PORTACOUNT® RESPIRATOR FIT TESTER AND INFORMATION TECHNOLOGY SYSTEM QUESTIONS

This application note answers questions from Hospital Information Technology (IT) personnel regarding PortaCount® Respirator Fit Testers and FitPro™ Ultra Software.

Overview of System

Description of PortaCount® Respirator Fit Tester and FitPro™ Ultra Software

The PortaCount® Respirator Fit Tester and FitPro™ Ultra Fit Test Software perform respirator fit tests on hospital personnel. The system consists of the PortaCount Respirator Fit Tester and the FitPro Ultra software application. FitPro Ultra software can be loaded on a computer/tablet provided by the facility. The system is not a medical device and no confidential healthcare data is stored on the system.

Mode of Operation

The PortaCount Respirator Fit Tester and FitPro Ultra software do not need to be connected to the facilities network to operate. The PortaCount Respirator Fit Tester communicates with the FitPro Ultra software through the direct USB connection or Wi-Fi® using a Wi-Fi® Dongle plugged into the instrument. This communication utilizes TCP/IP or USB Serial protocol and functions independent of the facilities network. The computer used to run FitPro Ultra software can be linked to a network to store fit test records. This would be similar to storing documents on a network instead of on the local hard drive, and is completely under the control of Hospital IT policies.

TCP/IP OR USB SERIAL

TCP/IP

Database

By default, the FitPro™ Ultra software creates a local SQLite® database on the computer that records and stores fit test records. The fit test records track many items related to fit tests and the instrument, some of the records are of the names of the persons being tested, date, mask types, mask size, Fit Factor, individual test scores, test results, daily check results, and instrument status. The data is stored locally on the computer and backup records can be stored on the facilities network as desired. The data is not stored to a cloud and TSI Incorporated (TSI) has no remote access capability to the database.

Optionally FitPro Ultra software can be configured to use a hospital-hosted MS SQL Server database under the control of Hospital IT personnel. A set of documents and scripts are included with the software providing guidelines on how to accomplish that. Security for such a connection is achieved using typical Windows® 10 operating system security measures as configured by Hospital IT personnel. This approach allows multiple instances of the FitPro Ultra software to share a single database robustly and securely.

Security, Encryption, and Login

TSI and the FitPro Ultra software have no control over the security and data encryption settings on the computer or tablet. These settings are all controlled using standard Windows® account settings. This is up to the individual facility to set the desired settings on the tablet. The user is responsible for configuring the tablet/laptop to match the facility requirements.

Frequently Asked Questions

Questions	FitPro Ultra Software and PortaCount Respirator Fit Tester
Is the system a medical device?	**No**. The PortaCount Respirator Fit Tester is not a medical device, the system performs a fit test on health care professionals wearing respirators.
What type of data is stored?	Health Care personnel names and fit test records. Fit test records include respirator size and type along with fit factor results.
Does the system store and/or transmit patient data or any other confidential data elements?	**No**. No confidential information and no patient data.
What type of database is used?	By default, FitPro Ultra software uses a file-based SQLite® database for the fit test records. This data is stored on the laptop/tablet that houses the application. Optionally. An external MS SQL Server database provided by the Hospital IT personnel can be used.
Is the data stored to the cloud?	The application does not store any data on the cloud.
Where will data be sent to?	The data is not sent anywhere (to TSI or any Cloud site) but data from PortaCount Respirator Fit Tester can be stored on the computer/tablet, and that computer can be connected to the facilities network, where the user can also store data to a network location.
Does TSI access the system remotely?	TSI does not access the system remotely. There is no remote troubleshooting or data backup being driven by TSI. TSI has no access to the data on the system.
How is the data transferred?	The PortaCount Respirator Fit Tester and on-premise tablet/laptop transfers fit testing results through either a USB connection or wireless connection. TCP/IP or USB Serial protocol is used. The user can select.

Questions	FitPro Ultra Software and PortaCount Respirator Fit Tester
Is the data encrypted?	FitPro Ultra software does not encrypt any of the data that is being transferred between the PortaCount Respirator Fit Tester and the laptop/tablet. Data in transit from the laptop on to the host network can be encrypted under the Users Control through the database and network connections settings.
Can Windows® Encryption (Bitlocker) be used?	Encryption can be setup on the laptop/tablet. This is a procedure that individual IT departments would need to do to meet their criteria before they deploy it. Like the account auditing etc.
Do you have a process for archiving data?	The hospital is responsible for backing up database files (SQLite®) and/or MS SQL Server databases.
What authentication controls will be in place for the application and Microsoft® Surface® Go tablet?	There are no controls on the application, The Microsoft® Surface® Go tablet has standard Microsoft® Windows® operating system.
Will the Microsoft® Surface® Go tablets be encrypted at rest using AES-256 bit encryption?	No encryption is setup by TSI
Can the tablet be encrypted with a third-party encryption (I.E. Sophos)?	**Yes**. The user can setup the system with an encryption software. This will not interfere with the operation of the application.
Does that device have an operating system (OS) or is it proprietary?	The PortaCount Respirator Fit Tester has proprietary firmware. FitPro Ultra software is a proprietary application that was developed by TSI.
Is the application web based?	**No**. The application is not web based. FitPro Ultra software is loaded on the desired tablet/laptop
Is firewall recommended for setup?	**No**. Connectivity between the PortaCount Respirator Fit Tester and FitPro Ultra software can be hindered by security software or firewall
How are users authenticated and authorized?	System log on only, no login functionality on application.
Does system have logging for Logins and Log-offs?	**No**. Local Windows® Group Policy could be configured to do this.
Does system have logging for failed login attempts?	**No**. Local Windows® Group Policy could be configured to do this.
Does system have logging for viewing of sensitive information?	**No**. There is no separate login for sensitive information.
Does the system have the ability to export and extract the logs if there is an incident?	Standard Windows® function Export Event logs from Event Viewer.

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Questions	FitPro Ultra Software and PortaCount Respirator Fit Tester
Does the system retain the logs for at least a year?	Local Windows® Group Policy could be configured to do this.
Is any removable media necessary for operation?	No removable media is necessary.
How do users access the application?	System log on only, no login requirements to application.
Are there any operation or maintenance fees?	**No**. Initial equipment purchase only, no maintenance fees.
Is any kind of integration expected?	No integration, software is standalone within each laptop/tablet.
Does the system require a server?	No server required.
Does the system operate on Windows® 10 operating system?	Windows® 10 64 bit operating system.
What applications must exist on workstation for this to operate properly?	Only the Fit Pro Ultra Software is required.
Does the software application or service store, process or transmit credit card or other forms of electronic payment information?	**No**. The application does not process any payment information.
Is there a mobile app component of this solution?	**No**. There is no mobile app available.
Is the application under an active support contract?	There are no software support contracts available. Customer support is done through TSI standard customer support.
Does the application have a disaster recovery plan?	The TSI application does not have a disaster recovery plan. The PortaCount Respirator Fit Tester will operate independent of the facilities network if the system is down.
Can the system be scanned by a vulnerability scanner (i.e., Nessus®)?	**Yes**. There would be no negative effects on the application.