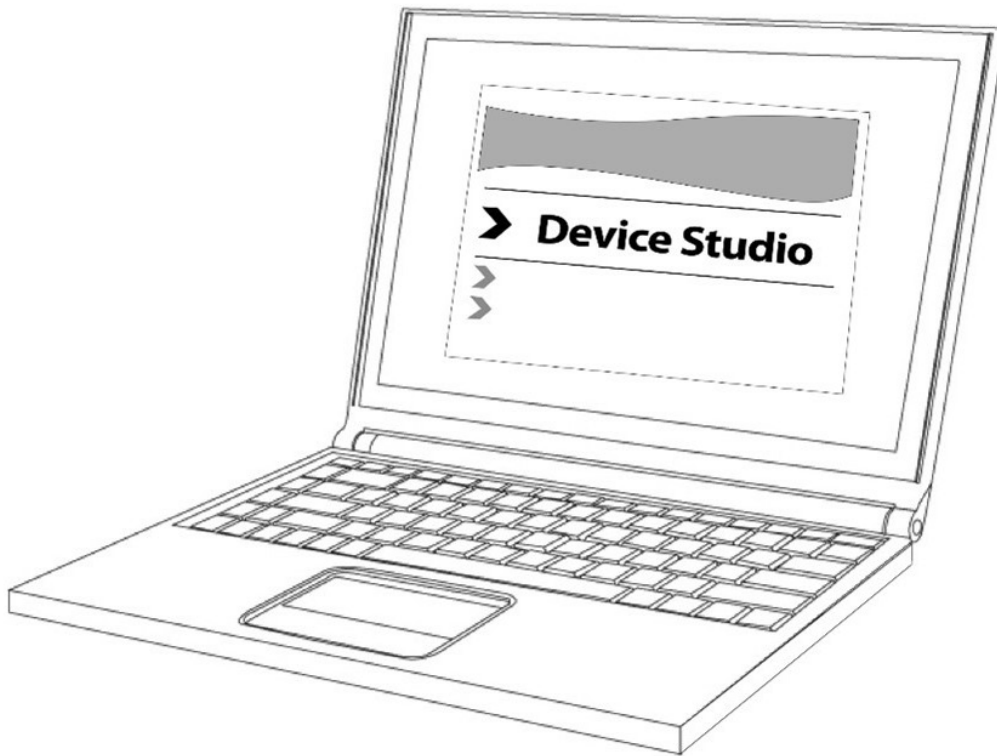




Device Studio



Instructions for Use

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1. Indications for Use

Device Studio is a PC based software application intended to generate PDF or printed reports to a user's PC from a standalone desktop or handheld spirometer, respiratory monitor or screener manufactured by Vitalograph®. Device Studio is intended for use by adult professionals or non-professionals (e.g. administrative staff) in a variety of healthcare environments, e.g. primary care, hospitals and occupational health centres.

2. Contraindications, Adverse Reactions, Warnings and Precautions.

2.1. Contraindications and Adverse Reactions

2.1.1. Contraindications

N/A

2.1.2. Adverse Reactions

N/A

2.2. Warnings and Precautions

N/A

3. Main Components of Vitalograph Device Studio

The main components are:

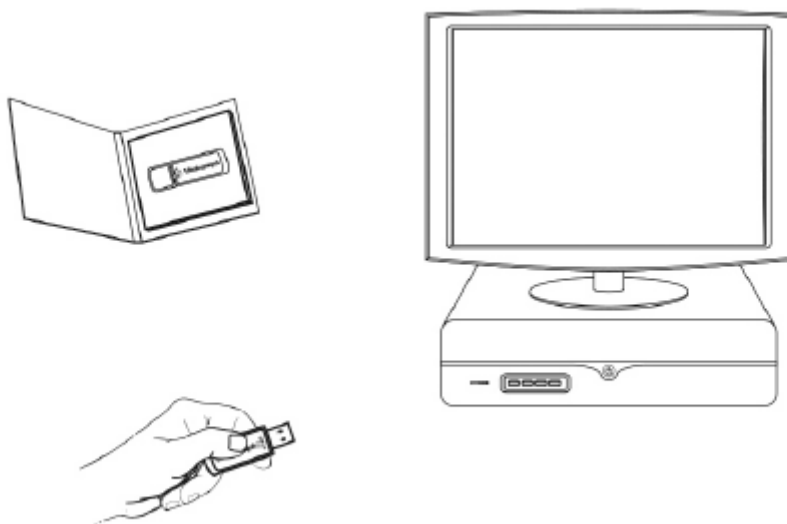


Figure 1 - Main Components of Vitalograph Device Studio

Note: Computer not supplied

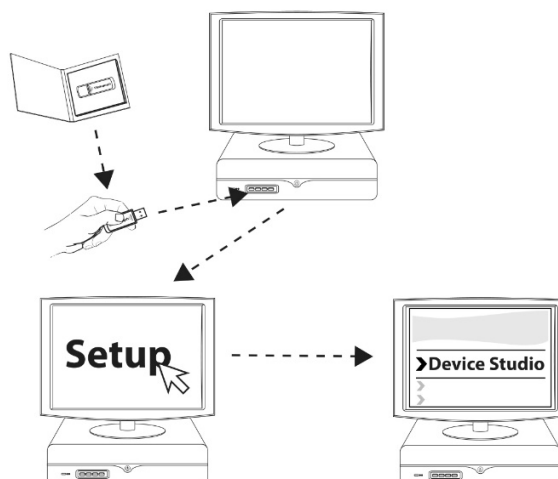
3.1. Features of Vitalograph Device Studio

The features include:

- Automatic detection and connection to supported Vitalograph devices
- Report generation including:
 - Archive to PDF
 - Print to External Printer
- Configurable report location and naming
- Customisation of report logo and report header text
- Backup and restore data on connected devices
- Update firmware on connected devices (Alpha, In2itive and micro)

4. Setting Up Vitalograph Device Studio

Refer to [Section 15](#) Technical Specification for recommended PC Requirements



1. Insert USB flash drive into USB port on the PC. Browse media contents and run Setup.
2. Follow onscreen instructions. Click "Install Device Studio" to start the installer.
3. If prompted "Do you want to allow this app to make changes to your device?", click Yes.
4. A message confirms when installation is complete. Click Close.

5. Operating Instructions

5.1. Starting Device Studio

1. Open Device Studio from the start menu or Vitalograph icon on the desktop.
2. The "No Current Device" icon displays until a successful connection has been established.
3. To connect a device, the device must be switched on and connected to the PC by USB cable. For instructions for compatible devices, refer to [Section 6](#) Devices.
4. The flashing green icon indicates a successful connection to the device.
5. The application shows on screen and the Vitalograph icon shows in the Windows® taskbar when the application is open.
6. Minimising removes the application from view on the screen and shows it in the task bar. It can be shown on screen again by double clicking the icon.

5.2. Assessment Reports

5.2.1. Searching Assessment Reports on Alpha & In2itive

There are 4 quick search options and a custom search tool.

The default search option shows sessions performed that day.

Searches can be filtered to include sessions performed over the last 7 days, last 30 days or all days.

Filter options in the custom search tool:

- From date – search for sessions from this date
- To date – search for sessions to this date
- Session Type – e.g. FVC, VC
- First name of subject
- Last name of subject
- Subject ID

5.2.2. Searching Assessment Reports on micro

Select the next available session on Device by clicking "Next Session" button.

The latest session performed on the micro will be next session available.

User can add the following to the Session for Printing:

- First Name
- Last Name
- Additional Subject Information
- Additional Session Information
- Additional Interpretation Information
- Session ID can be edited

Entered data can be cleared using the “Clear Text” option
Select to print or save the session report (see [Section 5.3](#))
Move to the Next Session on the Device by clicking the “Next Session” button.

5.2.3. Viewing Assessment Reports on AIM

If a report of training effort is required, the AIM device must be connected to Device Studio application before training begins.

As soon as the training effort is completed, the assessment report will be available to view on screen.

User can add any required information to the report.

5.3. Printing Assessment / Calibration Verification Reports

There are two options for printing session and accuracy reports:

1. Print selected reports to an external printer.
2. Save selected reports as PDF files to a chosen folder for archiving.

By default, Assessment Reports are saved as a PDF to the following location:

“C:\Vitalograph\DeviceStudio” folder.

To change default options, refer to [Section 5.4](#) Software Settings.

5.4. Software Settings

To change software settings, click on Settings menu on the main screen.

1. Automatic Start
 - Automatically start Device Studio on Windows start-up
2. Saved Reports
 - Save to Folder: Select a location for saving reports. The default location is C:\Vitalograph\DeviceStudio
 - Use File Name format:
 - Report Type, Assessment Date, Patient Name
 - Report Type, Assessment Date, Patient Number
 - Report Type, Assessment Date, Patient Number, Patient Name
3. Report Header
 - Customize Logo:
 - Select a new logo by clicking *Custom*
 - Select the default Vitalograph Logo by clicking *Default* or
 - Select no logo on the report by clicking *None*.
 - Header Text: Add a custom header to the report (up to a maximum of 34 characters).

5.5. Device Update for Alpha, In2itive and micro only.

Note – A backup should be performed prior to an update or formatting.

Note – No Backup is available for Micro Device

The following options are available:

- Update Firmware on Connected Device
- Manually from a File (file can be located on USB key or PC location)
- Select the ‘From File...’ Button
 - Perform a backup as prompted
 - Browse and select the firmware update package (.ipk file)
 - Select Update, the device will restart and disconnect from device studio
- Online (Internet access is required)
 - Select the ‘Check Online...’ Button
 - Perform a backup as prompted
 - If an update is available a notification will appear
 - Select Update, the device will restart and disconnect from device studio
- Backup Connected Device
 - Backup the connected device contents to a user defined folder location.
 - Restore previously backed up contents of a device from a folder location.
- Format Connected Device
 - Clear Memory: This option allows the user to format a device.

5.6. Shutting Down the Application

Shut down the application by clicking the X on the top right or via the Exit option. To continue to use Device Studio, restart the application from either the short-cut in the Start menu or on the Windows® Desktop.

6. Devices

6.1. Vitalograph Alpha/In2itive

6.1.1. Connecting to the Vitalograph Alpha/In2itive

- Open Device Studio on the computer.
- Power on the Alpha/In2itive.
- Ensure device is on the main screen where Subject, Quick Test and Configuration are displayed.
- Connect the Alpha/In2itive to the computer by USB cable, using the USB port at the back/side of the device.
- When the Alpha/In2itive is detected click on the Connect Device button.
- The Alpha/In2itive will display a USB connection symbol to confirm that connection has been made.

6.1.2. Disconnecting from the Vitalograph Alpha/In2itive

- Click on the Disconnect button
- The Alpha/In2itive shall return to its main menu.
- **Note:** *Removing the USB cable without first disconnecting shall result in the Alpha/In2itive restarting.*

6.2. Vitalograph micro

6.2.1. Connecting to the Vitalograph Micro

- Open Device Studio on the computer.
- If device does not have battery power:
 - Connect device by USB cable, using the USB port at the side of the device.
 - Power On
 - The micro will display a USB connection symbol to confirm that connection has been made
- If device does have battery power:
 - Power On
 - Ensure device is on the main screen where Subject, Quick Test and Configuration are displayed
 - Connect device by USB cable, using the USB port at the side of the device
 - The Micro will display a USB connection symbol to confirm that connection has been made.

6.2.2. Disconnecting from the Vitalograph Micro

- Remove the USB Cable from Device.

6.3. Vitalograph AIM

6.3.1. Connecting to the Vitalograph AIM

- Open Device Studio on the computer.
- Power on the Aim.
- Connect the AIM to the computer by USB cable, using the USB port at the side of the device.
- The AIM will automatically connect to Device Studio.

6.3.2. Disconnecting from the Vitalograph AIM

Click on the Disconnect button

7. Power Management

N/A

8. Cleaning & Hygiene

N/A

9. Fault Finding Guide

Problem Fault Symptoms:	Cannot connect to the attached device
Possible Solution: (In probable order)	For the Vitalograph Alpha, In2itive or micro, check the device is connected to the PC, powered on and on the main screen before starting the application. For the Vitalograph AIM, disconnect and reconnect the USB cable.
Problem Fault Symptoms:	The application indicates that a report was created but it does not appear to have been created/saved to the PC.
Possible Solution (In probable order):	Check that the PC user has full read/write access rights to the folder and sub-folders of both the location where the Device Studio application is installed, and also the location chosen to save the PDF report files. The System Administrator on the PC will have to set these security settings.
Problem Fault Symptoms:	An error message appears saying that an application instance is already running even though no Vitalograph icon is visible in the processes section of the taskbar.
Possible Solution (In probable order):	Check there are no other users logged onto the system with the application running. It may be that another user is also logged onto the system using the "Switch User" Windows® function and that user may have an application instance running.
Problem Fault Symptoms:	The application disappears on minimising.
Possible Solution (In probable order):	The application is running in the system tray. Double click its icon in the tray to view.

9.1. Software Check

Information about the software can be obtained from the About box. This information can be used if any queries are made to Vitalograph or a service agent. To access the About box, click on Help > About Device Studio on the toolbar of the application main screen.

10. Customer Service

Service and support should be carried out only by the manufacturer, or by Service Agents approved by Vitalograph. Contact information for approved Vitalograph Service Agents may be found at the start of this manual.

Any serious incident that has occurred in relation to this software should be reported to Vitalograph or its Authorised Representative and the Regulatory Authorities of the country. Refer to the Vitalograph contact information at the start of this manual.

This IFU is available on the Vitalograph website at the following location: https://vitalograph.com/ifu/vitalograph_device_studio_software_ifu.pdf







11. Consumables and Accessories







N/A

12. Disposal Instructions

N/A

13. Explanation of Symbols

Main Screen	
	Assessment reports or Calibration reports menu icon
	Settings menu icon
	Updates menu icon
	Connect/Disconnect device menu icon
	System information menu icon
	Help menu icon

	Exit application menu icon
	The device must be taken to separate collection at the product end-of-life. Do not dispose of these products as unsorted municipal waste
	Manufacturer
	Date of Manufacture (Date format YYYY-MM-DD)
	Country of Manufacture
	QR code - matrix bar code. All information in the bar code is included in the text under it

14. Description of Vitalograph Device Studio

Device Studio is an application that provides functionality for generating PDF reports for Vitalograph devices. The application also facilitates database backup/restore and firmware updates on these devices.

15. Technical Specifications

Product	Vitalograph Device Studio
Minimum PC System Requirements	
Processor Speed	2GHz or greater
RAM	2GB (Min), 4GB (Recommended)
Disk Space	1GB or greater
Operating System	Windows 7 or above
Display	A display supporting a resolution of 1280 x 800 pixels, higher recommended
Input Device	Microsoft® mouse or compatible pointing device
Other	Installation of .NET Framework 4.6.1 USB Port to connect to Vitalograph devices, e.g., Alpha Install the application as System Administrator and provide full read/write access rights to the folder and sub-folders where the application has been installed, for all applicable users. PDF Viewer

16. Electromagnetic Compatibility (EMC) Standards

N/A

17. FDA Notice

N/A

18. Regulatory Information

N/A

19. Guarantee

Terms of Guarantee

Subject to the conditions listed below, Vitalograph Ltd. and its associated companies, (hereinafter called the Company) guarantee to repair or at its option replace any component thereof, which, in the opinion of the Company is faulty or below standard as a result of inferior workmanship or materials.

The conditions of this guarantee are:-

1. This Guarantee shall only apply to hardware defects which are notified to the Company or to its accredited distributor within 1 year of the date of purchase of the equipment, unless otherwise agreed in writing by the Company.
2. Software (meaning computer software, or user installable modules) is guaranteed for 90 days from the date of purchase.
3. The Company warrants that the software when correctly used in conjunction with the hardware will perform in the manner described in the Company's literature and user manuals. The Company undertakes to rectify at no expense to the customer any software failure notified within the period stated above, provided that the failure can be recreated and the software has been installed and used in accordance with the user manual. Notwithstanding this clause, the software is not warranted to be free of errors.
4. This Guarantee does not cover any faults caused by accident, misuse, neglect, tampering with the equipment, use of consumable items or parts not approved by the Company, or any attempt at adjustment or repair other than by personnel accredited by the Company, nor does it cover reinstatement of any configuration changes caused by the installation of any software.
5. If a defect occurs please contact the supplier from it was purchased for advice. The Company does not authorise any person to create for it any other obligation or liability in connection with Vitalograph® equipment.
6. This Guarantee is not transferable and no person, firm or company has any authority to vary the terms or conditions of this guarantee.
7. To the maximum extent permitted by law, the Company does not accept liability for any consequential damages arising out of the use of, or inability to use any Vitalograph® equipment.
8. This Guarantee is offered as an additional benefit to the Consumer's statutory rights and does not affect these rights in any way.

