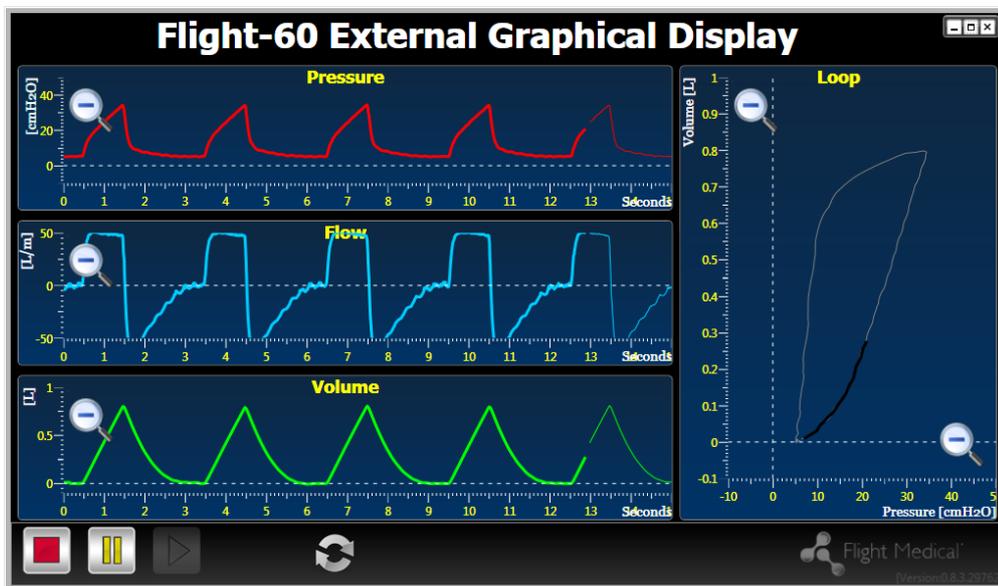


FLIGHT MEDICAL INNOVATIONS LTD.

Flight-60 External Graphical Display

Operator's Manual



QR-QA –EG-UM-01 Rev. B



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1 Introduction

1.1 Intended Use

The **Flight Medical External Graphical Display (EGD)** System is intended for viewing a graphical display of patient-ventilator interaction (ventilator waveforms).

The Flight 60 EGD is a restricted medical device intended for use by qualified, trained personnel under the direction of a physician; it is suitable for use in hospital, sub-acute, emergency room and home care environments, as well as for transport and emergency response applications.

2 Safety Instructions

2.1 General Warnings

-  The usage of the software is only allowed on a computer that is of medical grade and has passed all appropriate safety regulations.
-  The usage of the software is only allowed with an optical isolator placed on the cable between the ventilator and the external computer.
-  The usage of the EGD software and the connection of the external computer to the flight-60 ventilator is strictly prohibited for external computers that are running critical applications.
-  To prevent tripping over the RS 232 cable secure it to the ventilator and the external computer.
-  The Graphical Display have a latency, **Avoid** making any clinical decision making based only on the displayed graphics or numeric.
-  Make sure to connect the RS232 cable to the lower com port. Connecting to the wrong port on the ventilator may cause arbitrary data display.
-  the External Graphic Display can only be used with Flight Medical Innovation's Flight60 Ventilator .

3 Definitions, Acronyms and Abbreviations

Curr. f-	Frequency (Breath per minute)
Cyclic Display -	The signal (Pressure versus Time graph, Volume versus Time graph Volume versus Time graph) proceeds from left to right however when it reaches the right side of the graph it starts again on the left side.
EGD -	External Graphical Display
L -	Liter
Linear Display -	The signal (Pressure versus Time graph, Volume versus Time graph Volume versus Time graph) proceeds from left to right.
MVe -	Minute Volume Expiratory
USB -	Universal Serial Bus
Vte -	Tilde Volume Expiratory
Vti -	Tilde Volume Inspiratory

4 System Specification

4.1 Hardware

The platform on which the Flight Medical External Graphical Display (EGD) software should be installed and run is a PC or a laptop with an Intel, Core 2 Duo processor or better.

The memory constraints defined for this system are 2 GB RAM and 1 GB free disk space or more.

Prolific RS232 to USB cable.

4.2 Software

The Flight Medical External Graphical Display (EGD) runs under Microsoft Windows XP and Windows 7 with Microsoft .Net 3.5 Framework.

Prolific RS232 to USB cable driver.

4.3 Communication

RS232 to USB cable.

5 System Description

The following is the list of the software features:

5.1 Pressure waveform

The software displays the Pressure versus Time graph from -10 cmH₂O to 50 cmH₂O over a window width.

On the Pressure versus Time graph, the software allows the user to alternate between two Pressure scales : -10 to 50 and -20 to 100.

5.2 Flow waveform

The software displays the Flow versus Time graph from -50 L/min to 50 L/min over a window width.

On the Flow versus Time graph, the software allows the user to alternate between two flow scales: -50 to 50 and -100 to 100.

5.3 Volume waveform

The software displays the Volume versus Time graph from -0.1L to 1L over a window width.

On the Volume versus Time graph, the software allows the user to alternate between two Volume scales: -0.1 to 1L and -0.2 to 2L

5.4 Volume versus Pressure waveform

On the main screen, the software displays the Loop graph with volume values from -0.1L to 1L and pressure values from 0 cmH₂O to 50 cmH₂O.

On the Loop graph, the software allows the user to alternate between the two predefined Volume scales and two predefined Pressure scales.

5.5 Numerical Parameters

The software displays the V_{te} value, as calculated by the Flight-60 ventilator.

The software displays the V_{ti} value as calculated by the Flight-60 ventilator.

The software displays the M_{Ve} value, as calculated by the Flight-60 ventilator.

The software display the Curr. f value, representing the current breath frequency as implied by the last breath, as calculated by the Flight-60 ventilator.

5.6 Controls

Selecting between Linear and cyclic graphs display:



The waveform proceeds from left to right



The waveform proceeds from left to right however when it reaches the right side of the graph it starts again on the left side.

Control over the display of live Data:



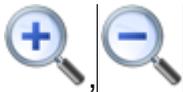
Play the waveforms



Freeze the waveforms, but continue to accumulate incoming live data in the background.



Stop the waveforms, ignoring live incoming data.



Zoom in and out for graph axis.

6 System Operation

Connect the Flight 60 ventilator to an external PC using the Serial RS232 to USB cable. The serial connector to COM2 (the low COM port on the ventilator) and the USB connector to a USB A type port on the PC.

Click the F60Monitor.exe file to log on the main screen

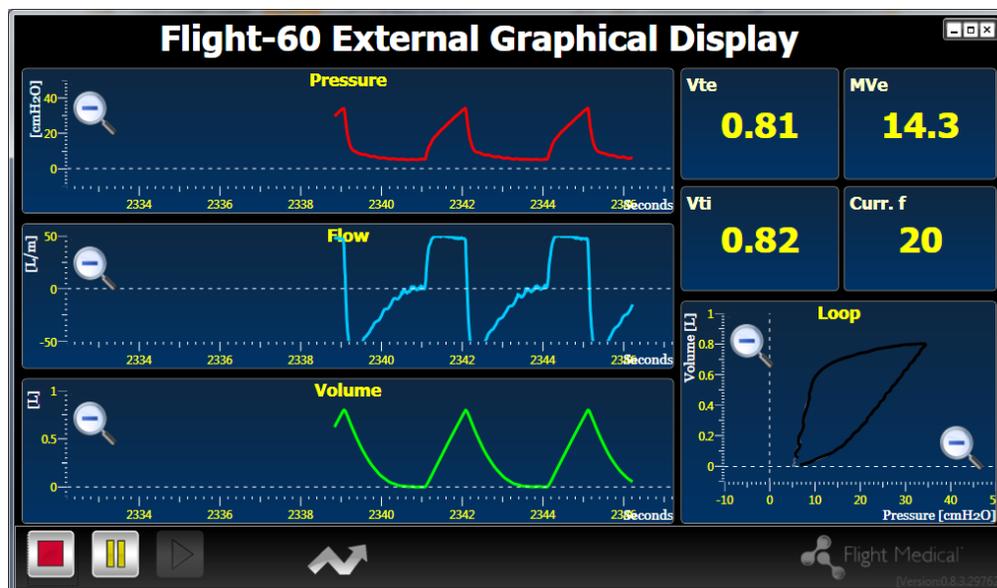
Upon system initialization, the software will load the configuration parameters' default values.

Upon loading the configuration parameters, the software allocates the available COM port.

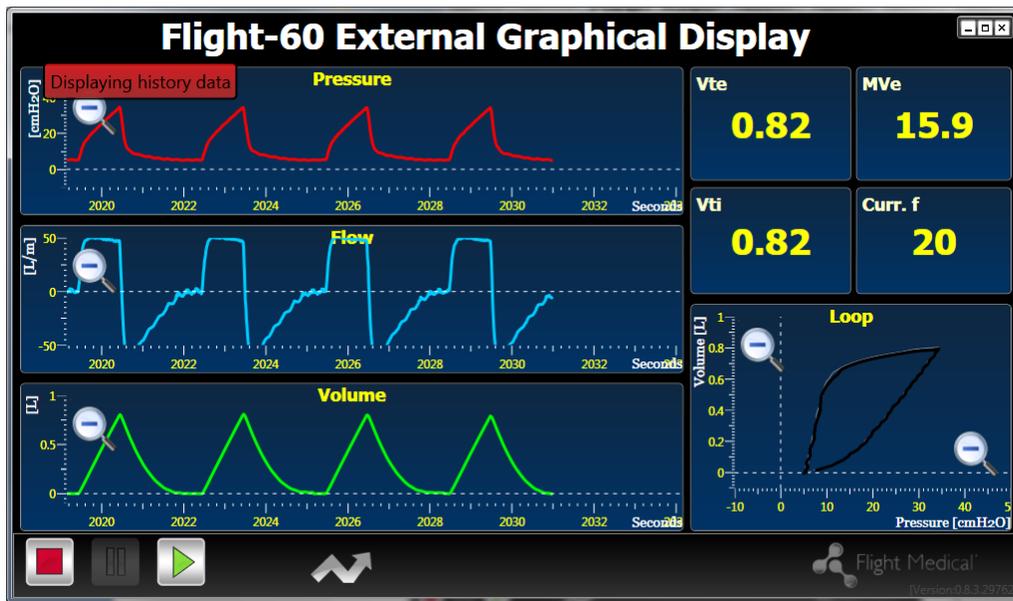


If the COM port is not found or live data do not stream from the ventilator or any rezone the software will post a notification on the screen and the data will be hidden.

6.1 Linear Display



On the main screen, if Linear Display is checked, upon clicking the "Play" button, the software stream the live data on the Pressure versus Time graph, Volume versus Time graph, Volume versus Time graph, Vte value, Vti value, MVe value, f value and the Loop graph.



On the main screen, if Linear Display is checked, upon clicking the "Freeze" button, the software stop displaying the live data while continuing to collect it in the background for later display and disable the "Freeze" button.

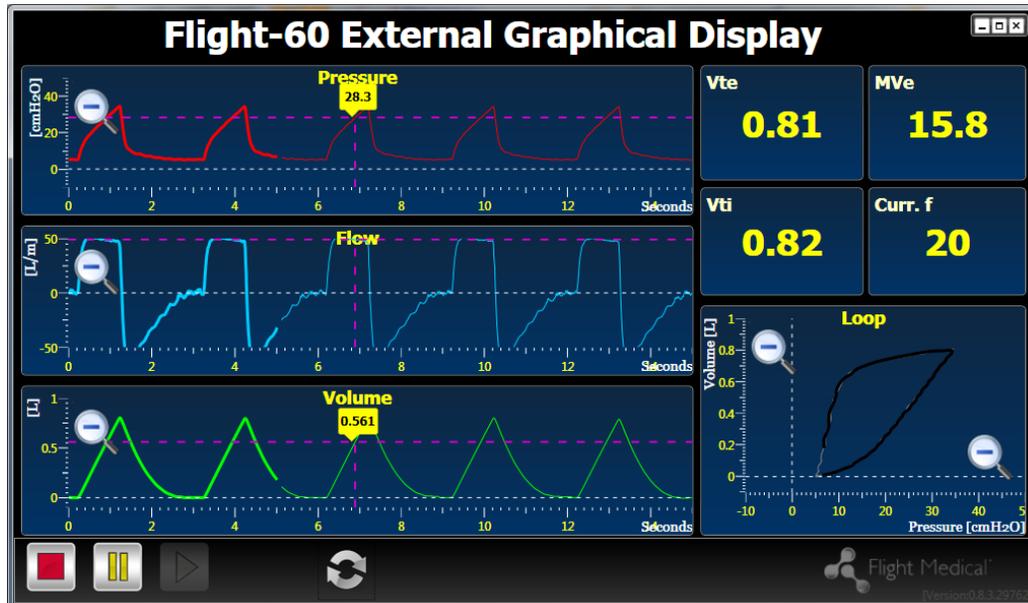
During the 'Freeze' it is possible to drag the mouse over the horizontal axis of every linear graph and display history data (up to 120s), The display is be labeled as showing history and not live data.



During Freeze mode the numerical values (VTe, Vti, MVe, Curr. F) continue to display the values coming in from the ventilator, and no longer display the last breath shown values!

On the main screen, if Linear Display is checked, upon clicking the "Stop" button, the software stop streaming the live data.

6.2 Cyclic Display

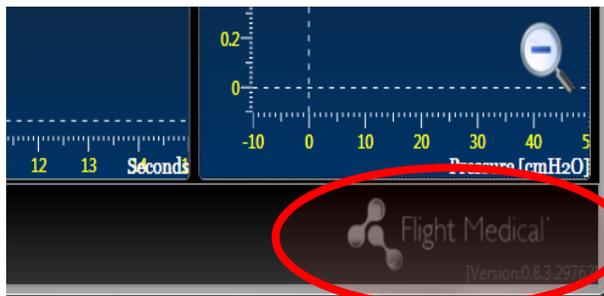


On the main screen, if Cyclic Display is checked, upon clicking the "Play" button, the software clear all the displayed data and stream the live data on the Pressure versus Time graph, Volume versus Time graph, Volume versus Time graph, Vte value, Vti value, MVe value, Curr. f value and the Loop graph.

On the main screen if Cyclic Display is checked, upon clicking the "Freeze" button, the software stop streaming live data and shall disable the "Freeze" button.

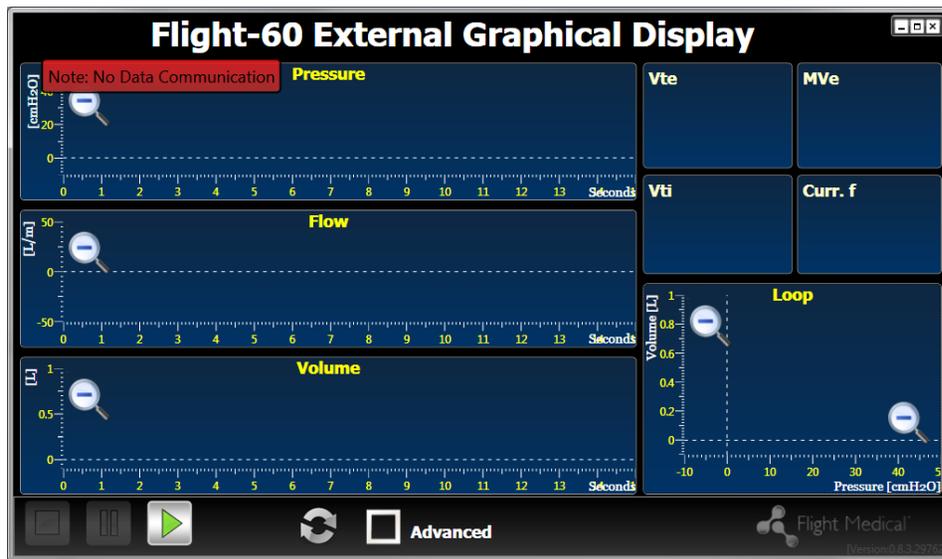
On the main screen if Cyclic Display is checked, upon clicking the "Stop" button, the software stop streaming the live data.

On the main screen, in Play mode, upon moving the mouse cursor onto the graph area, the software display a dynamic marker and display the current Pressure value, the current Flow value and the current Volume value in a digital display.



On the main screen, upon clicking the Flight Medical icon, the software display the software version.





On the main screen, if live data is not displayed, the software display a message stating No Live Data.

7 Installation of the EGD Software and Drivers

Open the "EGD install" folder. The following files are available:

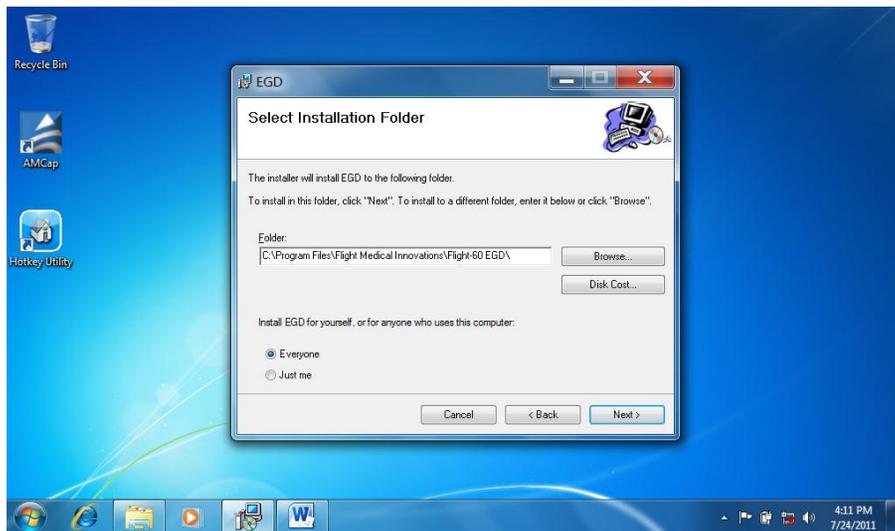
Name	Date modified	Type	Size
ProfilicUSBRS232	24/07/2011 17:33	File folder	
HASPUserSetup	20/10/2010 12:17	Application	11,422 KB
setup	12/07/2011 15:35	Application	457 KB
SimpleEGDSetup	12/07/2011 15:35	Windows Installer ...	2,579 KB

Step 1 – Installing the EGD SW

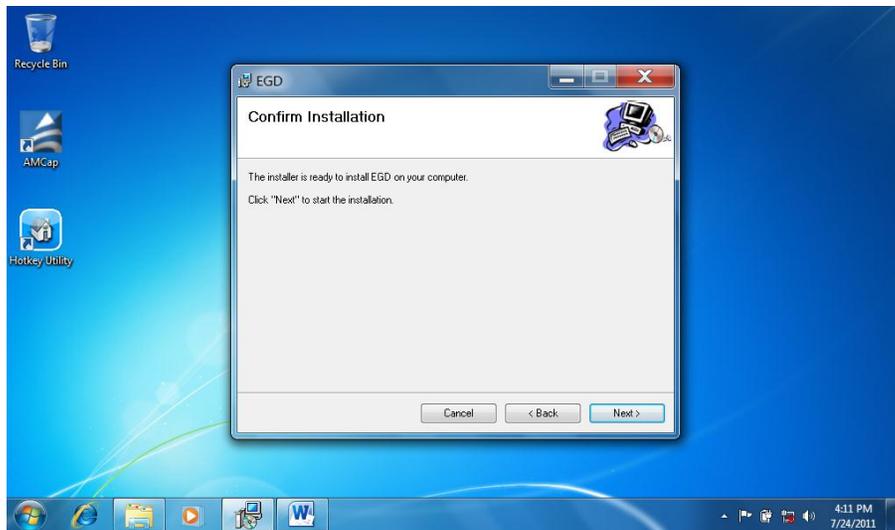
Double click the "SimpleEGDSetup.exe" ( SimpleEGDSetup) to open the set up file.



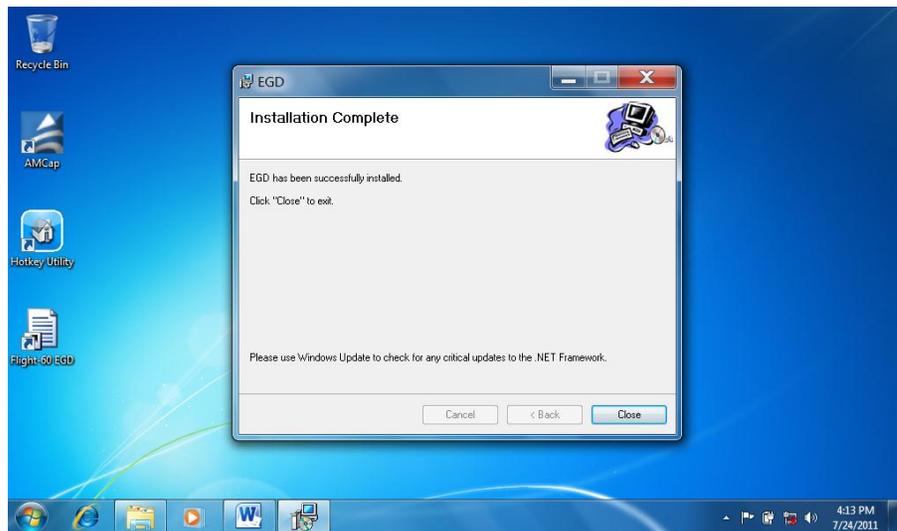
Click Next > to continue.



Choose the installation folder and press Next > to continue.



Click Next > to start the installation.



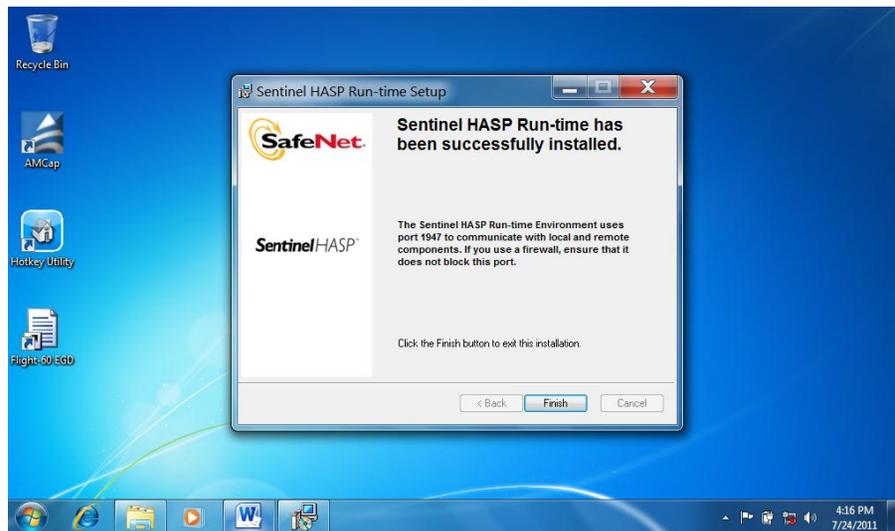
The installation has successfully completed. Click Close to exit.

Step 2 – Installing the EGD SW Drivers

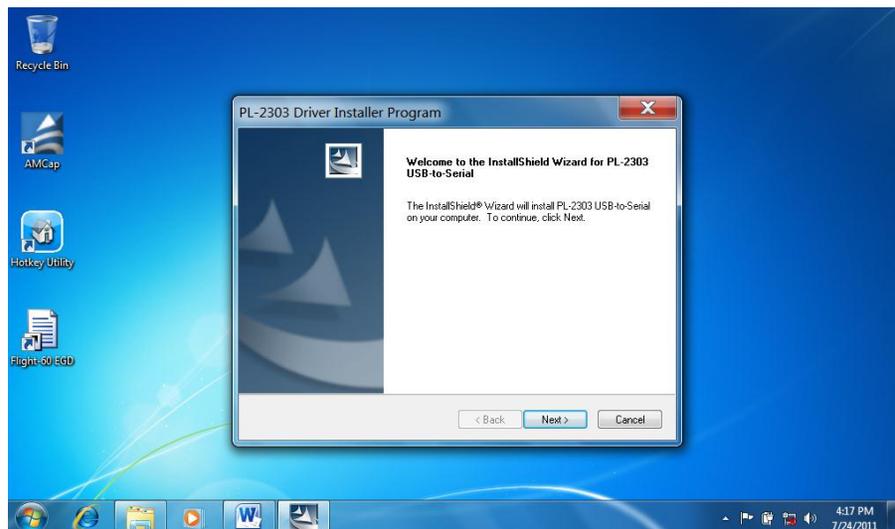
Double click the "HASPUUserSetup" to open the set up file.



Follow the instructions and click the Finish button to exit the installation when done.



Open the "ProfilicUSBRS232->Windows" folder to access the USB-RS232 set up application and double click to open the "Setup.exe" file.

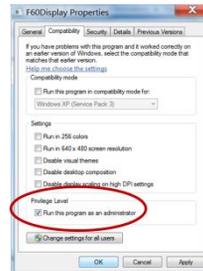


Follow the wizards and instructions and click the Finish button to exit the wizard when done.

Privilege Level Settings

In order to allow access for saving the history data files the EGD application should be run as an administrator. Please follow the instructions below:

1. Right click the EGD icon .
2. Go to "Properties".
3. Click the "Compatibility" tab.
4. Check the "Run this program as an administrator" check-box.
5. Click "OK" to close the properties window.



Running the EGD application

1. Connect the USB hardware protection key .
2. Double click the Flight 60 EGD icon  to run the EGD software application.

Appendix A – CE Labling

Product: Flight-60 External Graphical Display software

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