at 28.3 LPM flow rate, through supplied vacuum tubing and power cables. For dual air sampler operation, the maximum sampling distance is approximately 50-feet to each sampling head when using the 28.3 LPM flow rate. In both instances the 28.3 LPM flow rate allows for the greatest distance, with a reduction in the distance at 50 LPM, and then again at 100 LPM (for single head operation). In general, the lower the flow rate the farther the air sampler may be operated from the controller. During testing the sampled air volume drawn through each air sampler is HEPA filtered before being exhausted within the V100.

The V100 also supplies power and stepper motor rotational control of the turntable platform of both the R2S and RCG air samplers. Based on the set sampling period, the turntable, and a test plate located on the turntable, will rotate a approximately 355 degrees within the defined sampling period. This 355-degree rotation creates a none-sampled buffer zone on the test plate between the starting point and finishing point. This allows for the determination of the time of recovery of bacterial or fungal colony forming units (CFU) captured during the sampling period based upon the time recorded for the sample period and the location of the CFU on the test plate. This determination allows the operator to tie the contamination recovery event with operations that may have occurred at the time of the CFU recovery event.

The V100 software, allows for sampling periods of up to 240-minutes at the 28.3 LPM sample rate, while sample times are limited to 40-minutes at 50 LPM, and 20-minutes at 100 LPM. EMTEK strongly suggests that all sampling periods employed by be qualified by the user to verify appropriate organismal recovery. In addition, the V100 offers the user the capability of entering an initial sample delay, as well as hold and test periods for each sample run. This initial sample delay allows the user time to exit the immediate area of the sample location, while the hold and test period settings allows for intermittent sampling of an area or process for an extended time period, as determine appropriate by the user. For an example, the user may set an initial delay period of 3-minutes and then opt to sample for 5-minute periods with 5-minute hold periods between each 5-minute sampling period, which will occur for a period up to the maximum total sampling period defined for the flow rate chosen. If the flow rate chosen is 28.3 LPM the maximum active sampling period allowed is 60-minutes. This would allow for twelve (12) 5-minute test periods, followed by eleven (11) 5-minute hold periods, for a total plate exposure time of 118-minutes (including the 3-minute initial delay). This would result in a total of 60-minutes of active sampling. The motor powers down during hold periods. EMTEK recommends only 120-minutes of total plate exposure, including sampling and hold periods, but users may qualify other total plate exposure periods if longer hold periods are desired. At the 28.3 LPM sample rate, the software allows for up to 8-Hours of total plate exposure, which includes total sampling and hold periods.

The V100 maintains key sample parameter data within its internal memory until the memory buffer is cleared by the user, or the memory capacity is exceeded. The number of samples maintained within the systems internal memory is based upon available memory and can be viewed and output to a common spreadsheet through an Ethernet connection. The data maintained in the system includes set/actual flow rate, set/actual sample volume, sample start/end times, set delay, test and hold period, equipment and serial numbers, calibration date and due date of the controller/air sampler(s), and alarms during sampling. Each sample may also be assigned a user defined site identifier/description, which will be output on the sample label, and/or maintained within the system memory with key sample run parameters. An alphanumeric keypad is provided on the touch screen for entering user defined site identifiers/descriptions. All sample runs are date and time stamped and are also assigned a unique sample identification string which is comprised of the units assigned serial number and a non-repeating character string up to 99,999 samples. This data cannot be altered within the system of the V100. It may only be output or cleared from the system.

The V100 comes with a thermal printer, which can utilize both paper or label stock available from EMTEK. The printer outputs the defined key sample parameter data following each run (if desired). Additionally, the user can output duplicate labels/data from sample data stored in the memory buffer, based on a user entered date and time range or requested number of samples. The user may also set a specified number of replicate samples that will print at the end of each run. This is convenient when operating two sampling head with one controller when setting the replicate value to print two labels.

Sample runs on the V100 can be initiated through either the V100 touch screen Run Display screen, or the supplied Infrared Remote (IR Remote). From either the V100 display, or the IR Remote, the user can START, PAUSE, RESUME, or STOP a sampling session. The IR Remote allows for these functions at a distance of up to 40-Feet, or approximately 12 meters, with line of site to the V100 IR Receiver window located just above the touch screen display on the V100.

2.7 Safety Notices

Please read this entire manual before operating this equipment. Pay attention to all danger, warning and caution statements. Failure to do so could result in serious injury to the operator or damage to the equipment. To make sure that the protection provided by this equipment is not impaired, do not use or install this equipment in any manner other than that specified in this manual.

English

DANGER: Electric Shock or Electrocution Hazards

1. Disconnect all power sources before servicing the V100 or any sampler.
2. Do not disassemble the V100 controller or any sampler to attempt any repairs.
3. Contact EMTEK, LLC or other qualified service personnel if the unit malfunctions.
4. Do not submerse the V100 controller or any sampler in any liquid.

Français

DANGER: Décharge électrique ou Hasards d'Électrocution

1. Débrancher toutes les sources de pouvoir avant le fait d'assurer l'entretien le V100 ou le collectionneur aérien.
2. Ne désassembler pas le V100 ou de collectionneur aérien pour faire des réparations.
3. Contacter EMTEK, LLC ou d'autre personnel de service qualifié pour la réparation si l'unité mal fonctionne.
4. Ne faire pas submerse le V100 ou le collectionneur dans aucun liquide.

2.7.1 Referenced hazard information

English

DANGER

Indicates a potentially or imminently hazardous situation which, if not avoided, will result in death or serious injury.

Français

DANGER

Indique une situation potentiellement dangereuse ou imminent qui, si elle n'est pas évitée, entraîner la mort ou des blessures graves.

English

WARNING

Indicates a potentially or imminently hazardous situation which, if not avoided, could result in death or serious injury.

Français
AVERTISSEMENT
Indique une situation potentiellement dangereuse ou imminent qui, si elle n'est pas évitée, pourrait entraîner la mort ou des blessures graves.

English
CAUTION
Indicates a potentially hazardous situation that may result in minor or moderate injury.

Français
ATTENTION
Indique une situation potentiellement dangereuse qui mai entraîner des blessures plus ou modérée blessure.

Important Note: Indicates a situation which, if not avoided, may cause damage to the instrument. Information that requires special emphasis.

Note Importante : Indique une situation qui, si non évité, peut provoquer le dommage à le instrument. Les informations qui exigent l'accentuation spéciale.

Note: Information that supplements points in the main text.

2.7.2 Precautionary labels

Read all labels and tags attached to the instrument. Personal injury or damage to the instrument could occur if not observed.

English
Electrical equipment marked with this symbol may not be disposed of in European public disposal systems after 12 August of 2005. In conformity with European local and national regulations (EU Directive 2002/96/EC), European electrical equipment users must now return old or end-of life equipment to the Producer for disposal at no charge to the user.

Note: For return for recycling, please contact the equipment producer or supplier for instructions on how to return end-of-life equipment, producer-supplied electrical accessories, and all auxiliary items for proper disposal.

Français
Les équipements électriques marqués de ce symbole mai ne pas être éliminés dans les systèmes européens de disposition du public après le 12 août 2005. En conformité avec les réglementations locales européennes et nationales (Directive européenne 2002/96/CE), les utilisateurs européens d'équipements électriques doivent maintenant retourner vieux ou en fin de vie des équipements au producteur pour l'élimination, sans frais pour l'utilisateur.

Note: Pour le retour pour recyclage, s'il vous plaît contacter le producteur ou le fournisseur du matériel pour obtenir des instructions sur la façon de revenir en fin de vie des équipements, producteurs-fournis accessoires électriques, et tous les éléments auxiliaires pour une élimination appropriée.

English

This is the safety alert symbol. Obey all safety messages that follow this symbol to avoid potential injury. If on the instrument, refer to the instruction manual for operating on or safety information.

Français

Ceci est le symbole de sécurité. Respectez tous les messages de sécurité qui suivent ce symbole afin d'éviter d'éventuelles blessures. Si sur l'instrument, se reporter au manuel d'instructions pour l'exploitation ou de l'information sur la sécurité.

English

This symbol indicated the presence of devices sensitive to Electro-static Discharge (ESD) and indicated that care must be taken to prevent damage with the equipment.

Français

Ce symbole indique la présence de dispositifs sensibles à Electro-Static Discharge (ESD) et a indiqué que les soins doivent être prises pour prévenir les dommages aux équipements.

English

This symbol indicates that a risk of electrical shock and/or electrocution exists.

Français

Ce symbole signifie qu'il existe un risque de choc électrique et / ou d'électrocution existe.

2.8 Standards and Regulation

2.8.1 CE Declaration of Conformity

See Appendix 1

2.8.2 21 CFR Part 11 Compliance

Sample Parameter Information and Electronic Records

The V100 controller stores sample parameter information up to the limit of the internal 1 GB memory. This memory is flash RAM that is not removable or alterable by the user.

The sample parameter information maintained in the system includes set/actual flow rate, set/actual sample volume, sample start/end times, set delay, test and hold period, calibration date and due date of the controller, alarms during sampling, user sample description and unique sample identifier. The stored sample parameters can be cleared/deleted by the user but cannot be edited. Further, sample parameter information of a specific sampling event cannot be selectively deleted or altered by the user.

The V100 can re-print sample parameter information using a built-in thermal printer. The user can select a date and time range or specify the number of samples to be printed.

The sample parameter information stored in the internal memory of the V100 controller can be either printed to the onboard thermal printer or transferred to an external computer through an Ethernet connection. This sample parameter information can be deleted but cannot be altered while residing within the internal memory of the V100 controller. This sample parameter information may be exported from the internal memory. EMTEK, LLC does not provide software utilities to comply with the requirements of 21 CFR Part 11 after the data is transferred from a V100 controller to an external source. Users that are subject to FDA regulations are responsible for maintaining compliance with 21 CFR Part 11 after the data is transferred from a V100 controller to an external source.

2.9 Warranty

EMTEK, LLC provides a 2-Year Limited Warranty- See Appendix 2

Section 3 Product Introduction

The V100 is a state-of-the-art controller for use with the EMTEK, LLC line of microbial sampling devices. It uses mass flow control to accurately regulate the selected air-flow for precise measurement of the collected volume. Stepper motor control ensures a complete rotation of the testing plate in the selected sample time period for samplers possessing this functionality (R2S, RCG).

3.1 Feature Summary

Touch Screen Interface

User-friendly touch screen for intuitive operation.

Storage Functions

1 GB of internal flash memory for the storage of user sample sites and sample runs.
The quantity of the sample sites and sample runs is limited only by the available storage.

Compatible with Multiple EMTEK Sampling Heads:

Remote-Slit-Sampler (R2S)
Remote-Autoclavable-Sampler (RAS)
Remote-Compressed Gas/Confined Space-Sampler (RCG)
May operate one (1) or two (2) of the same sampling heads at the same time
Can be updated to support future EMTEK samplers

Thermal Printer:

An internal thermal paper/label printer can record sample parameter information such as the sample identification, unit identification, set flow rate, actual flow rate, sample volume collected, and high/low flow alarms.

Network/Input Functions:

Supports USB calibration programming and firmware updates
Remotely view/download sample parameter information
Software is updatable through Ethernet connectivity

IR Remote Control:

Supports Start / Stop of the sample period
Supports Pause / Resume of the sample period
Operates up to five (5) V100 Units

3.2 Sampler Compatibility Matrix

Sampler Option	Sampler Part#	Sample Rate (Liters/min)	Maximum Sample Period (Minutes)[1,3]	Volume Collected- Max Sample Period (Liters/m3/ft3)
R2S	V100.R2S.28	28.3	60 240[2]	1700 / 1.7 / 60 6800 / 6.8 / 240[2]
	V100.R2S.50	50	20 40	1000 / 1 / 35 2000 / 2 / 70
	V100.R2S.100	100	10 20	1000 / 1 / 35 2000 / 2 / 70
RAS	V100.RAS.28	28.3	60	1700 / 1.7 / 60
	V100.RAS.50	50	20	1000 / 1 / 35
	V100.RAS.100	100	10	1000 / 1 / 35
RCG	V100.RCG.28	28.3	60	1700 / 1.7 / 60
	V100.RCG.50	50*	20 40	1000 / 1 / 35 2000 / 2 / 70
	V100.RCG.100	100	10 20	1000 / 1 / 35 2000 / 2 / 70

* Note- The RCG is only available for Compressed Air/Gas sampling at 50 LPM in conjunction with EMTEK's Micro High Pressure Diffuser for pressure ranges from approximately 15-115 PSI.

1. Test Delay/Hold/Run function allows for extension of total sample/hold time period to 120-minuites with the RAS and RCG, and 480 minutes per test plate when sampling with the R2S. All Test Delay/Hold/Run cycles should be qualified by the user.
2. The V100 software allows for extended sampling periods up to 240-minutes with the R2S.
3. All sampling periods should be qualified by the user.

Note: Additional Domes for the 28.3, 50 and 100 LPM Sample Rates for the R2S and RCG can be purchased separately.

3.3 Unpacking or Packing

Remove all items from the shipping container and inspect them for damage. Make sure that all of the items listed are included (Fig 3.3.1), dependent upon purchase options. If any of the items not marked (optional) are missing or damaged, contact the manufacturer. A user manual is also shipped with the V100 Air Sampler Controller.

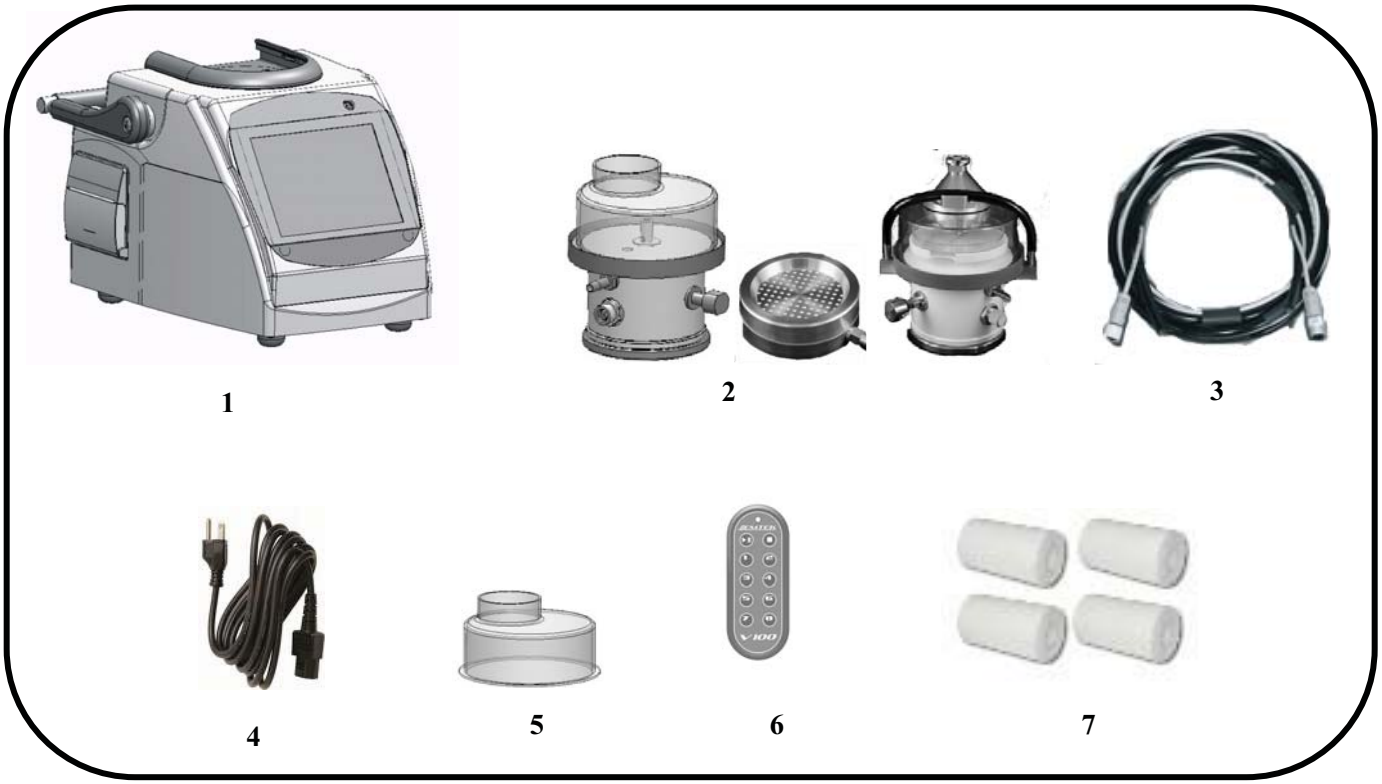


Fig 3.3.1
Packaged Items

Figure 3.3.1 Instrument Components

1 V100 Controller
2 One or more of the following (depending on purchase): Air Sampler and Dome- R2S, RCG, RAS Sieve Sampler
3 Power/Vacuum Supply Cable/Tubing (R2S and RCG). Vacuum Supply Tubing Only for RAS. Various lengths depending on purchase.
4 V100 Primary AC Power Cord (6ft)
5 (Optional) Additional Dome (R2S/RCG- 28.3, 50, 100 LPM) or Additional RAS Cover (RAS- 28.3, 50, 100 LPM)
6 IR Remote Control
7 Paper Rolls(2), Label Rolls(2)

Not Shown: User's Manual, NIST Traceable Calibration Reports(s).

NOTE: See Appendix 3 for Component Packaging

Section 4 Installation

English

Danger

Only qualified personnel should perform the tasks specified in this section.

Français

Danger

Le personnel seulement qualifié devrait exécuter les tâches spécifiées dans cette section.

4.1 Wiring safety information

Follow all warnings and notes when making wiring connections to the instrument (Safety information on page 8).

English

DANGER

Electric shock hazard. Always disconnect power to the instrument when making electrical connections.

Français

DANGER

Un choc électrique risque. Toujours couper l'alimentation de l'instrument lors des branchements électriques.

4.2 Electrostatic discharge (ESD) considerations

Important Note: To minimize hazards and ESD risks, maintenance procedures not requiring power to the V100 should be performed with power removed. Delicate internal electronic components can be damaged by static electricity, resulting in degraded instrument performance or eventual failure.

Note Importante: Pour minimiser les dangers et les risques de l'EDD, les procédures d'entretien non nécessitant une alimentation à la V100 devrait être exécuté avec la puissance retirés. Interne sensible composants électroniques, peuvent être endommagés par l'électricité statique, résultant en instrument une dégradation des performances ou de l'échec éventuel.

The manufacturer recommends taking the following steps to prevent ESD damage to your instrument:

- Before touching any instrument electronic components (such as printed circuit cards and the components on them) discharge static electricity from the body. To discharge static electricity, touch an earth-grounded metal surface such as the chassis of an instrument, or a metal conduit or pipe.

- To reduce static build-up, avoid excessive movement. Transport static-sensitive components in anti-static containers or packaging.

- To discharge static electricity from the body and keep it discharged, wear a wrist strap connected by a wire to earth ground.

- Handle all static-sensitive components in a static-safe area. If possible, use anti-static floor pads and work bench pads.

4.3 Electrical/Data Connections

English

DANGER

Electric shock hazard. Always disconnect power to the instrument when making electrical connections.

Français

DANGER

Un choc électrique risque. Toujours couper l'alimentation de l'instrument lors des branchements électriques.

Connect external power plug (4), air sampler electrical connection (1), USB cable (2), or Ethernet cable (3) to the V100 to enable functionality or to download data. Make connections where indicated (Figure 4.3.1).

Fig 4.3.1
V100 Rear View

1- Air Sampler (RCG, R2S) Electrical Connector
2- Ethernet Port
3- USB Port
4- Primary Power Inlet / Power Switch

Section 5 V100 Description

5.1 V100 Front View

Fig 5.1.1
V100 Front View

1- Sampler Transport Cup
2- Retractable/Extendable Transport Handle
3- IR Remote Receiving Sensor
4- Thermal Label/Paper Printer
5- Touch Screen Interface
6- KYDEX™ Cover with MICROBAN™ antimicrobial protection

5.2 V100 Rear View

Fig 5.2.1 V100 Rear View

1- Transport Handle
2- Sampler Transport Cup
3- Sampler Vacuum Connection
4- Sampler Electrical Connection
5- Ethernet Port
6- Power Supply Fan
7- Cooling Fan
8- USB Port
9- Power Switch / Primary AC Power Inlet

Section 6 Quick Start Guide

English

DANGER

Electric shock hazard. Always disconnect power to the instrument when making electrical connections.

Français

DANGER

Un choc électrique risque. Toujours couper l'alimentation de l'instrument lors des branchements électriques.

If you are already familiar with the V100 Controller, follow these steps to get your controller running:

1. Connect the sampler power cable (as applicable) and vacuum supply tubing to the V100 Controller. (Fig 5.2.1, #4 and #3)
2. Connect the sampler power cable(s) (as applicable) and vacuum supply tubing to the R2S, RCG, or RAS sampler. (Section 7.5)
3. Plug the primary AC power cable into the power supply on the back panel of the V100 (Fig 5.2.1, #9), and then attach to an appropriate AC power source 110-240 VAC, 50-60 Hz.
4. Turn the controller on using the power switch on the back panel of the V100. (Fig 5.2.1, #9)
5. Set required parameters using the touch screen interface. (Section 7.2)
6. If a label/paper output is desired, ensure that the printer is turned on (Fig 7.2.4, #8) and that the unit has and adequate supply of paper/labels (Section 7.5).
7. Follow the appropriate procedure to collect the required samples. See appendices for operating instructions for each sampler.

Section 7 Operating Instructions

7.1 Touch Screen- Test/Sample Screen

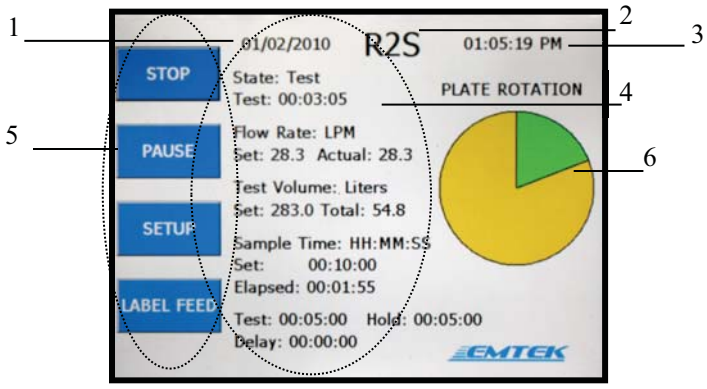


Fig 7.1.1 Touch Screen
User Interface (UI) Test/Sample Screen

Table 7.1.1 Items on Test/Sample Screen

Index	Type	Name	Description
1	Date Indicator	CURRENT DATE	1. Displays date set by user
2	Sampler Indicator	SAMPLER IDENTIFICATION	1. Displays sampler type selected by user
3	Time Indicator	CURRENT TIME	1. Displays time set by user
4	Sample/Test Information	STATE FLOW RATE TEST VOLUME SAMPLE TIME TEST/HOLD/ DELAY	1. Indicates the current state of a test period (Ramp, Delay, Test, Hold, Pause, Abort) and countdown of a test period. 2. Indicates the selected flow rate and actual flow rate during the sample period. 3. Indicates the selected volume (Liters /Cubic Feet/ Cubic Meters) and actual volume collected during the sample period. 4. Indicated the selected sample time and the elapsed time of the sample period. 5. Indicates the selected test period, hold period, and initial delay before test period.
5	Function Keys	START/ STOP PAUSE/ RESUME SETUP LABEL FEED	1. Start/Stop sample period. Key changes to read Start or Stop upon activation. 2. Pause/Resume sample period. Key changes to read Pause or Resume upon activation. 3. Access to setup screens. (See 3.2) 4. Advances individual labels
6	Sample Progress Indicator	PLATE/SAMPLE TIME TRACKING	1. Visual indication of elapsed sample period (for RAS) or plate rotation (for R2S, RCG). Yelllow = plate or period not-completed Green = plate or period completed Blue = Test period completed

7.2 Touch Screen- Setup Screens (1-4)

Setup Screen 1

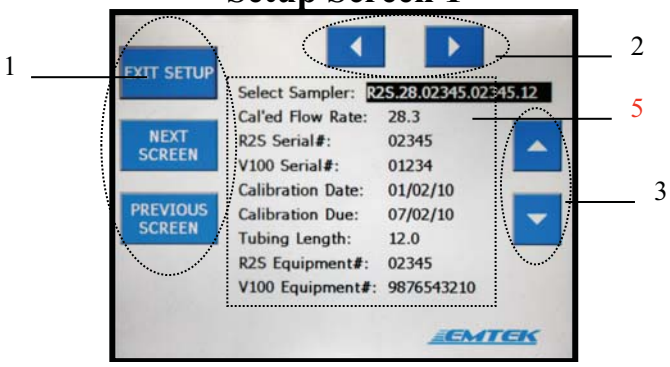


Fig 7.2.1 Setup Screen 1

Sampler Selection, Sample and Test Information

Table 7.2.1 Items on Setup Screen 1

Index	Type	Name	Description
1	Function Keys	EXIT SETUP NEXT SCREEN PREVIOUS SCREEN	1. Return to Main Sample/Test Information Screen. 2. Move to next setup screen. 3. Move to previous setup screen
2	Control Keys	SCROLL KEYS 【◀】 and 【▶】	Move between the selectable fields, left to right and top to bottom of screen.
3	Control Keys	SELECTION KEYS 【▲】 and 【▼】	Scroll through either a pre-populated list or through numerical values depending upon the field selected.
5	Parameter Keys	SELECT SAMPLER	1. Used to select desired sampler from list
		FLOW RATE	2. Identifies the flow rate of the selected sampler
		SERIAL NUMBER	3. Identifies the serial number of the selected sampler
		V100 SERIAL NUMBER	4. Identifies the serial number of the V100 Controller
		CALIBRATION DATE	5. Identifies the date that the selected sampler/ V100 were calibrated
		CALIBRATION DUE	6. Identifies the date that the selected sampler/ V100 are next due for calibration
		TUBING LENGTH	7. Identifies the calibrated tubing length
		SAMPLER EQUIPMENT NUMBER	8. Identifies the sampler equipment number
		V100 EQUIPMENT NUMBER	9. Identifies the V100 equipment number

Setup Screen 2

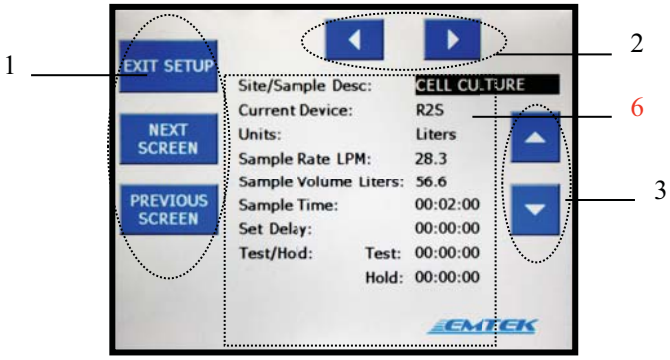


Fig 7.2.2 Setup Screen 2 Sample and Test Information

Table 7.2.2 Items on Setup Screen 2

Index	Type	Name	Description
6	Parameter Keys	SAMPLE/SITE DESC	1. Used to input sample and/or site identifier.
		CURRENT DEVICE	2. Indicates sampling head in use: R2S, RAS, or RCG
		UNITS	3. Select units (Liters/ Cubic Feet/ Cubic Meters)
		SAMPLE RATE	4. Select sample flow rate: 28.3, 50, or 100 LPM (1, 1.766, or 3.531 CFM, 0.0283, 0.05, 0.1 CM)
		SAMPLE VOLUME	5. Selects a specified total sample volume to be collected. Based upon the selected sample rate, setting a specific sample volume changes the SAMPLE TIME required. The maximum volume is 2000 liters / 79.7 cubic feet / 2 cubic meters. Larger total volumes are possible at the 28.3 LPM sampling rate.
		SAMPLE TIME	6. Set desired sample time. Based upon the selected flow rate, setting a specific time changes the SAMPLE VOLUME.
		SET DELAY	7. Set an initial delay period prior to initiating the sample period. OPTIONAL
		TEST/HOLD	8. Set a specified test period and a specified hold of the test period. OPTIONAL

Note: For Index 1-3 descriptions see Table 7.2.1.

Setup Screen 3

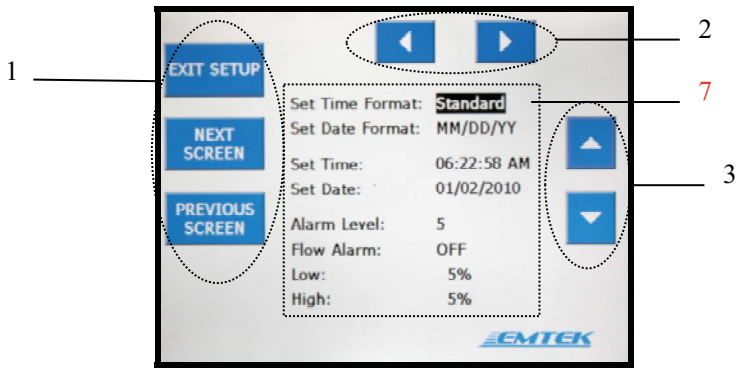


Fig 7.2.3 Setup Screen 3
Time, Date, and Alarm Information

Table 7.2.3 Items on Setup Screen 3

Index	Type	Name	Description
7	Parameter Keys	SET TIME FORMAT SET DATE FORMAT SET TIME SET DATE ALARM LEVEL FLOW ALARM LOW HIGH	1. Select the time format (Military or Standard) 2. Select the date format (MM:DD:YY, DD:MM:YY) 4. Sets the current time 5. Sets the current date 6. Select to adjust speaker volume. 7. Select to turn flow alarm on/off 8. Select to set low flow alarm % from set flow 9. Select to set high flow alarm % from set flow

Note: For Index 1-3 descriptions see Table 7.2.1.

Setup Screen 4

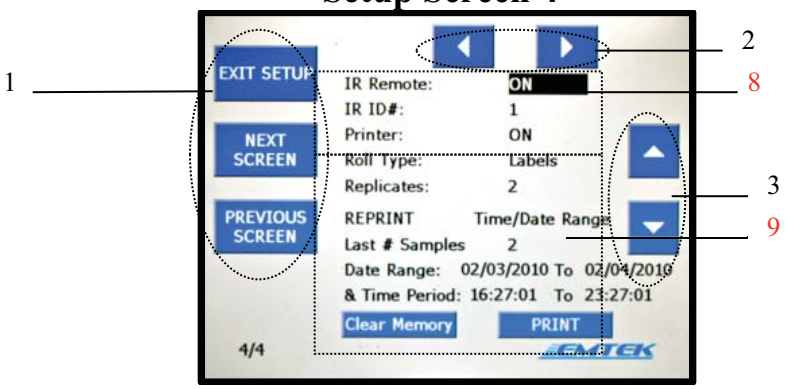


Fig 7.2.4 Screen 4
IR Remote, Printer Function and
Reprint Settings

Table 7.2.4 Items on Setup Screen 4

8	Parameter Keys	IR REMOTE IR ID# PRINTER	1. Turns the IR remote function ON and OFF 2. Sets the units IR ID # (1-6) 3. Turns the Printer function ON and OFF
9	Parameter Keys	ROLL TYPE REPLICATES CLEAR MEMORY REPRINT LAST NUMBER OF SAMPLES DATE RANGE TIME PERIOD	1. Selects either paper or labels for print function 2. Set number of replicate labels (#1-10) 3. Clears data held in memory 4. Selects mode of reprint, by date range and time period, by number of samples, or all samples. 5. Selects the number of samples to print 6. Select the date range to print 7. Select the time period to print

Note: For Index 1-3 descriptions see Table 7.2.1.

7.3 Making Selections through Touch Screen Control

Using the Function Keys – SET-UP, NEXT SCREEN, and PREVIOUS SCREEN – go to the required screen.

Set the desired parameter using either of the following methods:

1 Use the Scroll Keys 【◀】 and 【▶】 to highlight the desired parameter.
2 Directly touch either the parameter itself or the name identifier of the parameter.

The method used to specify a parameter's value depends on the function of the parameter. Some parameters use the Selection Keys 【▲】 and 【▼】 to chose the pre-populated parameter value, such as the Flow Rate. Other parameters require the use of an alpha-numeric keyboard (see section 4.2.2).

7.4 Using the Keyboard Function for Entering Parameters

Some parameters, such as the Site/Sample Description, require an alpha-numeric entry. In these cases upon activation of the selected parameter, a screen displays a variety of options- Add Entry, Edit Entry, Delete Entry, Cancel (see Figure 4-5).

- Selecting "Add Entry" allows you to create an additional Site/Sample
- Selecting "Edit Entry" allows you to edit the chosen Site/Sample description
- Selecting "Delete Entry" allows you to delete the chosen Site/Sample description
- Selecting "Cancel" returns you to the previous screen

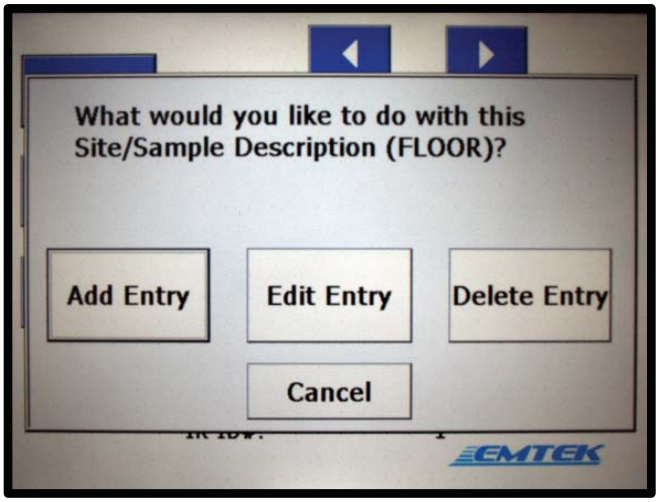


Figure 7.4.1 Site/Sample Description Parameter Screen

When you select the Add Entry or Edit Entry button, a keyboard is displayed (see Figures 7.4.2 and 7.4.3)

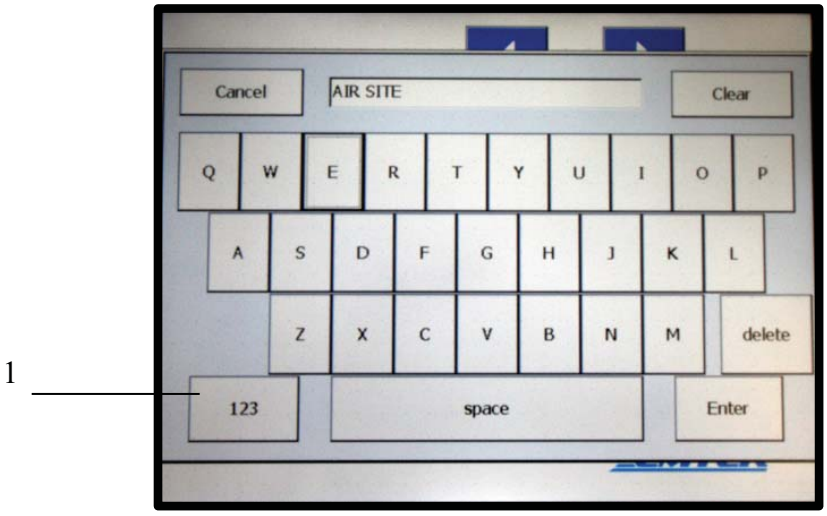


Fig 7.4.2 Keyboard (Alpha Display)

The keyboard allows input using a standard QWERTY keyboard. If numerical values are required, select the “123” button (1) in the lower left corner and a numeric keyboard is displayed (see Figure 4-7)

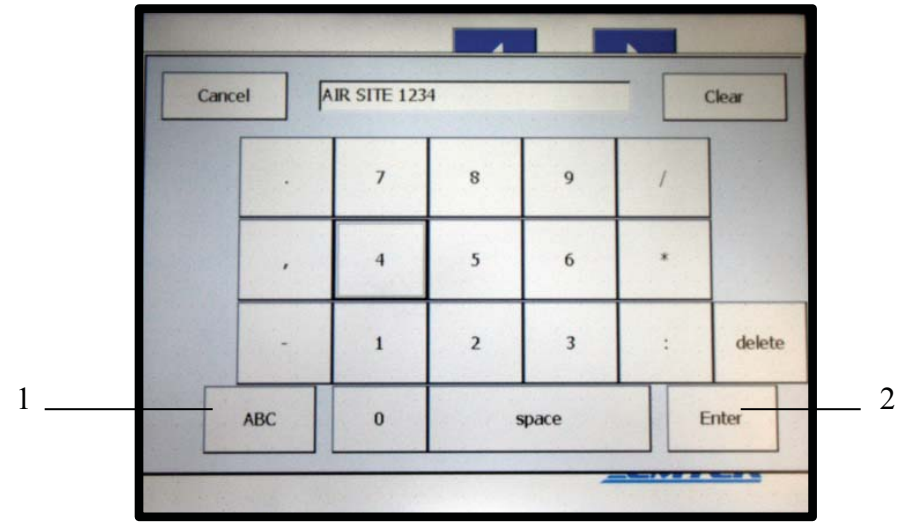


Fig 7.4.3 Keyboard (Numeric/Symbol Display)

In the numeric/symbol mode, the original entry is retained and additional numbers or symbols can be added to the text. To switch back to the alpha keyboard, select the “ABC” button in the lower left corner (1). When you finish creating the entry, select “Enter” (2) and the entry is saved.

7.5 Connecting the Samplers

Attach the appropriate end of the power supply cable to the connector on the R2S/RCG samplers (power is not required for the RAS). Align the two “keys” of the cable connector with the key-way. Firmly press the cable end connector onto the R2S/RCG connector while threading the collar clockwise until it becomes finger tight (Figs 7.5.2-R2S and 7.5.3-RCG). Attach the vacuum supply tubing to the R2S/RCG/RAS sampler by placing tubing over the barb and pressing firmly to achieve an airtight fit (Figs 7.5.1, 7.5.2, and 7.5.3).

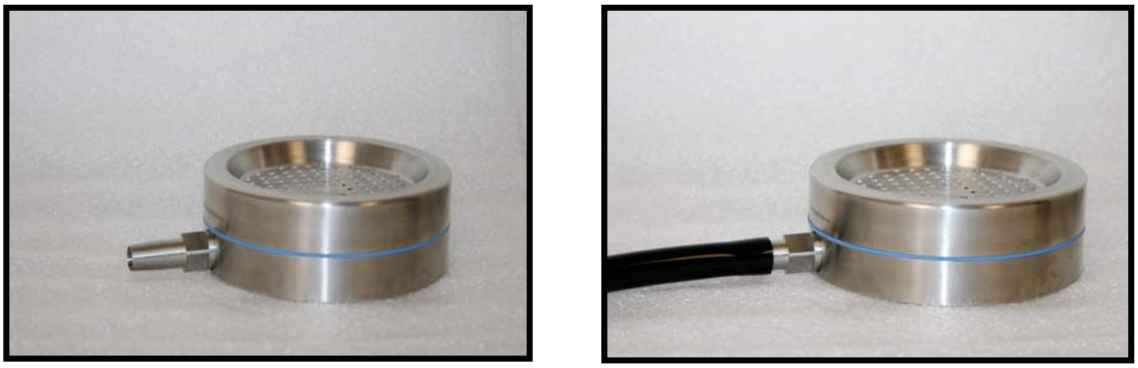


Fig 7.5.1
RAS Vacuum Supply Connection

Fig 7.5.2
R2S Power and Vacuum Supply Connection

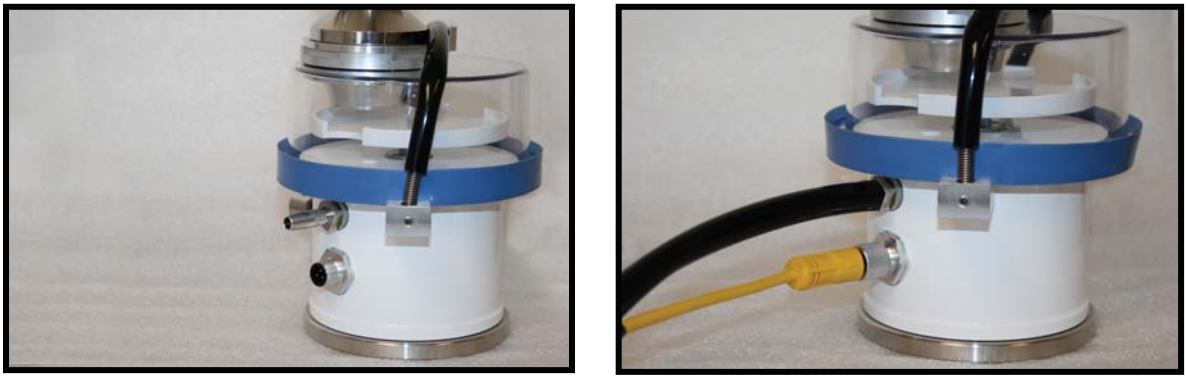


Fig 7.5.3
RCG Power and Vacuum Supply Connection

To connect to the V100 unit, attach the end of the power supply cable to the connector on the V100 (R2S and RCG). Align the two “keys” of the cable connector with the key-way. Firmly press the cable end connector into the power connector while threading the collar clockwise until it becomes finger tight (Figs 7.5.5). Attach the vacuum supply tubing (RAS, R2S, and RCG) to the V100 by placing the tubing into the tube connector and pressing down firmly to achieve an airtight fit (Fig 7.5.4-RAS, and 7.5.5-R2S/RCG).

SINGLE RAS HEAD OPERATION VACUUM CONNECTION

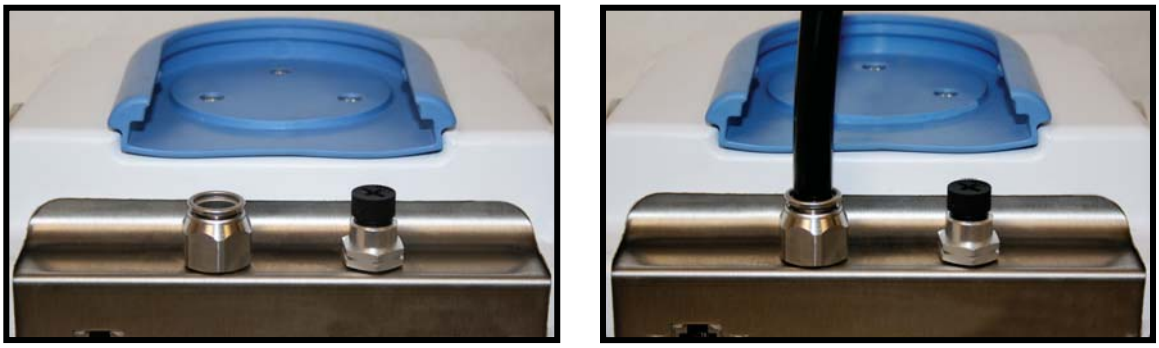


Fig 7.5.4.a
RAS With and Without Vacuum Supply Connection

DUAL RAS HEAD OPERATION VACUUM TUBING CONNECTIONS

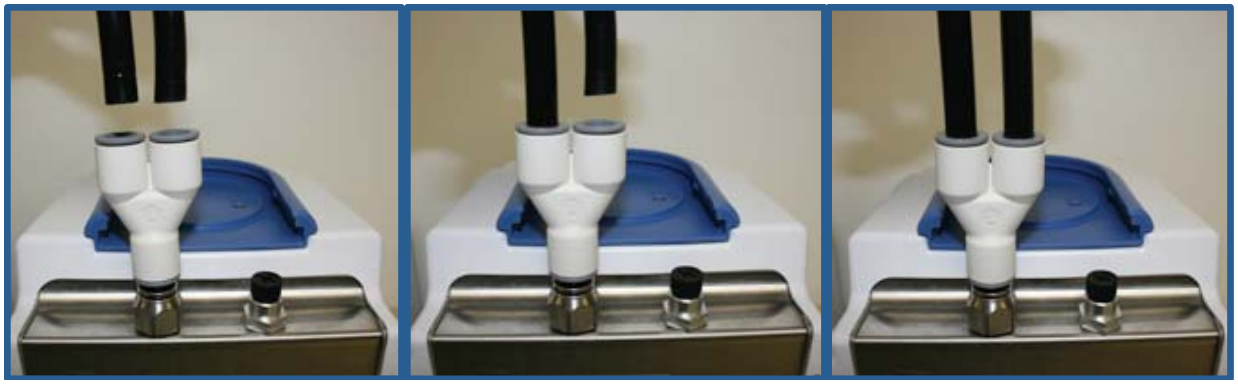


Fig 7.5.4.b
Dual RAS Tubing Connection Steps

SINGLE R2S/RCG HEAD OPERATION CONNECTIONS FOR POWER AND VACUUM

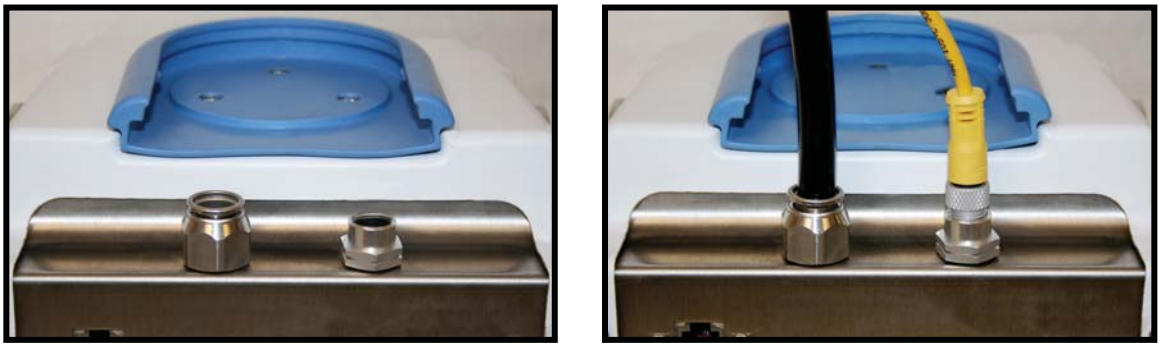


Fig 7.5.5.a
R2S/RCG With and Without Power and Vacuum Supply Connection

DUAL R2S HEAD OPERATION CONNECTIONS FOR VACUUM AND POWER SPLITTERS

Fig 7.5.5.b
Connecting Vacuum Tubing and Power Cables Pre-Connected to Splitters to V100

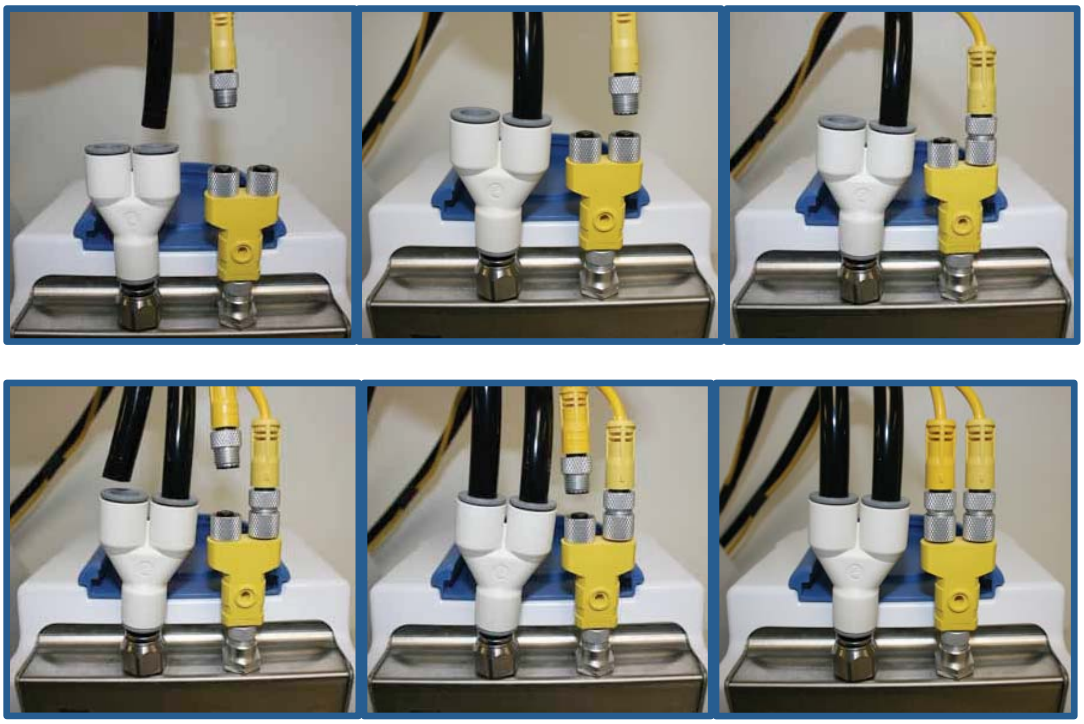


Fig 7.5.5.c
Connecting Vacuum Tubing and Power Cables to Splitters on V100

7.6 IR Remote Control

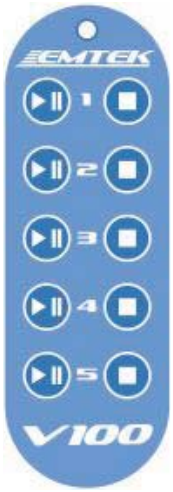


Fig 7.6.1
IR Remote Control

Table 7.6.1 Functions of Remote Control
Operation of 1 to 5 V100 Units

Button	Name	Description	Unit #
▶ ||	Sample On / Pause	Initiate / Pause / Resume sample period	Selected
■	Sample Abort/End	End or Abort sample period	Selected
1	Unit 1	Identifies Unit 1 for On/Off and Pause/Resume Functions	1
2	Unit 2	Identifies Unit 2 for On/Off and Pause/Resume Functions	2
3	Unit 3	Identifies Unit 3 for On/Off and Pause/Resume Functions	3
4	Unit 4	Identifies Unit 4 for On/Off and Pause/Resume Functions	4
5	Unit 5	Identifies Unit 5 for On/Off and Pause/Resume Functions	5

7.6.1 Loading the Batteries into the Remote Control

1. Remove the battery cover.
2. Insert two AAA batteries. Ensure that the poles (+ and -) are correctly positioned.
3. Replace the battery cover.

7.6.2 Operating the V100 (Unit #1) with the Remote Control

1. To start the sampling period, press the Start【#】key of the unit to be operated.
2. To start the sampling period, press the Start【On/P】key.
3. To pause the sampling period, press the【On/P】key while the unit is sampling.
4. To resume the sampling period, press the【On/P】key and the sample period resumes.
5. To stop the sampling period, press the【End】key.

7.7 Alarms/ Warning Screens

Flow Alarms: During operation, the V100 detects high and low flow rates. Alarms are triggered based on user-defined thresholds between 0 - 25% (see Fig 7.2.3, #7). If the required flow rate differs by more that the defined threshold for more than ten seconds, an alarm screen appears and requires an acknowledgement by pressing the "OK" button (see Fig 7.7.1.a).

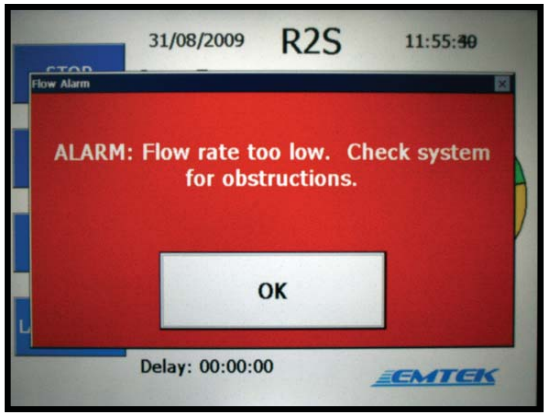


Fig 7.7.1.a
Flow Alarm Screen

Blower Alarms: CONTACT EMTEK FOR USE OF BLOWER ALARMS. If blower Alarms are set through the unit internal Configuration File (not through the Set Up Menu screens). During operation, the V100 detects high and low blower power voltages conditions. Alarms are triggered based on set threshold values ranging from ±5% to ±50% (100% = blower alarms off). If the required flow rate differs by more that the defined threshold for more than ten seconds, an alarm screen appears stating the high or low blower condition, and the sample cycle is also terminated. The alarms require an acknowledgement by pressing the "OK" button (see "Blower to High" Fig 7.7.1.a and "Blower too Low" 7.7.1.c).

Fig 7.7.1.b

Blower Alarm Screens Fig 7.7.1.c

Test in Progress: If a sample is in progress, the set-up screens cannot be accessed until the sampling period has completed or the sample is stopped. Pressing the set-up key while a sample is in progress activates a warning screen and requires an acknowledgement by pressing the “OK” button (see Fig 7.7.2).

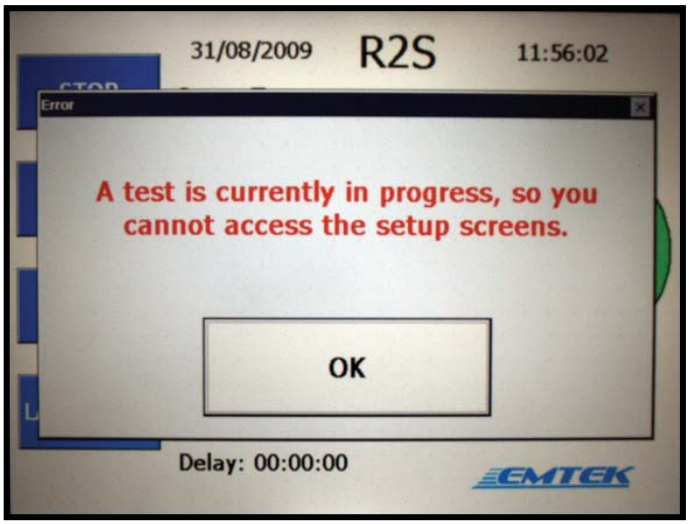


Fig 7.7.2
Test in Progress

No Labels Detected: Should the unit attempt to print or should the user attempt to advance a label/paper and the unit is out of labels/paper, a warning screen will appear notifying the user (see Fig 7.7.3).

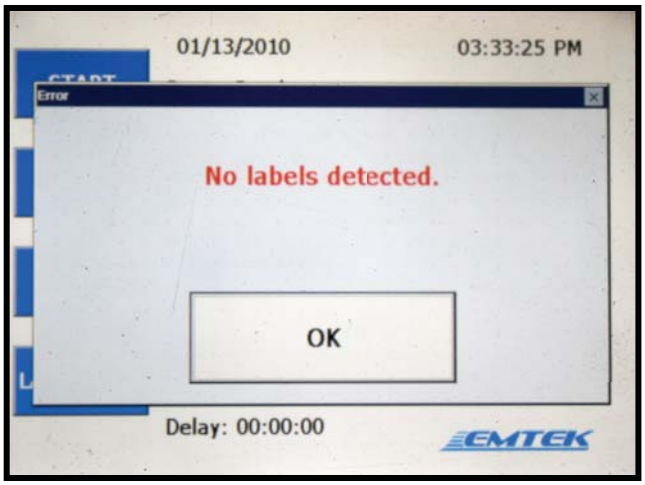


Fig 7.7.3
Paper/Label Out

7.8 Loading Printer Paper/Labels- Printer Operation

The V100 features an integrated thermal printer located on the side of the unit. The printer has the option for normal thermal paper operation or can be utilized with specified thermal labels.

Important Note: To prevent damage to the print head, the printer should not be operated without paper/labels. If the unit must be operated without paper/labels in the printer, set the Print Mode to Off.

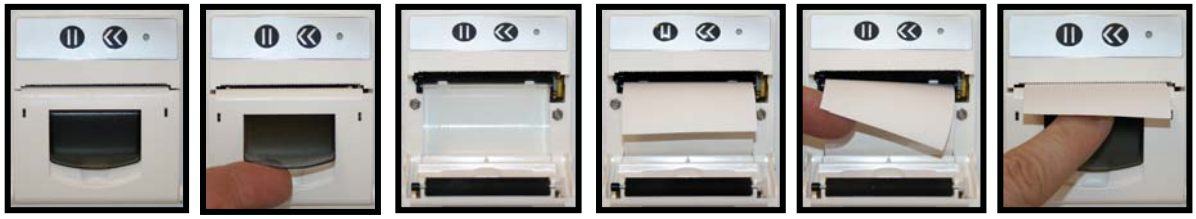
Important Note: Paper used in this printer is temperature-sensitive on one side and must go into the printer as explained in the instructions. Do not substitute other types of paper.

Important Note: Due to the paper/label properties, it is not compatible with or intended for permanent data recording/archival.

To install a roll of printer paper/labels (Fig 7.8.1):

1. Locate the printer on the back left side of the unit.
2. Pull up the handle in the center of the paper cover until a click is heard.
3. Fold the door down and remove the core from the previous roll.
4. Install the new paper, or label roll so the paper feeds from the top of the roll. Position the end of the paper over the black roller at the end of the printer feed door (Do not thread the paper under the roller). If label stock is used, align the leading edge of a black Top of Form (TOF) mark with the center of the printer door.
5. Push the printer door back until it clicks into place.
6. Press the LABEL FEED key once on the V100 front display to align the labels. The printer is now ready for operation.

Note: If the paper does not feed out or no image appears on the paper after a print command has been sent, perform the described steps, but check the orientation of the paper roll in the printer assembly.



Step 1 Step 2 Step 3 Step 4 Step 5 Step 6

Fig 7.8.1
Printer Paper/Label Installation

7.9 Replacing the HEPA Filter

English

DANGER: Electric Shock or Electrocution Hazard exists.
Disconnect all power sources before repair or service to the instrument.

Français

DANGER: Le Hasard d'Électrocution ou de Décharge électrique existe.
Débranchez toutes les sources de pouvoir avant la réparation ou le service à l'instrument.

English

Important Note: Take steps outlined in Step 4.2 to avoid ESD damage.

Français

Note Importante: Voir la section 4.2 pour éviter le dommage d'ESD.

The V100 is equipped with a HEPA filter exhaust. It is recommended to replace this filter every 6 to 12 months as part of periodic maintenance. To replace the HEPA filter, remove the filter door (Fig 7.9.1 and 7.9.2, #1). Release the filter from its connection port by gently pulling the filter straight out of the opening (Fig 7.9.3, #1). Once the filter is out of the unit, carefully remove the flow control tubing (Fig 7.9.3, #2). Replace the new filter by first connecting the flow control tubing and gently pushing the filter onto its connection port. A snug and complete fit is required for proper operation.

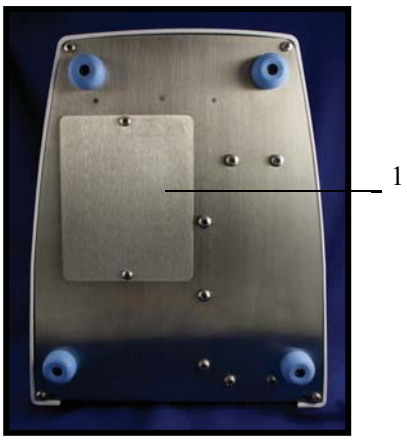


Fig 7.9.1

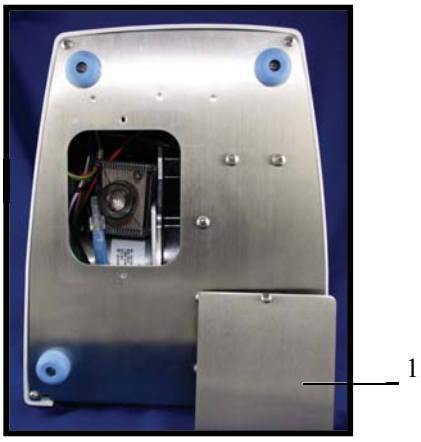


Fig 7.9.2

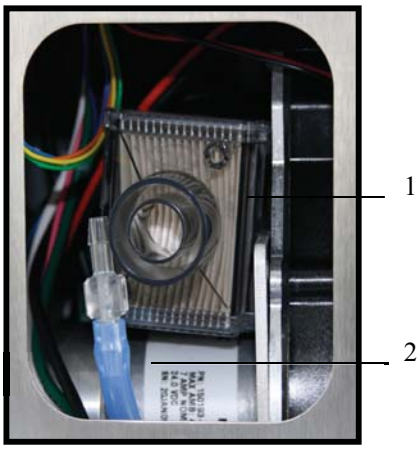


Fig 7.9.3

7.10 Touch Screen Sensor Calibration

The touch screen on the V100 is equipped with a calibration program. To perform the calibration, ensure that the main Test/Sample screen is selected (Fig 7.2.1). Hold one finger on the touch screen for approximately 3-seconds. An indicator beep will start. After the 7th beep, remove your finger from the touch screen. This activates the sequence of screens shown in Fig 7.10.1. Follow the on-screen instructions in selecting and holding each of the cross-hairs (Fig 7.10.1, Steps 1-5). Once complete, press the accept key (Fig 7.10.1, Step 6). If the calibration sequence is not followed within 15 seconds after initiated, the program returns to the Test/Sample screen.

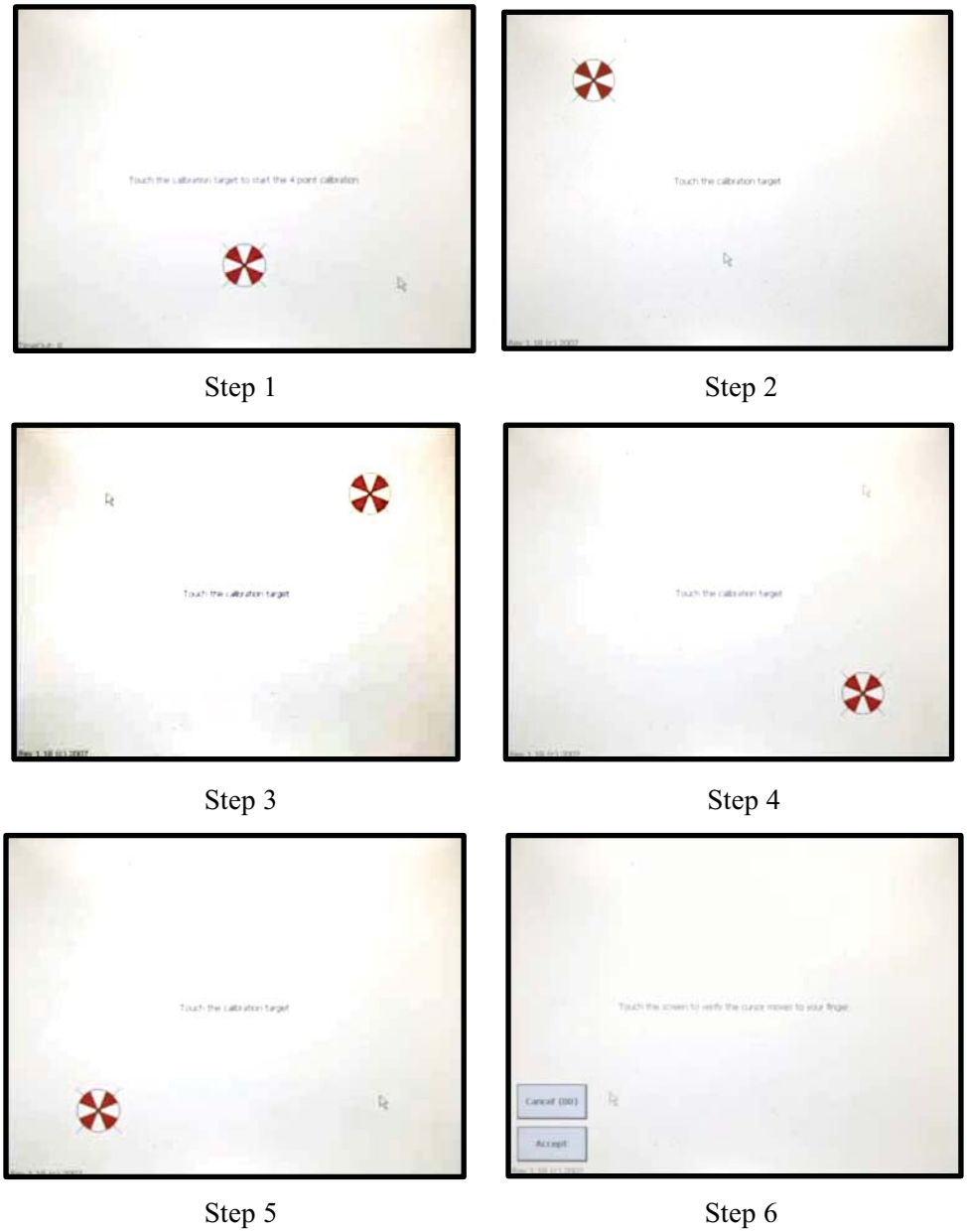
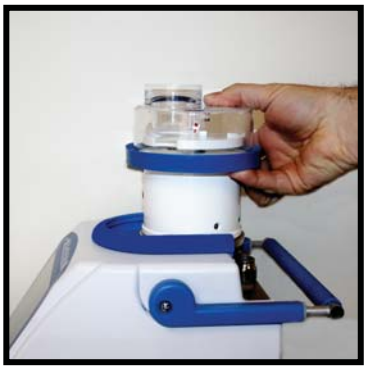


Fig 7.10.1
Touch Screen Calibration

7.11 Transporting the V100 and R2S/RCG Samplers

The V100 comes equipped with a transport cup mounted to the top of the unit. This cup is designed to securely support both the R2S and RCG samplers for transport with the aid of the collapsible handle. Both the R2S and the RCG samplers slide into the transport cup from the rear and seat under a supporting rim on the transport cup. The bottom of both the R2S and RCG samplers are concave and accept the raised circular center of the transport cup for a secure fit.


Once secure within the transport cup, the transport handle can be extended and raised to a position above the sampler. Use the handle to transport the V100 and R2S/RCG sampler to the desired location. Once in the desired location, the handle can be returned the rear of the V100 and collapsed into its storage position. When removing the samplers, ensure that the handle is out of the path of the sampler, lift the sampler up slightly and slide to the rear of the transport cup


Section 8 Network Operation of the V100

The V100 controller stores Sample Run Data (Run Data) up to the limit of the internal 1 GB memory. This memory is flash RAM that is not removable or alterable by the user.

The **USB port** is provided to allow for the Calibration of the unit via an external Calibration Software Program. Contact EMTEK, LLC for more information regarding the Calibration Software Program.

The Run Data maintained in the system includes set/actual flow rate, set/actual sample volume, sample start/end times, set delay, test and hold period, calibration date and due date of the controller, alarms during sampling, user sample description and unique sample identifier. The stored sample parameters can be cleared/deleted by the user but cannot be edited. Further, sample parameter information of a specific sampling event cannot be selectively deleted or altered by the user.

The V100 is equipped with an Ethernet 10BaseT-/100-BaseT Port that will allow for an outside program to view or extract the Sample Run Data (Run Data). The Sample Run Data can be downloaded or viewed, but cannot be modified while within the units memory.

The Run Data may be viewed through a **WEB browser**, as follows:

1) Attach the V100 to a Local Area Network (LAN) connection, or to a separate Ethernet hub through the Ethernet port.
2) Connect a computer (PC) to the LAN, or to the Ethernet Hub.
3) Open up a WEB browser (e.g., Windows Explorer) on the PC.
4) In the Address Line of the browser enter the following URL: http://emt#/runs where the "#" is equal to the Infrared Remote (IR) Number, IR ID#, as selected/displayed on Set Up Screen 4 (Fig 7.2.4, #8).
5) This will display the Run Files currently stored in the V100 memory. Double clicking on each Run File will open a new window view of the individual sample run parameters.
6) If viewing the run data while a run is in progress on the V100 you will be able to see the current run data, only when the run is complete, by using the refresh button on the browser.

The Run Data may be viewed through **PC Command Line access**, allowing direct viewing and download/copying of the Run Data stored in the V100's configuration file. While connected to a LAN, or Hub as described above, perform the following:

1) Open the Run Command Line on a PC and enter: \\emt#\runs
2) The "#" represents the setting of the IR ID# on Set-up Screen 4
   Example: If your V100 is set to IR ID# 1, you would enter: \\emt1\runs
3) The first time you connect with your computer, you will be asked for a user ID and Password. Use "emtek" in both the User ID and Password prompts. The PC will likely remember the User ID/Password.
4) Selecting "OK" will take you to the following Directory on the V100. These files are the individual sample run files.
5) Double-clicking a sample run file brings up the sample run parameter data for that run.
6) The data files can be saved to your desktop or specified file. The data cannot be modified and saved on the V100 unit. **IMPORTANT NOTE: Once the data is saved outside of the V100 system, the data integrity is not guaranteed by EMTEK. EMTEK. LLC does not provide outside software that is 21 CFR Part 11 compliant. Downloaded sample parameter data must be handled by the user in a compliant manner.**

Appendix A: Remote Compressed Gas (RCG) Sampler Operation for Compressed Air/Gas Systems

This section describes the procedure to monitor for viable airborne bacteria on a Compressed Air/Gas System with the Remote Compressed Gas (RCG) sampler from EMTEK, LLC.

A.1 RCG Operating Principles

The RCG compressed gas sample chamber is attached to a compressed gas drop through a short length of sample tubing and EMTEK's microbial high-pressure diffuser with the aid of sanitary connectors, gaskets, and clamps. A 90 mm agar based test plate is placed on the turntable of the RCG underneath the dome assembly and the dome assembly retention clip is put in place. The required sample time period is set on the V100 Controller and the testing period is initiated. With the EMTEK diffuser, compressed air/gas system may be tested at pressures ranging from approximately 15-115 PSI with the V100 using a flow rate of 50 LPM (See EMTEK Microbial High Pressure Diffuser Procedure for diffuser use and maintenance). The sample volume passes into EMTEK diffuser, which steps down the pressure that then passes through the sample tubing and into the RCG dome assembly through the sample chamber and sample slit. Airborne bacteria in the sampled volume of air/gas become impinged (captured) on the test plate within the RCG Dome assembly. The sampled air volume is then drawn through the vacuum line into the vacuum inlet of the V100 and through the controller. The sampled air volume passes through the system and is then exhausted from the V100, located outside of (or away from) the critical environment (or test area) through a 0.2 micron HEPA filter.

During testing, the test plate rotates on the turntable. This rotation removes recovered organisms from the direct path of incoming air to help prevent their desiccation, allows for easier enumeration of isolates recovered and for the determination of the approximate time of their recovery. Upon completion of the test period, the test plate is removed from the RCG and is incubated for a designated time period at a specified temperature. Following the required incubation period, the numbers of bacterial Colony Forming Units (CFU) are enumerated for the sampled volume of air/gas. The density of air borne bacteria per volume of air/gas, tested, can then determined.

A.2 Materials

- EMTEK RCG Compressed Air Sampler and V100 calibrated for operation at 50 LPM with power cable/vacuum tubing assembly.

- 50 LPM RCG Dome Assembly, with Green Distance Indicator Mount for 50 LPM

50 LPM RCG Dome-Green

- EMTEK Microbial High Pressure Diffuser, Sanitary sample tubing assembly, and sanitary fitting clamps (single, or multiple) autoclaved, or chemically sanitized for use.

- Gloves (Sterile or Clean)

- Standard 90 mm agar test plates (e.g., TSA Agar)

- Incubator(s) (e.g., 30-35°C or 20-25°C)

- Low Particulate Shedding Wipes (e.g., Wipe All, Gamma Wipes or equivalent or better)

- Disinfectants (e.g., Quaternary Ammonia Compounds, 70% 0.2µm filtered or sterilized alcohol)

Important Note: Phenolic disinfectants should not be used on the Clear Dome Assembly, as they will cause the dome to become brittle in a short period of use.

- Lab marker

A.3 Maintenance Inspection

To assure appropriate operation of the RCG sampling assembly, prior to each days use, sampling personnel should inspect the unit for any obvious physical defect. This inspection shall include but not be limited to the following:

- A visual check of the dome-to-base seal or dome assembly to assure it is not visibly damaged in a way that would keep it from sealing appropriately (tears in the seal, cracks or chips in the dome, etc.).
- A visual check that the spring-loaded dome assembly retention clip is functional and free from defect.
- The sample slit of the sample throat shall be visually inspected to assure that it is free of occlusions to assure proper sample flow through the slit.

If any maintenance need be performed, contact appropriate service or repair personnel.

IMPORTANT SAFETY PRECAUTIONS!!

English

TO MINIMIZE THE CHANCE OF ELECTRICAL HAZARD, assure that the primary AC power supply cord is not plugged in during sanitization.

DO NOT REMOVE THE PANELS or COVERS of the V100 to attempt any repairs. Contact EMTEK, LLC or other qualified service personnel if the unit malfunctions.

DO NOT SUBMERSE the V100 or RCG in any liquids!

TAKE ALL OTHER STANDARD ELECTRICAL SAFETY PRECAUTIONS when operating the RCG Sampling Assembly with the V100 controller

Français

Pour minimiser le risque DE DANGER ÉLECTRIQUE, s'assurer que les primaires d'alimentation Cordon d'alimentation secteur n'est pas branché au cours de désinfection.

NE PAS retirer les panneaux ou les couvertures de la V100 de tenter toute réparation. Contact Emtek, LLC ou de tout autre personnel de maintenance qualifié si les dysfonctionnements unité.

NE PAS immerger le V100 ou RCG dans tous les liquides!

PRENDRE TOUTES LES AUTRES MESURES DE SÉCURITÉ électriques standard pendant le fonctionnement du RCG échantillonnage Assemblée avec le contrôleur V100

A.4 RCG Sampler Assembly Set-Up and Testing

NOTES:

Before sampling with the V100 and RCG:

- Perform the sanitization procedure in Appendix E.
- The V100 and RCG Air Sampler(s) must be calibrated as a system with the desired configuration. This includes calibration of the V100 with the air sampling head, including the vacuum tubing length that will be employed during use.

English

WARNING: During compressed air/gas sampling, follow the procedure as stated to minimize the risk of injury from testing of these high-pressure systems. Safety glasses and/or a face shield should be worn at all times.

Français

AVERTISSEMENT: Lors de l'air comprimé / d'échantillonnage de gaz, de suivre la procédure comme il est indiqué pour réduire au minimum le risque de blessures en cas de test de ces systèmes à haute pression. Lunettes de sécurité et / ou un masque facial doit être porté en tout temps.

1. Attach the RCG power supply cable and vacuum supply tubing, as follows:

   1.1 Attach the appropriate end of the power supply cable to the connector on the RCG sampler. Align the two “keys” of the cable connector with the key-way. Firmly press the cable end connector onto the RCG connector while threading the collar clockwise until it becomes finger tight. Attach the vacuum supply tubing to the RCG sampler by placing tubing over the barb and pressing firmly to achieve an airtight fit. See Section 7.5 for connection images.

   1.2 Attach the other end of the power supply cable to the connector on the V100. Align the two “keys” of the cable connector with the key-way. Firmly press the cable end connector in to the front panel connector while threading the collar clockwise until it becomes finger tight. Attach the vacuum supply tubing to the V100 by placing the tubing into the tube connector and pressing down firmly to achieve an airtight fit. See Section 7.5 for connection images.

2. Place the RCG at the desired compressed air or gas test site (e.g., on a bench, cart, table, etc. within the constraints of the vacuum/power cable assembly and sanitary sample tubing (e.g., 2 feet).

3. Following the EMTEK 50 LPM Microbial High Pressure Diffuser Procedure to attach the RCG to the sample point. In general, attach the tubing end of the sanitized, or autoclaved, sanitary sample tubing to the EMTEK Microbial High Pressure Diffuser, which has been attached to the compressed air/gas drop using a sanitary clamp assembly. Attach the end of the sample tubing with the sanitary fitting to the sanitary fitting on the RCG sample inlet using a sanitary seal and clamp.

4. If the dome assembly has been chemically sanitized, assure residual disinfectant and particulate matter from cleaning and set up are removed from the sample chamber and dome assembly by purging the unit prior to attaching the vacuum tubing to the RCG sampler.

5. Assure that the dome assembly retention clip is in place and then slowly open the compressed air or gas drop. The drop should be regulated to between 15 and 115 PSI. This can be accomplished by having the system or drop regulated to the required PSI or by using the EMTEK Microbial High Pressure Diffuser to reduce the sampled flow of the drop.

   Note: The dome assembly retention clip is intended to retain the dome in place curing set up and purging while allowing excess pressure to escape between the dome flange and seal.

6. Run air/gas through the unit for approximately 2-3 minutes or until physically dry within the RCG dome assembly and then turn off the air/gas supply.

7. Turn on the V100 power switch at the bottom back corner of the unit.

8. Set the desired sample parameters on the V100 (see Section 7).

9. Verifying the flow rate to the desired flow (50 or 100 LPM for compressed air/gas sampling):

   9.1 Slowly open the compressed air/gas drop (regulated to 15- 115 PSI) and then press the Start key on the V100 or remote to start the blower.

   9.2 Once the blower ramps up to the appropriate flow rate (approximately 2 to 5 seconds), sampling on the V100 will begin.

   9.3 Ensure that the flow on the compressed air/gas drop is achieving the required airflow on the V100 controller.

   NOTE: Over pressurization of the drop will be evident by a higher registered flow rate than that set. Under pressurization will be evident by a lower registered flow rate than that set. In addition, low and high flow alarms can be set to alert the user of these conditions (see Section 7).

   9.4 Once the set volume is achieved, the blower motor will stop. To stop the unit sooner, press the Stop key on the V100 or remote to stop the unit and turn off the flow from the compressed air/gas drop.

10. Initiating Sampling:

   10.1 Remove the retention clip from the top of the dome assembly and place it on the edge of the dome seal.

   10.2 Aseptically place the test plate (e.g. 90 mm TSA plate) on the turntable as follows:

NOTE: Gloved hands should be cleaned with secondary disinfectant immediately prior to performing these steps.

10.3 Lift up the dome assembly just high enough to place the test plate on the turntable and remove its lid. Without inverting, place the lid of the test plate face down on a pre-sanitized surface.

NOTE: Removing and holding the dome only a few inches directly over the turntable will minimize the chance of contaminants settling on the sanitized components under the dome and on the test plate during this manipulation.

10.4 Place the dome assembly down over the test plate and turntable.

10.5 Securely seat the dome assembly in the "dome-to-base" seal and assure that the dome is properly seated in the seal.

10.6 Replace the dome assembly retention clip.

10.7 Adjust the Turntable / Test Plate Height Adjustment as follows:

10.7.1 View the test plate distance indicator through the side of the dome to assure that test plate is at the proper height.

10.7.2 Rotate the turntable adjustment knob clockwise or counter clockwise until the top of the test plate just touches the distance indicator on the interior center of the dome. This adjustment will assure the required distance of approximately 2-3 mm from the test plate surface to the opening of the sample slit.

10.7.3 Starting the Testing Period:

10.7.3.1 Assure that the sample time is set to the desired sample period and the drop is regulated to the predetermined rate, then slowly open the flow on the compressed air/gas drop and press the Start button on the V100 or remote to begin the test cycle.

10.7.3.2 Assure that the sampling assembly is not over or under pressurized. Air will be noted to escape from the base of the clear dome assembly if the system pressure is too high and/or the Actual Flow indicator on the V100 will register higher than the selected. In addition, high and low flow alarms can be set by the user to alert if the condition exists. See Section 7.

10.7.3.3 If desired, the test period can be paused/resumed by pressing the pause/resume key on the V100 or remote control at any time during the testing period.

10.7.4 Ending the Testing Period:

10.7.4.1 When the selected volume is achieved, the blower and the plate rotation automatically stop. If desired, the test period can be terminated by pressing the Stop key on the V100 or remote.

10.7.4.2 Immediately turn off the compressed air/gas supply.

NOTE: There is no check valve in place to cause back-pressure on the system at the completion of the sample period. The compressed gas/air will continue to flow through the system. The diffuser will allow the excess pressure from the compressed air/gas system to vent until the air/gas supply is turned off.

10.7.4.3 Remove the dome assembly retention clip and place on the edge of the blue dome seal.

10.7.4.4 Aseptically remove the test plate from the turntable as follows:

Note: Gloved hands should be rinsed with secondary disinfectant immediately prior to performing these steps.

10.7.4.4.1 Remove the dome from the RCG sampler with one hand and with the other hand; replace the lid of the test plate, being careful not to touch the inside of the lid or the agar surface. Do not move your hand over the exposed surface of the test plate. Allow the lid to lead your hand over the test plate as you replace it.

10.7.4.4.2 Remove the test plate, with the lid in place, from the turntable and place the dome back on the RCG sampler.

10.7.4.4.3 Secure the lid to the test plate with tape.

10.7.4.5 Assure all applicable information is recorded on the test plate, as required. Upon completion of the test period, a printout (label or Paper tape) is generated from the on-board thermal printer with the sample parameter information (e.g., Sample Start/Stop Time, Site #, Date, Operator Initials, etc.). The paper can be retained or the label can be affixed to the bottom of the agar plate or required paperwork. For sinlge head sampler operation it is ideal to set the Replicate Label Count to 1, for labeling of each plate (see Section 7.2 Setup Screen 4 details). The operator may initial and date the printout if desired.

10.7.4.6 Carefully inspect the test plate:

10.7.4.6.1 Without taking the lid off the test plate, assure that impingement marks are present on the agar surface and that they are reflective of the sampling period.

EXAMPLE 1:
The plate should make one full revolution if the sample completed its set time period and air impingement marks should be present around approximately 355° of the plate. A 5° buffer is present to determine the representative start and stop time.

EXAMPLE 2:
If the test period was stopped prior to its set time period, the impingement marks should be visible around the corresponding time period as represented on the plate. Half of the time period sampled would be indicative of almost half of the plate exhibiting impingement marks due to the 5° buffer.

10.7.4.6.2 If impingement marks are not present, the sample/test should be considered invalid unless impingement marks were noted during sampling. Excessive moisture can cause issues with retaining the impingement marks (see note below).

Note: Due to excessive moisture of a test plate, impingement marks, may be "erased" from the agar surface. Ensure that plates with excessive moisture are not used to avoid this situation.

10.7.5 Ensure that all applicable information is recorded on the test plate. The printer in the V100 can be used to print a printout/label with this information.

10.7.6 Repeat the applicable portions of this procedure for additional samples. A newly sanitized sample tubing assembly may be used for each sample. Chemical sanitization, or at least purging of the dome assembly should be performed at each sample location to assure a representative sample from that location following each set up.

A.5 Storage and Transport

1. For transport convenience:

1.1 The RCG sampler should be placed in the transport mount located at the top of the V100 controller for transport or for storage (see Section 7.11).

1.2 The V100 vacuum tube, sampler cable, and power cord should be coiled and can be placed over the V100 in the transport mount.

1.3 For transport outside of the facilities the entire assembly may be placed in a bag to minimize possible contamination of the unit.

1.4 A cover (e.g., sanitary cap, or bioshield) may be placed over the sanitary fitting opening of the sample conduit of the RCG dome assembly during transport and storage to minimize contamination.

2. Store the V100 and RCG assemblies in a clean and dry place.

3. The sanitary sample tubing assembly (attaching the RCG to the diffuser), and the diffuser, may be autoclaved, or chemically sanitized before, or after each use. It is ideal to package and store the assembly to minimize the contaminant load. Autoclave pouches may be used for this purpose. See EMTEK Microbial High Pressure Diffuser Procedure.

Appendix B: Remote Compressed Gas – Confined-Space (RCG) Sampler

Operation for Confined Spaces

This section describes the procedure to monitor for viable airborne bacteria in a Confined Space with the Remote Compressed Gas – Confined-Space (RCG) sampler from EMTEK, LLC.

B.1 RCG Operating Principles

The RCG Confined Space sampling head is attached to a critical zone, or location using a short length of sample tubing with sanitary connectors, or barbed fittings. A 90 mm agar based test plate is placed on the turntable of the RCG underneath the dome assembly and the dome assembly retention clip is put in place. The required sample time period is set on the V100 Controller and the testing period is initiated. During testing of the critical zone, the V100 operates at a flow rate of 28.3, 50, and 100 LPM as regulated by the V100 controller. This sample volume passes into the RCG dome assembly through the sample chamber and sample slit. Airborne bacteria in the sampled volume of air/gas become impinged (captured) on the test plate within the RCG Dome assembly. The sampled air volume is then drawn through the vacuum line into the vacuum inlet of the V100 and through the controller. The sampled air volume passes through the system and is then exhausted from the V100, located outside of (or away from) the critical environment (or test area) through a 0.2 micron HEPA filter.

During testing, the test plate rotates on the turntable. This rotation removes recovered organisms from the direct path of incoming air to help prevent their desiccation, allows for easier enumeration of isolates recovered and for the determination of the approximate time of their recovery. Upon completion of the test period, the test plate is removed from the RCG and is incubated for a designated time period at a specified temperature. Following the required incubation period, the numbers of bacterial Colony Forming Units (CFU) are enumerated for the sampled volume of air/gas. The density of air borne bacteria per volume of air/gas tested can then determined using the provided formula.

B.2 Materials

- EMTEK RCG Confined Space Air Sampler and V100 Controller Calibrated for operation at 28.3, 50, and/or 100 LPM with power cable and vacuum tubing assembly

- RCG Dome for 28.3, 50, or 100 LPM-Distance Indicator Mount is color coded for each flow rate, as follows:

28.3 LPM Dome-White

50 LPM Dome-Green

100 LPM Dome-Blue

- Sanitary Sample Tubing Assembly and sanitary fitting clamps (single, or multiple) Autoclaved, or Chemically Sanitized for use

- Standard 90 mm Test Plates (e.g., TSA Agar)

- Incubator(s) (e.g., 30-35°C and/or 20-25°C)

- Gloves (Sterile or Clean)

- Low Particulate Shedding Wipes (e.g., Wipe All, Gamma Wipes or equivalent/ better)

- Disinfectants (e.g., Quaternary Ammonia Compounds, 70% 0.2µm filtered or sterilized alcohol)

Important Note: Phenolic disinfectants should not be used on the Clear Dome Assembly as they will cause them to become brittle.

- Lab Marker

- Adhesive Tape

B.3 Maintenance Inspection

To assure appropriate operation of the RCG sampling assembly, prior to each days use, sampling personnel should inspect the unit for any obvious physical defect. This inspection shall include but not be limited to the following:

- A visual check of the dome-to-base seal or dome assembly to assure it is not visibly damaged in a way that would keep it from sealing appropriately (tears in the seal, cracks or chips in the dome, etc.).
- A visual check that the spring-loaded dome assembly retention clip is functional and free from defect.
- The sample slit of the sample throat shall be visually inspected to assure that it is free of occlusions to assure proper sample flow through the slit.

If any maintenance need be performed, contact appropriate service or repair personnel.

IMPORTANT SAFETY PRECAUTIONS!!

English

TO MINIMIZE THE CHANCE OF ELECTRICAL HAZARD, assure that the primary AC power supply cord is not plugged in during sanitization.

DO NOT REMOVE THE PANELS or COVERS of the V100 to attempt any repairs. Contact EMTEK, LLC or other qualified service personnel if the unit malfunctions.

DO NOT SUBMERSE the V100 or RCG in any liquids!

TAKE ALL OTHER STANDARD ELECTRICAL SAFETY PRECAUTIONS when operating the RCG Sampling Assembly with the V100 controller

Français

Pour minimiser le risque DE DANGER ÉLECTRIQUE, s'assurer que les primaires d'alimentation Cordon d'alimentation secteur n'est pas branché au cours de désinfection.

NE PAS retirer les panneaux ou les couvertures de la V100 de tenter toute réparation. Contact Emtek, LLC ou de tout autre personnel de maintenance qualifié si les dysfonctionnements unité.

NE PAS immerger le V100 ou RCG dans tous les liquides!

PRENDRE TOUTES LES AUTRES MESURES DE SÉCURITÉ électriques standard pendant le fonctionnement du RCG échantillonnage Assemblée avec le contrôleur V100

B.4 RCG Sampler Assembly Set-Up and Testing

NOTES:
Before sampling with the V100 and RCG:

- Perform the sanitization procedure in Appendix E.
- The V100 and RCG Air Sampler(s) must be calibrated as a system with the desired configuration. This includes calibration of the V100 with either single or dual air sampling heads, including the vacuum tubing length that will be employed during use.

1. RCG Sampling Assembly Set-Up and Testing

1.1 Attach the RCG power supply cable and vacuum supply tubing:

1.1.1 Attach the appropriate end of the power supply cable to the connector on the RCG sampler. Firmly press the cable end connector onto the RCG connector while threading the collar clockwise until it becomes finger tight. Attach the vacuum supply tubing to the RCG sampler by placing tubing over the barb and pressing firmly to achieve an airtight fit. See Section 7.5 for connection images.

1.1.2 Attach the other end of the power supply cable to the connector on the V100. Firmly press the cable end connector in to the front panel connector while threading the collar clockwise until it becomes finger tight. Attach the vacuum supply tubing to the V100 by placing the tubing into the tube connector and pressing down firmly to achieve an airtight fit. See Section 7.5 for connection images.

1.2 Place the RCG at the desired test site (e.g., on a bench, cart, table, etc. within the constraints of the vacuum/power cable assembly and sanitary sample tubing (e.g., 2 feet)

1.3 Attach one end of the sanitized, or autoclaved, sanitary sample tubing/seal to the desired location using a sanitary clamp assembly. Attach the other end of the sample tubing assembly to the sanitary fitting on the RCG sample inlet using a sanitary clamp.

1.4 If the dome assembly has been chemically sanitized, assure residual disinfectant and particulate matter from cleaning and set up are removed from the sample chamber and dome assembly by purging the unit prior to attaching the vacuum tubing to the RCG sampler.

1.4.1 Turn on the V100 power switch at the bottom back corner of the unit.

1.4.2 Set the sample time for 2-3 minutes at the desired flow rate (see Section 7).

1.4.3 Assure that the dome assembly retention clip is in place.

NOTE: The dome assembly retention clip is intended to retain the dome in place during set up and purging.

1.4.4 Press Start on the V100 or on the remote to initiate the blower motor.

1.4.5 Once the sample completes, determine if the inside of the RCG is visibly dry. Repeat steps 1.4.2 through 1.4.4 as required until dry.

1.5 Initiating Testing:

1.5.1 Set the desired sample parameters on the V100. See Section 7.

1.5.2 Remove the retention clip from the top of the dome assembly and place it on the edge of the dome seal.

1.5.3 Aseptically place the test plate (e.g. 90 mm TSA plate) on the turntable as follows:

NOTE: Gloved hands should be cleaned with secondary disinfectant immediately prior to performing these steps.

1.5.4 Lift up the dome assembly just high enough to place the test plate on the turntable and remove its lid. Without inverting, place the lid of the test plate face down on a pre-sanitized surface.

NOTE: Removing and holding the dome only a few inches directly over the turntable will minimize the chance of contaminants settling on the sanitized components under the dome and on the test plate during this manipulation.

1.5.5 Place the dome assembly down over the test plate and turntable.

1.5.6 Securely seat the dome assembly in the “dome-to-base” seal and assure that the dome is properly seated in the seal.

1.5.7 Replace the dome assembly retention clip.

1.5.8 Adjust the Turntable / Test Plate Height Adjustment as follows:

1.5.8.1 View the test plate distance indicator through the side of the dome to assure that test plate is at the proper height.

1.5.8.2 Rotate the turntable adjustment knob clockwise or counter clockwise until the top of the test plate just touches the distance indicator on the interior center of the dome. This adjustment will assure the required distance of approximately 2-3 mm from the test plate surface to the opening of the sample slit.

1.5.9 Press Start on the V100 or on the remote to initiate the blower motor.

1.5.10 If desired, the test period can be paused/resumed by pressing the pause/resume key on the V100 or remote control at any time during the testing period.

1.6 Ending the Testing Period:

1.6.1 When the set volume is achieved, the blower and the plate rotation automatically stop. If desired, the test period can be terminated by pressing the Stop key on the V100 or on the remote.

1.6.2 Remove the dome assembly retention clip and place on the edge of the blue dome seal.

1.6.3 Aseptically remove the test plate from the turntable as follows:

Note: Gloved hands should be rinsed with secondary disinfectant immediately prior to performing these steps.

1.6.3.1 Remove the dome from the RCG sampler with one hand and with the other hand; replace the lid of the test plate, being careful not to touch the inside of the lid or the agar surface. Do not move your hand over the exposed surface of the test plate. Allow the lid to lead your hand over the test plate as you replace it.

1.6.3.2 Remove the test plate, with the lid in place, from the turntable and place the dome back on the RCG sampler.

1.6.3.3 Secure the lid to the test plate with tape.

1.6.4 Upon completion of the test period, a label is generated from the on-board thermal label printer with the sample parameter information. This label can be affixed to the bottom of the agar plate. The operator may initial and date the label if desired.

1.6.5 Carefully inspect the test plate:

1.6.6 Without taking the lid off the test plate, assure that impingement marks are present on the agar surface and that they are reflective of the sampling period.

EXAMPLE 1:
The plate should make one full revolution if the sample completed its set time period and air impingement marks should be present around 355° of the plate. A 5° buffer is present to determine the representative start and stop time

EXAMPLE 2:
If the test period was stopped prior to its set time period, the impingement marks should be visible around the corresponding time period as represented on the plate. Half of the time period sampled would be indicative of almost half of the plate exhibiting impingement marks due to the 5° buffer.

1.6.7 If impingement marks are not present, the sample/test should be considered invalid unless impingement marks were noted during sampling. Excessive moisture can cause issues with retaining the impingement marks (see note below).

NOTE: Due to excessive moisture of a test plate, impingement marks, may be "erased" from the agar surface. Ensure that plates with excessive moisture are not used to avoid this situation.

1.6.8 Assure all applicable information is recorded on the test plate, as required. Upon completion of the test period, a printout (label or Paper tape) is generated from the on-board thermal printer with the sample parameter information (e.g., Sample Start/Stop Time, Site #, Date, Operator Initials, etc.). The paper can be retained or the label can be affixed to the bottom of the agar plate or required paperwork. For dual head sampler operation it is ideal to set the Replicate Label Count to 1, for labeling of each plate (see Section 7.2 Setup Screen 4 details). The operator may initial and date the printout if desired.

1.6.9 Repeat the applicable portions of this procedure for additional samples.

1.6.10 A newly sanitized sample tubing assembly may be used for each sample.

1.6.11 Chemical sanitization, or at least purging of the dome assembly should be performed at each sample location to assure a representative sample from that location following each set up.

B.5 Storage and Transport

1. For transport convenience:

1.1 The RCG sampler should be placed in the transport mount located at the top of the V100 controller for transport or for storage (see Section 7.11).

1.2 The V100 vacuum tube, sampler cable, and power cord should be coiled and can be placed over the V100 in the transport mount.

1.3 For transport outside of the facilities the entire assembly may be placed in a bag to minimize possible contamination of the unit.

1.4 A cover (e.g., sanitary cap, or bio-shield) may be placed over the sanitary fitting opening of the sample conduit of the RCG dome assembly during transport and storage to minimize contamination.

2. Store the V100 and RCG assemblies in a clean and dry place.
3. The sanitary sample tubing assembly (attaching the RCG to sample location) may be autoclaved, or chemically sanitized before, or after each use. It is ideal to package and store the assembly to minimize the contaminant load. Autoclave pouches may be used for this purpose.

Appendix C: Remote-Autoclavable-Sampler (RAS) Operation

PURPOSE

To describe the procedure to monitor for viable airborne bacteria with the Remote-Autoclavable-Sampler Assembly (RAS) from EMTEK, LLC.

C.1 RAS Operating Principles

A 90 mm agar based test plate is placed on the base plate of the RAS underneath the top cover assembly. The required sample time period is set on the V100 controller and the testing period is initiated. During testing, the vacuum pump of the V100 draws 28.3, 50, or 100 SLPM into the RAS sampler(s) through the sample inlets. Airborne bacteria in the sampled volume of air become impinged (captured) on the test plate. The sampled air volume is then drawn through the vacuum line into the vacuum inlet of the V100 and through the controller. The sampled air volume passes through the system and is then exhausted from the V100, located outside of (or away from) the critical environment (or test area) through a 0.2 micron HEPA filter.

Upon completion of the test period, the test plate is removed from the RAS and is incubated for a designated time period at a specified temperature. Following the required incubation period, the number of bacterial Colony Forming Units (CFU) are enumerated. The density of air borne bacteria per volume of air tested can then determined.

C.2 Materials

- EMTEK RAS Air Sampler and V100 Controller, Calibrated for operation at 28.3, 50, or 100 LPM with vacuum tubing assembly
- Standard 90 mm TSA Agar Test Plates
- 30-35°C and/or 20-25°C Incubators
- Gloves (Sterile or Clean)
- Low Particulate Shedding Wipes (e.g., Wipe All, Gamma Wipes or equivalent/better)
- Disinfectants (e.g., Quaternary Amonium Compounds, 70% 0.2µm Filtered or sterilized alcohol)
- Lab Marker and/or Pre-Printed Labels
- Adhesive Tape

C.3 Maintenance Inspection

To assure appropriate operation of the RAS sampling assembly, prior to each days use, sampling personnel should inspect the unit for any obvious physical defect. This inspection shall include but not be limited to the following:

- A visual check of the base seal to assure it is not visibly damaged in a way that would keep it from sealing appropriately (tears in the seal, etc.).
- The sample inlets shall be visually inspected to assure that they are free of occlusions to assure proper sample flow.

If any maintenance need be performed, contact appropriate service or repair personnel.

IMPORTANT SAFETY PRECAUTIONS!!

English

TO MINIMIZE THE CHANCE OF ELECTRICAL HAZARD, assure that the primary AC power supply cord is not plugged in during sanitization.

DO NOT REMOVE THE PANELS or COVERS of the V100 to attempt any repairs. Contact EMTEK, LLC or other qualified service personnel if the unit malfunctions.

DO NOT SUBMERSE the V100 or RCG in any liquids!

TAKE ALL OTHER STANDARD ELECTRICAL SAFETY PRECAUTIONS when operating the RCG Sampling Assembly with the V100 controller

Français
Pour minimiser le risque DE DANGER ÉLECTRIQUE, s'assurer que les primaires d'alimentation Cordon d'alimentation secteur n'est pas branché au cours de désinfection.

NE PAS retirer les panneaux ou les couvertures de la V100 de tenter toute réparation. Contact Emtek, LLC ou de tout autre personnel de maintenance qualifié si les dysfonctionnements unité.

NE PAS immerger le V100 ou RCG dans tous les liquides!

PRENDRE TOUTES LES AUTRES MESURES DE SÉCURITÉ électriques standard pendant le fonctionnement du RCG échantillonnage Assemblée avec le contrôleur V100

C.4 RAS Sampler Assembly Set-Up and Testing

NOTES:
Before sampling with the V100 and RAS:

- Perform the sanitization procedure in Appendix E.
- The V100 and RAS Air Sampler(s) must be calibrated as a system with the desired configuration. This includes calibration with either single or dual air sampling heads, including the vacuum tubing length that will be employed during use.

1. RAS Sampling Assembly Set-Up and Testing

1.1 Attach the RAS Vacuum Supply Tubing for single or dual head operations (see Section 7.5 images):

1.1.1 Attach one end of the vacuum tubing to the vacuum tube connection on the V100.

1.1.2 Attach the other end of the vacuum tubing to the barb on the RAS Sampler.

1.2 Upon completion of sanitization per Appendix E (If applicable), place the RAS at the desired test site.

1.3 Place the V100 outside or below (i.e., on a cart) the testing area, within the constraints of the power supply cord and vacuum supply line.

NOTE: Contact EMTEK, LLC for additional information on the maximum length of the vacuum supply line allowable.

1.4 Initiate unit power as follows:

1.4.1 Plug the Primary AC Power Supply Cord into an appropriate power outlet.

1.4.2 Turn on the unit power switch found at the bottom back corner of the V100 controller unit.

1.4.3 If the RAS has been chemically sanitized, ensure residual disinfectant and particulate matter from cleaning and set up are removed from the sample chamber by purging the unit prior to initiating testing.

1.4.3.1 Set the sample parameters on the V100 to sample for 2-3 minutes (see Section 7).

1.4.3.2 Press the Start key on the V100 to start the blower motor.

1.4.3.3 Once the blower ramps up to the appropriate flow rate (approx. 2-5 seconds), sampling on the V100 will begin.

1.4.3.4 The V100 will stop once the selected sample volume is attained.

1.4.3.5 Check to ensure that the RAS is physically dry. Repeat steps 1.4.3.2 through 1.4.3.4, as necessary until visibly dry.

1.5 Begin testing by following the steps below:

1.5.1 Set the sample parameters on the V100 to sample for the desired flow rate and sample volume/sample time, etc (see Section 7).

NOTE: An initial sample delay can be set to allow for clearance of the area by personnel prior to the start of sampling. A test/hold function is also available as well as IR remote control (see Section 7).

1.5.2 Aseptically place the test plate (i.e., 90 mm TSA plate) on the turntable as follows:

NOTE: Gloved hands should be cleaned with secondary disinfectant and allowed to dry immediately prior to performing these steps.

1.5.3 Lift up the top sampling cover just high enough to place the test plate on the turntable and remove its lid. Without inverting, place the lid of the test plate face down on a pre-sanitized surface next to the RAS.

NOTE: Removing and holding the top sampling cover only a few inches directly over the base plate holder will minimize the chance of contaminants settling on the sanitized components under the dome and on the test plate during this manipulation.

1.5.4 Place the top sampling cover down over the test plate and onto the seal on the base plate holder.

1.5.5 Assure that the top sampling cover is properly seated on the seal.

1.6 Starting the Testing Period:

1.6.1 Press the Start button on the V100 or remote control to begin the test cycle.

1.6.2 If desired, the test period can be paused/resumed by pressing the pause/resume key on the V100 or remote control at any time during the testing period.

1.7 Ending the Testing Period:

1.7.1 When the required volume is attained the blower motor automatically shuts off. If desired, the test period can be terminated by pressing the Stop key on the timer or on the remote.

1.7.2 If desired, the test period can be Pause/Resume by pressing the Pause/Resume key on the V100 or remote control at any time during the testing period.

1.8 Aseptically remove the test plate as follows:

NOTE: Gloved hands should be rinsed with secondary disinfectant and allowed to dry immediately prior to performing these steps.

1.8.1 Remove the top sampling cover with one hand and, with the other hand; replace the lid of the test plate. Be careful not to touch the inside of the lid or the agar surface. Do not move your hand over the exposed surface of the test plate. Allow the lid to lead your hand over the test plate as you replace it.

1.8.2 Remove the test plate, with the lid in place, from the base plate holder and replace the top sampling cover.

1.8.3 Secure the lid to the test plate with tape.

1.8.4 Carefully inspect the test plate:

1.8.4.1 Without taking the lid off the test plate, assure that impingement marks are present on the agar surface.

1.8.4.2 If impingement marks are not present, the sample/test may be considered invalid.

NOTE: Due to excessive moisture of a test plate, impingement marks, may be “erased” from the agar surface. Ensure that plates with excessive moisture are not used to avoid this situation.

1.8.5 Assure all applicable information is recorded on the test plate, as required. Upon completion of the test period, a printout (label or Paper tape) is generated from the on-board thermal printer with the sample parameter information (e.g., Sample Start/Stop Time, Site #, Date, Operator Initials, etc.). The paper can be retained or the label can be affixed to the bottom of the agar plate or required paperwork. For dual sampler operation it is ideal to set the Replicate Label Count to 2, for labeling of each plate (see Section 7.2 Setup Screen 4 details). The operator may initial and date the printout if desired.

1.9 If additional samples are to be taken at the same location during the same test period (e.g., for continuous process monitoring), repeat Steps 2.4 through 2.4.5 for each additional sample required.

1.10 When testing is complete at a specified location:

1.10.1 Turn off unit power and disconnect from AC power supply.

1.10.2 Sanitize the RAS sampling assembly to remove any contaminants or test media.

1.11 If additional samples are to be taken at different locations in the same area on the same day, move the RAS Sampling Assembly to the next location and repeat applicable portions of this procedure. If the unit is to be used in a different area on the same day (i.e., moved from one classified area to another) it is suggested to repeat applicable sanitization procedures in the next area prior to monitoring.

C.5 Storage and Transport

1. For transport convenience:

1.1 The RAS sampler should be placed in a clean/sterile bag for transport.

1.2 The V100 vacuum tube, sampler cable, and power cord can be coiled and can be placed over the V100 handle when in the extend position for transport if desired, or within a clean/sterile bag.

2. For transport outside of the facilities the entire assembly may be placed in a bag to minimize possible contamination of the unit.

3. A cover (e.g., sanitary cap, or bioshield) may be placed over the sample inlet cover of the RAS during transport and storage to minimize the potential of contamination.

4. Store the V100 and RAS assemblies in a clean and dry place.

Appendix D: Remote-Slit-Sampler (R2S) Operation

PURPOSE

To describe the procedure to monitor for viable airborne bacteria with the Remote-Slit-Sampler Assembly (R2S) from EMTEK, LLC.

D.1 R2S Operating Principles

A 90 mm agar based test plate is placed on the turntable of the R2S underneath the dome assembly. The required sample time period is set on the V100 Controller and the testing period is initiated. During testing, the V100 operates at a flow rate of either 28.3 LPM, 50 LPM, or 100 LPM as regulated by the setting on the V100 controller. This sample volume passes into the R2S dome assembly through the sample chamber and sample slit. Airborne bacteria in the sampled volume of air become impinged (captured) on the test plate within the R2S Dome assembly. The sampled air volume is then drawn through the vacuum line into the vacuum inlet of the V100 and through the controller. The sampled air volume passes through the system and is then exhausted from the V100, located outside of (or away from) the critical environment (or test area) through a 0.2 micron HEPA filter.

During testing, the test plate rotates on the turntable with one full revolution in the time period selected. This rotation removes recovered organisms from the direct path of incoming air to help prevent their desiccation, allows for easier enumeration of isolates recovered and for the determination of the approximate time of their recovery. Upon completion of the test period, the test plate is removed from the R2S and is incubated for a designated time period at a specified temperature. Following the required incubation period, the numbers of bacterial Colony Forming Units (CFU) are enumerated for the sampled volume of air. The density of air borne bacteria per volume of air tested can then determined based upon the total CFU recovered in the total volume of air sampled.

D.2 Materials

- EMTEK R2S Air Sampler and V100 Controller calibrated for operation at 28.3, 50, and/or 100 LPM with power cable and vacuum tubing assembly

- R2S Dome for 28.3, 50, or 100 LPM-Distance Indicator Mount is color coded for each flow rate, as follows:

28.3 LPM Dome-White

50 LPM Dome-Green

100 LPM Dome-Blue

- Standard 90 mm Test Plates (e.g. TSA Agar)

- Incubators (e.g. 30-35°C and/or 20-25°C)

  - Gloves (Sterile or Clean)

  - Low Particulate Shedding Wipes (e.g., Wipe All, Gamma Wipes)

  - Disinfectants (e.g., Quaternary Ammonium Compounds, 70% 0.2µm filtered or sterilized alcohol)

  - Lab Marker (as required)

  - Adhesive Tape

D.3 Maintenance Inspection

To assure appropriate operation of the R2S sampling assembly, prior to each day's use, sampling personnel should inspect the unit for any obvious physical defect. This inspection shall include but not be limited to the following:

- A visual check of the dome-to-base seal or dome assembly to assure it is not visibly damaged in a way that would keep it from sealing appropriately (tears in the seal, cracks or chips in the dome, etc.).

- A visual check of the sample throat to assure that it is free of occlusions to assure proper sample flow through the slit.

If any maintenance need be performed, contact appropriate service or repair personnel.

IMPORTANT SAFETY PRECAUTIONS!!

English

TO MINIMIZE THE CHANCE OF ELECTRICAL HAZARD, assure that the primary AC power supply cord is not plugged in during sanitization.

DO NOT REMOVE THE PANELS or COVERS of the V100 to attempt any repairs. Contact EMTEK, LLC or other qualified service personnel if the unit malfunctions.

DO NOT SUBMERSE the V100 or RCG in any liquids!

TAKE ALL OTHER STANDARD ELECTRICAL SAFETY PRECAUTIONS when operating the RCG Sampling Assembly with the V100 controller

Français

Pour minimiser le risque DE DANGER ÉLECTRIQUE, s'assurer que les primaires d'alimentation Cordon d'alimentation secteur n'est pas branché au cours de désinfection.

NE PAS retirer les panneaux ou les couvertures de la V100 de tenter toute réparation. Contact Emtek, LLC ou de tout autre personnel de maintenance qualifié si les dysfonctionnements unité.

NE PAS immerger le V100 ou RCG dans tous les liquides!

PRENDRE TOUTES LES AUTRES MESURES DE SÉCURITÉ électriques standard pendant le fonctionnement du RCG échantillonnage Assemblée avec le contrôleur V100

D.4 R2S Sampler Assembly Set-Up and Testing

NOTES:
Before sampling with the V100 and R2S:

- Perform the sanitization procedure in Appendix E.
- The V100 and R2S Air Sampler(s) must be calibrated as a system with the desired configuration. This includes calibration of the V100 with either single or dual air sampling heads, including the vacuum tubing length that will be employed during use.

1. R2S Sampling Assembly Set-Up and Testing

1.1 Attach the R2S power supply cable and vacuum supply tubing:

1.1.1 Attach the R2S power supply cable and vacuum supply tubing, as follows:

1.1.1.2 Align the two “keys” of the cable connector with the key-way. Firmly press the cable end connector onto the R2S connector while threading the collar clockwise until it becomes finger tight. Attach the vacuum supply tubing to the R2S sampler by placing tubing over the barb and pressing firmly to achieve an airtight fit. See Section 7.5 for connection images.

1.1.1.3 Attach the other end of the power supply cable to the connector on the V100. Align the two “keys” of the cable connector with the key-way. Firmly press the cable end connector in to the front panel connector while threading the collar clockwise until it becomes finger tight. Attach the vacuum supply tubing to the V100 by placing the tubing into the tube connector and pressing down firmly to achieve an airtight fit. See Section 7.5 for connection images.

1.2 Upon completion of sanitization and set up (If applicable), place the R2S at the desired test site.

1.3 Place the V100 outside or below (e.g., on a cart) the testing area, within the constraints of the power supply cord and vacuum supply line.

NOTE: Various lengths of power supply cable and vacuum tubing can be employed if desired dependant upon flow rate. Contact EMTEK, LLC for additional information.

1.4 If the dome assembly has been chemically sanitized, assure residual disinfectant and particulate matter from cleaning and set up are removed from the sample chamber by purging the unit prior to initiating testing.

1.4.1 Plug the V100 into an available power supply.

1.4.2 Turn on the V100 power switch at the bottom back corner of the unit.

1.4.3 Set the sample parameters on the V100 to sample for approximately 2 minutes (See Section 7).

1.4.4 Press the Start key on the V100 or on the remote to start the blower.

1.4.5 Once the blower ramps up to the appropriate flow rate, sampling on the V100 will begin.

1.4.6 The V100 will stop once the selected sample volume is attained.

1.4.7 Check to ensure that the dome assembly is physically dry. Repeat steps 1.4.4 through 1.4.7 if necessary

1.5 Begin testing by following the steps below:

1.5.1 Set the sample parameters on the V100 to sample for the desired flow rate and sample volume/sample time, etc. (see Section 7).

NOTE: An initial sample delay can be set to allow for clearance of the area by personnel prior to the start of sampling. A test/hold function is also available as well as IR remote control (see Section 7).

1.5.2 Aseptically place the test plate (e.g. 90 mm TSA plate) on the turntable as follows:

NOTE: Gloved hands should be cleaned with a disinfectant (e.g., 70% alcohol) immediately prior to performing these steps.

1.5.3 Lift up the dome assembly just high enough to place the test plate on the turntable and remove its lid. Without inverting, place the lid of the test plate face down on a pre-sanitized surface.

NOTE: Removing and holding the dome only a few inches directly over the turntable will minimize the chance of contaminants settling on the sanitized components under the dome and on the test plate during this manipulation.

1.5.4 Place the dome assembly down over the test plate and turntable.

1.5.5 Securely seat the dome assembly in the “dome-to-base” seal and assure that the dome is properly seated in the seal.

1.5.6 Adjust the Turntable / Test Plate Height Adjustment as follows:

1.5.6.1 View the test plate distance indicator through the side of the dome to assure that test plate is at the proper height.

1.5.6.2 Rotate the turntable adjustment knob clockwise or counter clockwise until the top of the test plate moves to just touch the distance indicator pin. This adjustment will assure the required distance of approximately 2-3 mm from the test plate surface to the opening of the sample slit.

1.5.7 Press the Start button on the V100 or remote control to begin the test cycle.

1.5.8 If desired, the test period can be paused/resumed by pressing the pause/resume key on the V100 or remote control at any time during the testing period.

1.6 Ending the Testing Period:

1.6.1 When the timer counts down from the set time period or the required volume is attained the blower and the plate rotation automatically stop.

1.6.1.1 If desired, the test period can be terminated by pressing the Stop key on the V100 or remote control at any time during the testing period.

1.6.2 Aseptically remove the test plate from the turntable as follows:

NOTE: Gloved hands should be rinsed with disinfectant immediately prior to performing these steps.

1.6.2.1 Remove the dome from the R2S sampler with one hand and with the other hand; replace the lid of the test plate, being careful not to touch the inside of the lid or the agar surface. Do not move your hand over the exposed surface of the test plate. Allow the lid to lead your hand over the test plate as you replace it.

1.6.2.2 Remove the test plate, with the lid in place, from the turntable and place the dome back on the R2S sampler.

1.6.2.3 Secure the lid to the test plate with tape.

1.6.3 Assure all applicable information is recorded on the test plate, as required. Upon completion of the test period, a printout (label or Paper tape) is generated from the on-board thermal printer with the sample parameter information (e.g., Sample Start/Stop Time, Site #, Date, Operator Initials, etc.). The paper can be retained or the label can be affixed to the bottom of the agar plate or required paperwork. For dual sampler operation it is ideal to set the Replicate Label Count to 2, for labeling of each plate (see Section 7.2 Setup Screen 4 details). The operator may initial and date the printout if desired.

1.6.4 Carefully inspect the test plate:

1.6.4.1 Without taking the lid off the test plate, assure that impingement marks are present on the agar surface and that they are reflective of the sampling period.

EXAMPLE 1:
The plate should make one full revolution if the sample completed its set time period and air impingement marks should be present around 355° of the plate. A 5° buffer is present to determine the representative start and stop time.

EXAMPLE 2:
If the test period was stopped prior to its set time period, the impingement marks should be visible around the corresponding time period as represented on the plate. Half of the time period sampled would be indicative of almost half of the plate exhibiting impingement marks due to the 5° buffer.

1.6.4.2 If impingement marks are not present, the sample/test should be considered invalid unless impingement marks were noted during sampling. Excessive moisture can cause issues with retaining the impingement marks (see note below).

NOTE: Due to excessive moisture of a test plate, impingement marks, may be "erased" from the agar surface. Ensure that plates with excessive moisture are not used to avoid this situation.

1.6.5 Assure all applicable information is recorded on the test plate (e.g., Sample Start/Stop Time, Site #, Date, Product information, etc., as applicable). The printer in the V100 can be used to print a label or paper tape with this information.

1.6.6 Repeat the applicable portions of this procedure for additional samples. A newly sanitized dome assembly may be used for each sample. Chemical sanitization, or at least purging of the dome assembly should be performed at each sample location to assure a representative sample from that location following each set up.

D.5 Storage and Transport

1. For transport convenience:

   1.1 The R2S sampler can be placed in the transport mount located at the top of the V100 controller for transport or for storage (see Section 7.11).

   1.2 The V100 vacuum tube, sampler cable, and power cord can be coiled and can be placed over the V100 in the transport mount.

2. For transport outside of the facilities the entire assembly may be placed in a bag to minimize possible contamination of the unit.

3. A cover (e.g., sanitary cap, or bioshield) may be placed over the sample conduit of the R2S dome assembly during transport and storage to minimize the potential of contamination.

4. Store the V100 and R2S assemblies in a clean and dry place.

Appendix E: V100 Controller and Air Sampler Sanitization

This section applies to the V100 Controller and all air samplers as specified.

V100-Air Sampler Controller
R2S- Remote-Slit-Sampler
RCG- Remote-Compressed Gas/Confined Space-Sampler
RAS- Remote-Autoclavable-Sampler

E.1 Materials

- Gloves (Sterile or Clean)
- Low Particulate Shedding Wipes (e.g., Wipe All, Gamma Wipes)
- Primary Disinfectants (e.g., Quaternary Ammonium Compounds)

  Important Note: Phenolic disinfectants should not be used on the Clear Dome Assembly as it will cause the dome to become very brittle in a short period of use.

- Secondary Disinfectants (e.g., 70% 0.2µm filtered or sterilized alcohol)

E.2 Sanitization Procedure

1. Don a pair of clean or sterile gloves

   Note**:** Gloved hands should be sanitized with a disinfectant (e.g., 70% alcohol) throughout this procedure.

English

DANGER: TO MINIMIZE THE CHANCE OF ELECTRIC SHOCK disconnect the V100 primary AC power supply cord during sanitization.

DANGER: DO NOT SUBMERSE the V100 controller or sampler in any liquids!

Français

DANGER: pour minimiser le risque d'électrocution V100 primaires déconnectez le cordon d'alimentation AC au cours de désinfection.

DANGER: NE PAS immerger le contrôleur de V100 ou de l'échantillonneur dans tous les liquides!

2. V100 Sanitization:

2.1 To sanitize the V100 Controller, sanitize the exterior of the sampler, vacuum tubing, power supply cable, IR Remote, V100 and primary AC power supply cord with a wipe saturated with disinfectant. It is ideal to wipe the components with a primary disinfectant (Quaternary Ammonium) followed by a secondary disinfectant (70% IPA, or Ethanol).

English

WARNING: DO NOT DIRECTLY SPRAY THE V100 with any disinfectants, or other liquids!

Français

ATTENTION: NE PAS pulvériser directement Le V100 avec les désinfectants ou d'autres liquides!

Important Note: Spraying the unit would potentially allow the disinfectant to enter into the interior of the case and damage its components, causing it to fail.

Note Importante: La pulvérisation de l'unité permet éventuellement le désinfectant pour entrer dans l'intérieur de l'espèce et les dégâts de ses composants, provoquant son échec.

3. Air Sampler Sanitization:

3.1 Remove the R2S/RCG dome assembly from the sampler or RAS top cover.

3.2 Sanitize the exterior surfaces of the sampler (i.e., the body, dome-to-base seal, turntable, turntable adjustment knob, RAS cover and base exterior, RAS base seal, etc.) with a new wipe saturated with secondary disinfectant.

WARNING: Be careful not to saturate the air passageway opening located beneath the R2S/RCG turntable or in the RAS base, as this would allow the disinfectant to be drawn into the pump and pose an electrical hazard.

ATTENTION: Soyez prudent de ne pas saturer l'ouverture de passage d'air situé sous le R2S/RCG tourne-disque ou dans la base de RAS, car cela permettrait au désinfectant d'être entraîné dans la pompe et de présenter un danger électrique.

Important Note: Saturating the air passageway opening located beneath the R2S/RCG turntable or in the RAS base would potentially allow the disinfectant to be drawn into the pump and damage it.

Note Importante: Saturant l'ouverture de passage d'air situé sous le R2S/RCG tourne-disque ou dans la base de RAS permet éventuellement le désinfectant d'être entraîné dans la pompe et l'endommager.

3.3 For initial cleaning each testing day, the R2S/RCG dome-to-base seal or the RAS base seal may be removed for sanitization. Sanitize the surfaces of the seal with a wipe saturated with secondary disinfectant. Alternatively, the R2S/RCG dome-to-base seal and RAS base seal may be autoclaved for each use.

3.4 Interior Dome Assembly/RAS Base Sanitization:

3.4.1 The entire RAS sampler and the R2S/RCG dome assembly may be autoclaved prior to each days testing if desired, or chemical sanitized.

3.4.2 With a new saturated wipe, sanitize the interior surfaces of the sampler.

3.4.3 For chemical sanitization of the R2S/RCG dome assembly and interior of the RAS, saturate a wipe with a primary disinfectant (e.g., Quaternary Ammonium Compound) and wipe all surfaces of the dome and sample chamber assembly, allowing appropriate contact time. Wipe off residual disinfectant with a new wipe.

3.5 Next, saturate a wipe with a sterile secondary disinfectant (e.g., 70% alcohol) and wipe all surfaces of the dome assembly and sample chamber. Allow for the appropriate contact time and allow to dry.

3.7 Following sanitization, replace the dome-to-base seal on the sampler (if applicable), and then place the dome and sample chamber assembly back on the sampler. For the RCG, assure that the dome is properly seated in the seal and the spring clip is place. For the RAS, replace the top cover over the base and base seal.

3.8 For the RCG sampler, the sanitary sample tubing assembly may be autoclaved before use each day if desired.

Appendix F: Suggested Sample Submission and Results Recording

This section applies to all sampler types.

1. Submit the test plate(s) and test parameter information to in the appropriate lab for recording and further testing.

2. Qualified personnel record the required test parameter information on the appropriate electronic or hard copy test report form and place the test plates "On-Test" in incubation.

3. Incubate the test plates with an appropriate incubation scheme (e.g., 30-35°C for a minimum of 5-days [*other incubation requirements or schedules may be used as appropriate*]).

4. Following the required incubation period, count all Colony Forming Units (CFU) found within the air impingement zone.

5. Determine Total CFU/ Specified Volume and record the results in the appropriate section of the electronic or hard copy test report form. This result is calculated as follows:

$$\frac{\text{Total CFU per Test Plate}}{\text{Volume Sampled}} = \text{CFU/ Identified Volume (L/ft}^3\text{/m}^3\text{)}$$

EXAMPLE:

If the test period was set to sample at 100 LPM for 10-minutes, the total volume collected would be 1000 Liters (L) or 1 cubic meter (m^3). If following incubation, 20 CFU were recovered in the impingement zone of the plate. The calculation would be:

- Total CFU/Test Plate = 20
- Total Volume = 1000 L (or 1 m^3)

$$\frac{\text{20 CFU/Test Plate}}{\text{1000 L (or 1 m}^3\text{)}} = \frac{\text{20 CFU}}{\text{1000 L (or 1 m}^3\text{)}} = \text{0.02 CFU/L (or 20 CFU/m}^3\text{)}$$

6. Record date "Off-Test" in the appropriate section of the test report form.

7. If Microbial Identification of organism recovered is required, submit plate for ID according to applicable procedures related for sample submission and processing for Microbial Identification. Discard all other plates in an appropriate Bio-Hazard container for disposal.

8. Test Report Forms, once completed, should be reviewed for accuracy and completeness, and signed by a second qualified analyst.

Appendix 1: CE Declaration of Conformity

Declaration of Conformity

The Manufacturer of the Products covered by this Declaration is

EMTEK
MICROBIAL AIR SAMPLERS

EMTEK, LLC, located at 1430 Nelson Rd., Suite 210A, Longmont, CO 80501

The Directives covered by this Declaration

2004/108/EC Electromagnetic Compatibility Directive (EMC)

2006/95/EC Low Voltage Directive (LVD)

The Products Covered by this Declaration

V100 Air Sampler Controller; Model number: 001; Serial Numbers: 00001-99999

The Basis on which Conformity is being Declared

The manufacturer hereby declares under his sole responsibility that the products identified above comply with the protection requirements of the EMC directive and with the principal elements of the safety objectives of the LVD directive, and that the following standards have been applied:

CENELEC EN 61010-1*BEI, *Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use Part 1: General Requirements; Issued:2001/03/01*

BSI BS EN 61326-1*BEI, *Electrical equipment for measurement, control and laboratory use EMC requirements Part 1: General requirements-: 1998; Issued:2006/06/30*

UL 61010-1*EEI, *UL Standard for Safety Electrical Equipment For Measurement, Control, and Laboratory Use; Part 1: General Requirements; Issued:2004/07/12 Ed:2 Rev:2008/10/28*

CAN/CSAC22.2#61010-1*AEI, *Standard for Safety Electrical Equipment For Measurement, Control, and Laboratory Use; Part 1: General Requirements; Issued: 2004/07/01 Ed: 2*

The technical documentation required to demonstrate that the products meet the requirements of the Low Voltage Equipment directive has been compiled and is available for inspection by the relevant enforcement authorities. It is held at the manufacturers given address.

The CE mark was first applied in: ***2010***

Signed: Date: 4 March 2010

Name: Erik Swenson Position: Managing Member EMTEK, LLC

Attention: The attention of the specifier, purchaser, installer, or user is drawn to special measures and limitations to use, which must be observed when these products are taken into service to maintain compliance with the above directives. Details of these special measures and limitations to use are available on request, and are also contained in the product manuals.

EMTEK, LLC • 1430 Nelson Rd., Suite 210A • Longmont • Colorado • USA • www.emtekair.com
Telephone: 303.682.3168 • Fax: 303.223.2804 • E-mail: sample@emtekair.com

Appendix 2: Two Year Warranty

EMTEK, LLC

1430 Nelson Rd. Suite 210A Longmont, Colorado 80501 USA

TEL 877.850.4244 e-mail: sample@emtekair.com www.emtekair.com

Standard Two Year Warranty

Customer satisfaction is a prime objective of EMTEKEK, LLC (EMTEK). Toward that objective, the products offered by EMTEK have been designed, manufactured and field tested with care and technical competence.

(1) In any instance where an EMTEK instrument fails to perform to the customer's satisfaction, it is EMTEK's policy to provide prompt and effective investigation of the situation.

(2) EMTEK warrants that products of its manufacture will perform according to stated specifications, and that the products will be free from defects in workmanship and materials, provided that the defect of malperformance occurred under normal and proper use of the products. Decision regarding such normal and proper use will be made by EMTEK following factory inspection and investigation of the application.

(3) Claims under the terms of this warranty must be submitted in writing within a period not not exceeding 24 months following dateof shipment of the product from EMTEK to the purchaser, All products on which warranty claims are established must be submitted to EMTEK within the specified time period to the EMTEK business address, unless otherwise specified by EMTEK in writing, with freight transportation charges prepaid. Products judged by EMTEK to be defective will be repaired or replaced and returned to the customer, with return freight transportation charges prepaid by the customer.

(4) EMTEK reserves the right to disallow claims for warranty coverage in instances where there is evidence that the EMTEK product has been placed in a severe or corrosive atmosphere, outside the specified operating parameters specified for the product.

(5) Similarly, this warranty will be invalidated in instances where the malperformance is attributable to tampering or adjustment by other than factory approved personnel.

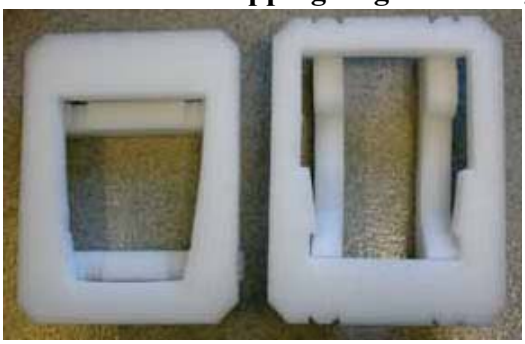
(6) EMTEK's Liability under the terms of this warranty is limited to repair or replacement of defective of products at no charge to the customer. EMTEK expressly disclaims any liability to its customers, sales representatives or users of its products, or to any other person or persons, for consequential damages of any kind arising out of or in any way connected with the use or EMTEK's products. Representations and warranties made by any person, including sales representatives of EMTEK, which are inconsistent or in conflict with the terms of this warranty shall not be binding upon EMTEK, unless specifically stated in writing and approved as a document supplementary to this warranty by an authorized officer of the EMTEK organization.

EMTEK.WRNT.MAR.2010

Appendix 3: Packaging Materials and Packaging of Components

-Maintain all Custom Packaging Components for System Shipments-

V100 Controller Shipping Cage-Load Cage Base into Shipping Box, place V100, Place Cage Top



BASE TOP

V100 in Bottom of Cage

Cage Top On

Air Sampler Component Trays, Tray Cover, Manual/Cable Tray & Loading

Air Sampler Components Component Tray

Loaded Component Tray

Tray Cover Foam Manual/Cable Tray

Tray w/Manual & Cables

Appendix 3: Packaging Components and Packaging (continued)

NOTES:

- **Place V100 and Air Sampler Components/Packaging in the EMTEK Shipping box in the following order.**

- **Components are not shown as packaged in additional protective clear bags. It is strongly suggested to additionally package components in appropriately size bags for storage and/or shipment**

1) V100 in Cage

2) Component Tray

3) Component Tray Cover

4) Manual/Cable Tray