Acumen Analytics Software

User Guide



Edwards Lifesciences Acumen Analytics Software User Guide

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Edwards Technical Support

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Using This Guide

The Edwards Lifesciences Acumen Analytics software user guide is comprised of six chapters. Figures in this manual are intended for reference only and may not be an exact replication of the screens as a result of continuous software improvements.

Chapter	Description
1	Introduction
2	Setup and Customization
3	Importing and Viewing Files
4	File Organization
5	Cohort Summary and Comparison
6	Exporting and Saving Data

Contents

Introduction

1.1 Overview	1
1.2 Intended Use	1
1.3 User Interface	2
1.3.1 Key Features	. 2
1.4 Clinical Platform Parameters	5
1.5 Acronyms and Abbreviations	5
1.6 Cyber Security	6
1.7 HIPAA	7

Setup and Customization

2.1 System Requirements	8
2.2 Software Installation and Updates	8
2.2.1 Software Updates	. 8
2.3 System Settings	9
2.3.1 Hypotension Thresholds	. 9
2.3.2 Clinician List	. 9
2.3.3 Procedure List.	. 9
2.3.4 Audit History	10
2.4 User Preferences	10
2.4.1 Theme Color	10
2.4.2 Language	10
2.5 Help	10
2.5.1 Welcome	10
2.5.2 User Guide	10
2.5.3 Contact Us	10
2.5.4 Data Access	10
2.5.5 About	11

Importing and Viewing Files

3.1 Importing Files
3.1.1 Single File Import
3.1.2 Multiple File Import
3.2 Viewing Individual Files
3.2.1 Primary Toolbar
3.2.2 Trends Tile

3.2.3 Secondary Toolbar	
3.2.4 Data Tiles	 14
3.2.5 Move Data Tiles	 15

File Organization

4.1 File List Screen		18
----------------------	--	----

Cohort Summary and Comparison

5.1 Cohort Summary	21
5.2 GDT Summary Plots	21
5.3 IOH Summary Plots	22
5.4 Cohort Comparison	23

Exporting and Saving Data

6.1 Print to PDF	25
6.2 Exporting GDT Reports	25
6.3 Exporting Case Reports	26
6.4 Exporting Patient Data Files	26

Chapter 1

Introduction

1.1 Overview

Acumen Analytics[™] software is a retrospective, educational tool that provides clinicians with hemodynamic insights when managing patient care. Acumen Analytics software enhances PGDT (Perioperative Goal Directed Therapies) to include a deeper and broader analysis for hypotension. By understanding both pressure and flow parameters, Acumen Analytics software can provide clinicians with a more thorough assessment of patient perfusion.

Each patients' data can be reviewed individually or grouped into cohorts for analysis. This facilitates identifying and comparing patient groups that belong to specific clinical study arms.

1.2 Intended Use

Acumen Analytics[™] software is an educational tool that provides clinicians with hemodynamic insights when managing patient care. Acumen Analytics software is a Medical Device Data System (MDDS) that allows clinicians to download, view, and manage unaltered monitoring data exported from the EV1000 clinical platform and HemoSphere advanced monitoring platform. Acumen Analytics software does not control the function or parameters of the EV1000 clinical platform and HemoSphere advanced for active patient monitoring.

1.3 User Interface

Acumen Analytics										-		×
					Acumen	Analytics				తి	¢₿ţ	?
File List	ያ Sum	mary 🔗 Compa	ison					Q Find	× Ŧ	ilter	ē	PDF
		All Files										
6 files		Patient ID	Gender	Age	Height (cm)	Weight (kg)	Start	Clinician	Procedure			
⁹⁰ c l	2	TC2	Female	64	142	55	Mar 25, 2018					
as conorts	<u> </u>	2757737	Female	76	147	40.8	Aug 23, 2018					
+ Add Cohort		TC8	Female	65	142	55	Mar 25, 2018					
Cohort 01		TC2	Female	64	142	55	Mar 25, 2018					
0 files		HPITEST	Female	64	142	55	Mar 25, 2018					
Cohort 02		FLOTRAC	Male	88	224	85.3	Aug 3, 2015	Dr. Chester Kildare				
Cohort 03												
Long cohort name example text 2 files												
		└ Import Files	Select F	iles								

Figure 1-1 Primary screen

The EV1000 clinical platform provides hemodynamic parameters through the Acumen IQ sensor, FloTrac sensor and ClearSight finger cuff. The HemoSphere advanced monitoring platform provides hemodynamic parameters through the Acumen IQ, FloTrac, TruWave DPT, and ForeSight Elite sensors. These monitoring sessions and associated demographic data can be imported into Acumen Analytics software.

Data files can be imported into Acumen Analytics software and organized into cohorts. The primary screen appears as shown in Figure 1-1. This interface allows the user to analyze data within and between cohorts. With a streamlined tile layout, the main viewing page organizes a list of all files, cohort summaries, and cohort comparison for convenient overviews.

1.3.1 Key Features

All Files	
🗟 Cohorts	
+ Add Cohort	
Cohort 01	
Cohort 02	

Cohort Sidebar

Cohort names and file content are organized in the cohort sidebar. The cohort sidebar can be hidden by clicking the arrow icon. This sidebar does not appear while viewing individual patient files (as shown in Figure 2-1).

Title and Settings Bar

Acumen Analytics

😳 🔢 🕐

PDF

Define application settings, set user preferences and find help and application information from the icon buttons.

Primary Toolbar

File List	Summary	Comparison	S PGDT	🖗 юн	🖉 Customize
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Select the content displayed in the main viewing pane with the tabs on the left. The action buttons on the right vary depending upon the tab selected.

See Chapter 4 for file list view and Chapter 5 for cohort and cohort comparison views.

Main Viewing Pane

Description		Age Distribution (years)
Number of Files First Case Start Timestamp Last Case Start Timestamp	6 Mar 25, 2018 9:46:28 AM Aug 23, 2018 2:10:19 PM	10 Mean: 66, Median: 65, Std dev: 6 8
		0
Height Distribution (cm)	Maan: 157 Marijan: 162 Std dau: 15	<20 20-29 30-39 40-49 50-59 60-69 70-79 80-89 90+ Weight Distribution (kg)

File lists, demographic data, and cohort summaries are viewed and organized in the main viewing pane. Data tiles are used to display individual patient and cohort data.

Cohort Summary

The customizable cohort summary screen displays data collected for the chosen patient or patient group.

GDT Summary

These summaries provide insights into Goal Directed Therapy (GDT) sessions within the monitored cases. Insights include session duration, files with GDT sessions, and trend of the Time-in-Target parameter.

SVV Mean Trend Graph

The advanced hemodynamic parameter of SVV is plotted against elapsed monitoring, offering key insights into the dynamic parameter often used for indicating preload responsiveness when managing volume.

Cohort Comparison

The cohort comparison screen allows clinicians to compare data from two cohorts. When viewing intraoperative hypotension data, key callouts include time spent in hypotension and MAP events under 65 mmHg.

Trend Parameters

At the core of Acumen Analytics software is hemodynamic parameter data. Clinicians can review recorded data on available parameters on the EV1000 clinical platform and the HemoSphere advanced monitoring platform.

Symbol	Description
Title and Set	tings Bar
	Settings
မှုမှု	User Preferences
?	Help
Primary Tool	bar
	File List
00	Cohorts Summary Comparison
(%)	PGDT
\bigcirc	ЮН
	Customize
\sim	Trend Analysis
-	Filter
\bigcirc	Annotate
\Leftrightarrow	Pan
+	Zoom In
Q	Zoom Out
\square	Autoscaling
	PDF

Table 1-1 User Interface Symbols

Table 1-1 User Interface Symbols (continued)

Symbol	Description
$\langle\!$	Back
Secondary T	oolbar
	Import Files
	Export Files
20	Remove from Cohort
ſ	Delete
	Select Files
G	GDT Report
С	Case Report
Cohort Sideb	bar
00	Cohorts
	Edit
╋	Add Cohort
<u>ش</u>	Delete
Ľ	Close
Main Viewing	g Pane
	Modify (GDT targets)
∇	Intervention Event
\leftrightarrow	Combine Graphs

1.4 Clinical Platform Parameters

Table 1-2 EV1000 Clinical Platform and HemoSphere Advanced Monitoring Platform Parameters

Parameter	Description
Cardiac output (CO)	Continuous measurement of the volume of blood pumped by the heart measured in liters per minute
Cardiac index (CI)	Cardiac output relative to body surface area (BSA)
Diastolic pressure (DIA)	Diastolic blood pressure
Mean arterial pressure (MAP)	Averaged systemic blood pressure over one cardiac cycle
Pulse rate (PR)	Number of ventricular contractions per minute
Stroke volume (SV)	Volume of blood pumped with each heart beat
Stroke volume index (SVI)	Stroke volume relative to body surface area (BSA)
Systemic vascular resistance (SVR)	The resistance that the left ventricle must overcome to eject stroke volume with each beat
Systemic vascular resistance index (SVRI)	SVR relative to body surface area
Stroke volume variation (SVV)	The percent difference between SVmin, max and mean
Central venous oximetry (ScvO ₂)	Venous oxygen saturation as measured in the superior vena cava
Mixed venous oximetry (SvO ₂)	Venous oxygen saturation as measured in the pulmonary artery
Systolic pressure (SYS)	Systolic blood pressure
Tissue Oximetry (StO ₂)	Absolute tissue oxygen saturation as measured at anatomical surface below sensor locatoin

1.5 Acronyms and Abbreviations

Acronyms and abbreviations used in this guide.

Abbreviation	Definition
BP	Blood Pressure
BSA	Body Surface Area
CI	Cardiac Index
СО	Cardiac Output
CVP	Central Venous Pressure
DIA	Diastolic Pressure
GDT	Goal Directed Therapy
HIS	Hospital Information Systems
HGB	Hemoglobin
IOH	Intraoperative Hypotension
MAP	Mean Arterial Pressure
PDF	Portable Document Format
PGDT	Perioperative Goal-Directed Therapy
PR	Pulse Rate
ScvO ₂	Central Venous Oxygen Saturation
StO ₂	Tissue Oximetry
SV	Stroke Volume
SVI	Stroke Volume Index

Table 1-3	Acronyms	and Abbrev	viations
-----------	----------	------------	----------

Abbreviation	Definition
SvO ₂	Mixed Venous Oxygen Saturation
SVR	Systemic Vascular Resistance
SVRI	Systemic Vascular Resistance Index
SVV	Stroke Volume Variation
SYS	Systolic Pressure
USB	Universal Serial Bus
TWA	Time Weighted Average

Table 1-3 Acronyms and Abbreviations (continued)

1.6 Cyber Security

Patient data can be transferred to and from Acumen Analytics software. It is important to note that any facility using Acumen Analytics software must take measures to protect the privacy of patients' personal information in accordance with country-specific regulations and consistent with the facility's policies for managing this information. Steps that can be taken to safeguard this information and the general security of Acumen Analytics software include:

- Physical Access: Limit use of Acumen Analytics software to authorized users.
- Active use: Users of the monitor should take measures to limit data storage.
- Network Security: The facility must take measures to ensure the security of any shared network to which the monitor may be connected to.
- Device Security: Users should only use Edwards approved accessories. In addition, ensure that any connected device is free of malware. The use of Acumen Analytics software outside of its intended purpose could pose cyber security risks. No Acumen Analytics software connections are meant to control the operations of another device.

Edwards recommends using encrypted USBs for monitoring Acumen Analytics software application data transactions to ensure that the integrity and authenticity of the data is preserved.

Edwards recommends using run-time protection features on the Acumen Analytics software hosting node, such as EDR tools or, at minimum, enabling security logging on the operating system for events such as:

- Successful logons of users
- Unsuccessful attempts to log on by remote user
- Account lockout due to unsuccessful authentication attempts
- Unlocking of a locked account
- Start of critical services and system processes
- Stop of critical services and system processes
- Start of critical applications
- Stop of critical applications
- Successful modifications to system configuration files
- Unsuccessful attempts to access and/or modify system configuration files

- Successful modifications to access control rules
- Unsuccessful attempts to access and/or modify access control rules
- Network anomalies

Edwards recommends using industry best practices to ensure the security of the Acumen Analytics software hosting platform, such as:

- Hardening the operating system per operating system provider security guidelines
- Ensuring that operating system access is authenticated
- Ensuring that operating system level accounts are following the RBAC model and the principle of less privilege is employed
- Ensuring that the length, complexity, and rotation period of operating system passwords are in line with latest NIST recommendations
- Ensuring the operating system passwords are rotated periodically and operating system accounts are audited on annual basis
- Ensuring that a system firewall is in place, enabled and configured using provider security guide settings
- Ensuring that full-disk encryption is enabled

1.7 HIPAA

The Health Insurance Portability and Accountability Act of 1996 (HIPAA), introduced by the U.S. Department of Health and Human Services, outlines important standards to protect individually identifiable health information. If applicable, these standards should be followed during data transfer.

Chapter 2

Setup and Customization

2.1 System Requirements

Operating system: Windows 7, Windows 8 or Windows 10 (32-bit and 64-bit) Memory: 8 GB RAM (minimum)

Hard disk: 32 GB hard drive (minimum) with 3 GB of available disk space

Note: Utilize screen resolution of 100% scale and size

2.2 Software Installation and Updates

Acumen Analytics software can be downloaded from the Edwards Lifesciences website as follows:

- 1 Visit the Acumen Analytics software web page at: www.edwards.com/analytics
- 2 Fill out contact form.
- 3 Receive a unique download key and a download link from an Edwards representative via email.
- 4 Once downloaded, double-click on the .msi file to launch the installation wizard.

Please contact your Edwards representative or Technical Support for additional information on how to download the application, if needed.

2.2.1 Software Updates

Acumen Analytics software will automatically prompt you when an update for the software is available. The update can be deferred to the next session at which time an update reminder will be presented.

1 When the Acumen Analytics application is opened it automatically checks for available updates. If one is available, you will be notified with the following prompt:

Acumen Analytics Update
A new version is available for your computer The application must be run as administrator before starting the update.
Do It Later Update Now

9

- 2 To update, click on the **Update Now** button. The application will immediately begin downloading the update. A download progress bar will appear on the bottom right corner of the window.
- 3 Once the download completes, the update files will start to load.
- 4 When the update has finished loading, it is ready to be installed. Acumen Analytics software will begin the install process and the application will close.
- 5 Administrative privileges will be required to complete the update and will be requested after Acumen Analytics software closes and begins the update installation.
- 6 Acumen Analytics software will open and close several times during the update process. Once the update process is complete the application will remain open and be ready to use.

Please contact your Edwards representative or Technical Support for additional information for help with the update process, if needed.

2.3 System Settings

This menu contains features that allow you to edit system settings, and review and audit Hypotension Threshold.

2.3.1 Hypotension Thresholds

Modify the global Hypotension Threshold value after importing files into Acumen Analytics software.

After a threshold is modified, the Hypotension Statistics and chart visualizations will update displaying the revised global threshold value. Trend graph shading will also change for any time period for which a threshold value has been edited.

2.3.2 Clinician List

Edit the list of clinicians available for associating with patient files. It is recommended to customize the available clinicians before importing files. Clinicians may be added or removed. When a clinician's name is deleted from the list it is removed from all patient files.

2.3.3 Procedure List

Edit the list of procedures available for associating with patient files. It is recommended to customize the available procedures before importing files. Procedures may be added or deleted. When a procedure is deleted from the list it is removed from all patient files.

Acumen Analytics Opdate		
An update is ready to b	e installed. Acumen Analytics wi	I now be closed.



Downloaded 32% of 100%

Unpacking started

2.3.4 Audit History

Click on this option to access a log of user edits that have occurred in the application since it was installed. These edits include: adding annotations, deleting annotations, editing annotations (See "Annotate" on page 17) and editing GDT targets (See "Modify GDT Targets" on page 15).

2.4 User Preferences

This menu allows you to edit your preferred theme color and language.

2.4.1 Theme Color

The Acumen Analytics software interface can be displayed using a light or dark theme. Select your preferred style from the drop-down menu.

			Acumen	Analytics							Acı	umen Analy	tics	
File List 🔗 Su	immary 🔗 Comp	parison					🗮 File List	<u> </u>	mary 🔗	Comparisor				
	All Files													
All Files 6 files	Patient ID	Gender	Age	Height (cm)	Weight (kg)	Sta	All Files					Height (cm)	Weight (kg)	
	TC2	Female	64	142	55	Ma	Se Caborto	F //						
	2757737	Female	76	147	40.8	Auş		+	TC256489	Female	43	142	55	09/24/1

Figure 2-1 Light and dark theme colors

2.4.2 Language

Select your preferred language of Acumen Analytics software. Acumen Analytics software is available in English, French, Italian, German, and Spanish.

2.5 Help

This menu contains access to help, the user guide, contacting Edwards Lifesciences and application information.



2.5.1 Welcome

View the welcome screens and starting information shared upon first use of Acumen Analytics software.

2.5.2 User Guide

Download the Acumen Analytics software user guide by clicking on the User Guide link.

2.5.3 Contact Us

Share feedback via email by clicking the Contact Us link.

2.5.4 Data Access

Acumen Analytics software allows the sharing of anonymous usage data to help improve the product. You can opt-in or opt-out of sharing usage data.

2.5.5 About

Determine the version and PP Number of your Acumen Analytics software. Also access the legal licensing information for Acumen Analytics software.

Chapter 3

Importing and Viewing Files

Acumen Analytics software imports and displays monitoring session data saved from the EV1000 clinical platform using software version 1.9 or higher or the HemoSphere advanced monitoring platform software version 1.01.000.025 or higher.

3.1 Importing Files

Patient data files can be imported into the **All Files** folder or into a specific cohort. Creating and organizing cohorts is detailed in Chapter 5. File import specifications are:

- A maximum of 512 files can be imported at one time.
- A maximum of 16 cohorts can be created at one time.
- Supported Excel files contain data points at 20-second time intervals.
- An individual file should not exceed 10 MB in size.

Note: Ensure that imported files represent data from a single patient case.

To import files:

🗮 File List

Select the **File List** tab in the primary toolbar.



Click **Import Files** on the secondary toolbar and select file(s) to import. Alternatively, you can drag and drop patient files from your desktop to the application screen.

Note: The import screen will vary depending on the number of files selected for import. Any unsupported files will display an error message.

3.1.1 Single File Import

Patient demographic data and start/end times for the selected monitoring session will be displayed on the left side of the import window. Before importing the file, the following options are available:

- In the **File Details** section, you can associate the imported files to a clinician(s), a procedure(s) and/or add comments.
- You can select a Cohort with which the file will be categorized.
- A Case Report or GDT Report can also be generated when the file is imported. See Chapter 6 for more information on this option.

3.1.2 Multiple File Import

A list of selected files for import will be displayed on the left side of the import window.

Before importing the files, the following options are available:

- In the File Details section, you can associate the imported files to a clinician(s), a procedure(s), and/or add comments.
- Select a Cohort with which all the files will be categorized.

Import Click Import to finish importing the file(s). An individual file import is opened in the file view screen. A multiple file import is opened in the file list view.

See "Organizing Cohorts" on page 19 for details on creating cohorts. See "File List" on page 18 for instructions on how to organize imported files into cohorts.

3.2 Viewing Individual Files

The individual file screen is divided into movable data tiles. Each tile contains specific information about the monitoring session. Key features of this screen are described below.

EV1000	FV1000 408	220 080118 062050 vls		(а) IOH	Trend Analysis	Qo Cohorts	
		239_000110_003930.83					
Description			Add Details				
Patient ID	Unk	nown ID	Add Clinician				
Gender	Mal	e	Enter clinician name				
Age	88						
Weight	85.3	3 kg / 188 lbs					
Height	224	cm / 88 in					
BSA	2.40	0 m ²					
Start	Aug	3, 2015 10:31:29 AM					
End	Aug	3, 2015 1:25:29 PM	Add Procedure				
			Enter procedure name	ę			
Event Review	v						
08/03/2015	10:30:26 am	BSA Change					
08/03/2015	10:30:45 am	HRS zeroed					
08/03/2015	10:31:07 am	ClearSight Monitoring Started	Comment				
08/03/2015	10:31:46 am	[IA#4] GDT Session Started: #1					
08/03/2015	10:34:08 am	[IA#5] Fluid Challenge: Red Blood Cells 250 mL					
08/03/2015	12:31:07 pm	Cuff Pressure Released					
GDT Session							
001 0000000	•						_
Case Re	port ⊆ GD	T Report T Export					Delete

Figure 3-1 Individual file view

3.2.1 Primary Toolbar

The Primary toolbar contains the following features and functions:

The file name is displayed in place of the tab buttons.



Select the data type to display by clicking on either the PGDT or IOH button.



View the trends data in full screen by clicking the Trend Analysis icon.



Click the **Cohorts** button to designate cohorts for the displayed file. The file can be associated to more than one cohort.



Click the **Print to PDF** button to generate a PDF copy of the current file.



While viewing an individual patient file, click on the **Back** button to return to the main Acumen Analytics software screen.

3.2.2 Trends Tile

All monitored parameters are displayed within the trend tile.

3.2.3 Secondary Toolbar

From the toolbar you can create reports, export or delete a file. See Chapter 6 for more information.

3.2.4 Data Tiles

The data contained in patient files is organized into different panes or tiles on the screen.

Description

The description tile displays the patient ID and start/end date and time for the monitored session. This tile also displays the following patient demographic data:

- gender
- age
- weight
- height
- BSA

Event Review

This tile contains a log of parameter and system related events that occurred during the monitoring session. Refer to the clinical platform operator's manual for more information on events listed.

Add Details

This tile contains the clinician name, procedure, and any comments for the file. These items can be entered while importing the file or in this tile at any time. Up to three clinicians and procedures can be entered for each patient file. As the clinician name or procedure is typed, a drop-down list will appear and auto-populate with the three closest matches.

The list of clinician names and procedures available can be edited through the settings screen. See Chapter 2: *System Settings*.

GDT Sessions

Through enhanced parameter tracking, key parameters are managed in the optimal range enabling a clinician to perform Goal Directed Therapy (GDT). The GDT sessions tile displays a summary of these parameters.

The Time-in-Target parameter value is the accumulated percentage of time the parameter was in target during an active tracking session. This value is displayed below the key parameter within a circular percentage bar. Up to four parameters are shown per session. Scroll up or down within the tile to view all sessions.

Modify GDT Targets

GDT session target values can be edited after importing files into Acumen Analytics software.



Hover over the parameter name within the GDT Sessions tile and click on the **Edit** icon.

A **GDT Target** popup window will appear with session time stamps and associated target values for that parameter's tracking session. Only target values and operators can be edited. The time a session started, was paused, resumed or ended cannot be modified.

If no modification is desired, click **Cancel** to return to the individual file screen.

Click **OK** to accept any target edits. The text "(edited)" will appear next to the parameter name for that session in the GDT Sessions tile and on the trend graph for that parameter. Trend graph shading will also change for any time period for which a target value has been edited.

Trends

This tile mirrors the graphical trend monitoring view displayed by the clinical platform during patient monitoring. The trend plot is autoscaled to show the entire monitoring session. The first four plots displayed are those of the key parameters selected during monitoring. Scroll down to view trend data for all parameters. The plot line is color-coded to indicate parameter target ranges:

Green indicates that the parameter was within target range.

Yellow indicates that the parameter was outside of target but within physiological range.

Red indicates that the parameter was in the alarm range.

For details on the expanded full screen view of this tile, see "Trend Analysis" below.

3.2.5 Move Data Tiles

Drag the data tiles to change their location on the screen. The trend data tile is anchored.

Trend Analysis

The trend data tile can be enlarged to full screen by clicking on the Trend Analysis button.

ımen /	nalytics					-		_
€	EV1000_EV1000 408239_080118_063950.xls	O Annotate	⇔ Pan	⊕ Zoom In	\bigcirc Zoom Out	Autoscaling On	ē	Ρ
со	(L/min)							
20								
15 -								
10 -								
5 -				2:13:49 pm D 2.2 L/min				
						· · · · · · · · · · · · · · · · · · ·	_	
SVI	(mL/b/m ²)							
⁰⁰]								
00 - 50 -								
00 - 50 -			٩					
00 - 150 - 50 -	Pw		٩	12:13:49 pm /l 11 mL/b/m ²			_	

Figure 3-2 Trend analysis

The trend analysis screen has the following features:

Trend Plot Order

The order of the parameters displayed from top to bottom can be re-arranged by dragging trend plots to the desired position.

Trend Line Value

Hover over the plot line to view parameter values and corresponding monitoring time.

Autoscaling



Autoscaling adjusts the y-axis range to fit the minimum and maximum of the trend data. Turning off Autoscaling will change the y-axis range values to the default parameter display ranges.

Scale View



To zoom in, click and drag the cursor horizontally over the desired monitoring time frame. Click on zoom out on the toolbar to go back to the previous level of magnification.

Pan



While in zoom-in mode, a magnifying glass cursor is displayed. Click on the toolbar **Pan** icon to pan backwards and forwards through data. Click on the **Zoom** icon to turn off Pan mode.

Intervention Events



Markers appear on the trend graphs to signify if an intervention event occurred during monitoring. Click on the intervention event marker to display a pop-up balloon with the type and time of intervention. Scroll through multiple intervention events by using the arrows. Refer to the Intervention Events section of the clinical platform operator's manual for more information on intervention types.

Annotate



Click the **Annotate** button to add notes at any location along the trend graph. A red balloon on the x-axis of all parameter trend graphs will indicate an annotation was added. Click on the balloon to edit the annotation or use the arrows to scroll through to other annotations or interventions on the graph.

GDT Sessions

The plot area will appear shaded during GDT tracking sessions. The plot area will be shaded blue for active tracking, gray for paused tracking and green for modified target values.

To return to the file view screen, click on the **Back** button.

Chapter 4

File Organization

4.1 File List Screen

Acumen Analytics									-			
					Acumen	Analytics			٥	ti (?		
File List 🔗 S	Sum	nmary 🔗 Compa	rison					Q Find	× Ξ Filter	PDF		
		All Files										
6 files		Patient ID	Gender	Age	Height (cm)	Weight (kg)	Start	Clinician	Procedure			
		TC2	Female	64	142	55	Mar 25, 2018					
as Cohorts		2757737	Female	76	147	40.8	Aug 23, 2018					
+ Add Cohort		TC8	Female	65	142	55	Mar 25, 2018					
Cohort 01				TC2	Female	64	142	55	Mar 25, 2018			
as o files		HPITEST	Female	64	142	55	Mar 25, 2018					
Cohort 02		FLOTRAC	Male	88	224	85.3	Aug 3, 2015	Dr. Chester Kildare				
S 1 file												
Long cohort name example text & 2 files												
		✓ Import Files	Select F	iles								

Figure 4-1 File list screen

File List

Click the **File List** tab on the primary toolbar to display the file list screen. This screen displays all files already imported into the system and those within a specific cohort.

Cohort Sidebar

Select a cohort to view the list of grouped files.

File List Heading

Organize file lists in ascending or descending order by clicking on any column heading. Drag and drop columns to rearrange order from left to right.

Find Files

Q Find ×

To find a specific file(s), enter query text into the input field. You can find files based on patient ID, patient demographics, monitoring session timestamps, comments, clinician, and procedure.

Filter Files



Click the Filter icon to refine the files displayed in the File List screen.

Print to PDF



Click the **Print** icon to print the file list to PDF.

Import Files

IV	
`	

Click the **Import Files** icon to import additional data files. See "Importing Files" on page 12.

Select Files



Click the **Select Files** icon to select multiple files for cohort editing. See "Organizing Cohorts" on page 19.

Organizing Cohorts

Data files can be organized into study arms to facilitate comparison of data between patient cohorts. The cohort sidebar displays a list of all named cohorts and the number of files contained within each cohort.

Edit Cohort List



Click the **Edit** icon at the top of the cohort sidebar to edit the cohort listings. To edit a cohort name, click on the name to make the change.



To add a new cohort, click the **Plus** icon. This will also open the edit cohort sidebar when not in edit mode. A new cohort will be added to the sidebar.



To delete a cohort, click **Delete**. Click **Delete** to confirm.



Click the **Close** icon to exit edit cohort sidebar.

Add/Remove Files to Cohorts

Enter the File List screen to add or delete files from cohorts.



Drag and drop individual files onto the cohort sidebar or use the **Select Files** icon on the secondary toolbar to select multiple files.

The **Select All** and **Select None** buttons can be used with large file lists. These icons appear on the toolbar after clicking **Select Files** as shown in Figure 4-2.

iie List 음 Sum	imary 🔗 Compar	ison
	All Files	
6 files	Patient ID	Gender
	TC2	Female
Scohorts	2757737	Female
+ Add Cohort	TC8	Female
Cohort 01	TC2	Female
S o files	HPITEST	Female
Cohort 02	FLOTRAC	Male
3 files		
Cohort 03		
As 1 file		
Long cohort name		
2 files		

Figure 4-2 Select files screen

Drag and drop the selected files into the desired cohort on the sidebar.

In Figure 4-2, all the imported files are being added to the cohort named "Cohort 03."



Click **Delete** to permanently delete a file from the application. A confirmation popup will appear. Click **Delete** to confirm.



Click **Remove from Cohort** to remove a file from a cohort file list. A confirmation popup will appear. Click **Remove** to confirm.

Click **Done** to exit the Select File screen.

Chapter 5

Cohort Summary and Comparison

5.1 Cohort Summary

The cohort summary screen displays an overview of all patient monitoring data contained within the cohort. Data is summarized into tiles, as shown in Figure 1-1 on page 2. The description tile lists the number of files and the first and last case start timestamp. The remaining data tiles on the cohort summary screen are customizable.



To select which data tiles appear on the screen, click on the **Customize View** icon and a dialog will display your choices. Visible tiles are highlighted.

Drag and drop tiles to rearrange their order on the screen. Expand the width of the tile to full screen or shrink to half screen by hovering over the right or left edge of the tile until a double arrow appears. Click and drag the edge to expand or shrink the tile width.

Patient Demographic Summary



Height, weight, and age are summarized by individual distribution plots. The mean, median, and standard deviation are displayed above the histogram plot.

5.2 GDT Summary Plots

GDT Session Duration



Patient Files with GDT Session



This chart displays the duration of GDT sessions and monitoring time. Overlapped columns display total GDT monitoring time in front of the total monitoring time. The accumulated monitoring durations are displayed by month. Hover over any column to display what percentage of total monitoring time was tracked by GDT sessions.

This pie chart displays the percentage of files with at least one GDT session recorded.

Pooled Time-in-Target™ Parameter

Pooled Time in	Target (Mea	n % time	in target	vs mo	
100				-	
75					-
50					-
25					-
0 Mar 2018 May	2018 Jul 2018	Sep 2018	Nov 2018	Jan 2019	-

This data tile displays a box plot trend of the cohort's averaged percentage of Time-in-Target[™] parameter by month. Each GDT session average is calculated from the mean percent Time-in-Target parameter of all monitored parameters within the session. The average for each patient file is calculated as the mean of all GDT session averages. The box plot is calculated from these patient file averages by

month. Hover over the box plot to display the sample size (number of patient files), mean, and median for that time period. If fewer than five files with GDT sessions are available for a month, the box plot will indicate n<5.

SVV Mean Trend Graph



SVV mean is plotted against elapsed monitoring time. The mean is averaged at five-minute intervals and the 95% confidence interval of the mean at these time points is also displayed.

5.3 IOH Summary Plots

Average Time in Hypotension per Procedure



This data shows how much time each patient spends, on average, in hypotension. The time spent in hypotension is indicated as both a percentage and as an absolute number, so you can compare easily across different procedure times.

Total Number of Hypotensive Events in Cohort



This is a visual representation of the total occurrences of hypotensive events during a procedure. A hypotensive event is defined as one minute below the set threshold with the default set to MAP < 65 mmHg.

The Y-axis of the graph demonstrates the length in time of each hypotensive event, while the X-axis demonstrates the procedure time. Each tick mark indicates an individual occurrence of a hypotensive event, so you can track when events are occurring across procedures.

Percent of Patients with Hypotension



This is a visual representation of the number of patients in a cohort that experienced a hypotensive event. A hypotensive event is defined as one minute below the set threshold with the default set to MAP < 65 mmHg.

Hypotension Statistics

Hypotension statistics	
Gender	ນີ້ 40 % (male) ຊີ້ 60 % (female)
Age	₹ 56.93 ± 10.24
Weight	$\overline{\times}$ 96.64 ± 32.61 kg $\overline{\times}$ 213.2 ± 71.95 lbs
Height	x 166.4 ± 9.06 cm x 65.47 ± 3.52 in
Total monitoring time of the cohort	3800.67 minute(s)
Monitoring time per patient	
Number of patients with hypotension	9 of 15 60%
Total number of hypotensive events in dataset	30 event(s)
Average number of hypotensive events per patient	× 2 ± 2.45 [0, 1, 3.5] event(s)
Total duration of hypotension in cohort	90.33 minute(s)
Average duration of each hypotensive event	
Mean MAP under 65mmHg per patient	
Area under 65mmHg for MAP per patient (AUT)	
TWA* (MAP < 65mmHg) per patient	
% of patients that experience an event under 50mmHG	1 of 15 6.67%
Total number of events when a patient is under 50mmHG	1 event(s)
Lowest MAP among all patients	48 mmHg

A list of key hypotensive calculations, such as average number of hypotensive events, duration of each event, and time-weighted average of hypotension for each patient, that provides a case summary of the patient.

5.4 Cohort Comparison

Use the cohort comparison screen to view a side-by-side summary of two cohorts. The main viewing pane is divided in half lengthwise as shown in Figure 5-1.

Acumen Analytics							-	□ ×
		Acumen /	Analyti	cs			٢	iłi (?)
File List 🔗 Su	immary လု Comparison					🎯 юн	🖉 Customize	PDF
	Baseline Cohort Cohort 01 -			Cohort 02 👻				
All Files 6 files		12.0%	Time spe hypotens	ent in sion	9.2	%		Í
+ Add Cohort Cohort 01		5	MAP eve under 50	nts 9 mmHG	12		\sim	
Cohort 02	Description			Description				
3 files	Cohort Name	Cohort 01		Cohort Name		Coho	rt 02	
Cohort 03	Number of Files	6		Number of File	s	3		
A 1 file	First Case Start Timestamp	Aug 3, 2015 8:42.19 AN	٩	First Case Start	Timestamp	Aug	3, 2015 8:42.19 AM	
Long cohort name example text	Last Case Start Timestamp	Aug 1, 2018 8:00.31 AN	1	Last Case Start	Timestamp	Aug	I, 2018 8:00.31 AM	1
2 files	Hypotension statistics		\leftrightarrow	Hypotension	statistics		←	•
	Gender	ប៉ី 100 % (male) ភ្មំ 0 % (female)		Gender		Û Ô	100 % (male) 0 % (female)	
	Age	₹ 77.33 ± 15.09		Age		$\overline{\times}$	77.33 ± 15.09	
	Weight	 x 80.58 ± 10.55 k x 177.67 ± 23.11 lbs 		Weight		$\overline{\times}$	80.58 ± 10.55 k 177.67 ± 23.11 lbs	

Figure 5-1 Cohort comparison

When viewing IOH data, the top tile presents a dashboard comparison view of the Time Spent in Hypotension data and the MAP Events under 50 mmHg data.

The cohort comparison screen has the following features.

Select Cohort

Select a cohort \cdot	
All files	
New Cohort 1	
New Cohort 2 🖉	
New Cohort 3	
New Cohort 4	

Use the drop-down menus at the top of the main viewing pane to select a cohort for the left and right sides.

Data Tiles

The order of tiles can be re-arranged from top to bottom. The appearance and selection of data tiles are identical to those available on the cohort summary page. See "Cohort Summary" on page 21.

Customize View

Click the Customize View icon to display a menu of available data tiles.

Customize View	
Hypotension	
Time in Hypotension	Statistics
Events	Severe Events

Cluster Cohort Data

By default, tiles of both cohorts appear identical to the cohort summary screen.

Click the **Combine Graphs** icon to plot data from both cohorts onto one graph that spans the full width of the main viewing pane. Click on the icon again to separate cohort data back into two individual plots.

Tiles that display cohort description and percentage of cases with GDT sessions cannot be clustered.

Note: In addition to IOH, cohort comparisons for PGDT can be viewed by selecting the PGDT button in the primary toolbar.

Chapter 6

Exporting and Saving Data

6.1 Print to PDF



This icon appears on the primary toolbar for most screens. Click the Print PDF button to export data displayed on the main viewing pane in Adobe PDF format.

Exported PDFs will list the data in the same order as it appeared on the screen at the time of export. PDFs have a white background and a header listing summary information pertinent to the type of screen displayed at the time.

6.2 Exporting GDT Reports

G	

A GDT Report icon will appear on the secondary toolbar while viewing individual patient files with GDT sessions. A GDT report contains trend graphs of a selected GDT session.

- Click the desired patient file from the File List screen.
- Click the **GDT Report** icon. A popup menu will appear. See Figure 6-1.
- Select and highlight sessions to export them. Each session is exported to a separate PDF.
- Click **Print** and enter a name and select a location for the exported file.

Include			
Session 1	08/09/2015	4:23:58 PM	(a minute)
Session 2	08/09/2015	4:26:48 PM	(a few seconds)
Session 3	08/09/2015	4:33:08 PM	(2 hours)

Figure 6-1 GDT report popup menu

Exported PDFs have a header with the session start/end time and patient identifying information if de-identify was unchecked. The body of the PDF contains tracked parameter trend graphs and a table of intervention events for the GDT session time frame.

6.3 Exporting Case Reports

Γ	С	1
L		ι.
L		

A Case Report icon will appear on the secondary toolbar while viewing individual patient files. A case report contains trend graphs of selected parameters.

- Click the desired patient file from the File List screen.
- Click Case Report. A popup menu will appear. See Figure 6-2.
- Select parameters from the list to include them in the case report.
- Click **Print** and enter a name and select a location for the exported file.

Report Content				
Include HPI CO DIA M	D CI SV IAP	SVI SVV	PR SYS	•
☑ De-ident	tify		Cancel	Print

Figure 6-2 Case report popup menu

Exported PDFs have a header with the monitoring start/end time and patient identifying information if de-identify was unchecked. The body of the PDF contains selected parameter trend graphs and a table of intervention events for the monitoring session.

6.4 Exporting Patient Data Files



Patient data files are exported from Acumen Analytics software using the Export File icon. Exported files have an .ew extension and include original monitoring data plus any user edits. These edits include entering procedures, clinicians, comments, annotations, or GDT target modifications. These files can be imported back into the

application.

Caution: Federal (USA) law restricts this product to sale by or on the order of a physician.

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