# Acumen Analytics Software

**User Guide** 



#### Edwards Lifesciences Acumen Analytics Software User Guide

Because of continuing product improvement, prices and specifications are subject to change without notice. Changes to this guide, either in response to user input or to continuing product improvements, are accomplished through reissue. If, in the normal use of this manual, errors, omissions, or incorrect data are noted, please contact Edwards Technical Support or your local Edwards representative.

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

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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.

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

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# **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 hemodynamics. By understanding pressure and flow parameters, Acumen Analytics software can provide clinicians with a more thorough assessment of patient perfusion.

Each patient's 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 allows clinicians to download, view, and manage unaltered monitoring data exported from the EV1000 clinical platform and HemoSphere monitor suite of products (HemoSphere, HemoSphere Vita, and HemoSphere Alta monitor advanced monitoring platforms). Acumen Analytics software does not control the function or parameters of the platforms mentioned above and is not intended for active patient monitoring.

# 1.3 Acronyms and Abbreviations

Acronyms and abbreviations used in this guide.

Abbreviation	Definition
BP	Blood Pressure
BSA	Body Surface Area
CI	Cardiac Index
CO	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

**Table 1-1 Acronyms and Abbreviations** 

Abbreviation	Definition
PDF	Portable Document Format
PGDT	Perioperative Goal Directed Therapies
PR	Pulse Rate
ScvO <sub>2</sub>	Central Venous Oxygen Saturation
StO <sub>2</sub>	Tissue Oximetry
SV	Stroke Volume
SVI	Stroke Volume Index
SvO <sub>2</sub>	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 1-1 Acronyms and Abbreviations (continued)

## 1.4 User Interface

					Acume	n Analyt	ics			😳 👯 🕐
File List	၃၀ Sum	imary <u>२</u> ००	omparison					Q Find	×	\Xi Filter 🖨 PDF
□ All files		All files								
9 files		Patient ID ▲	Gender	Age	Height (cm)	Weight (kg)	Start	Clinician	Proce	dure
Os Cohorts	T.	AGD-7516	Male	25	173	86.2	Mar 18, 2020			
<u></u>		AJO-1945	Male	25	191	72.6	Jan 15, 2020			
+ Add Cohort		CUE-2567	Male	25	173	86.2	Mar 17, 2020			
		KED-8472	Male	25	191	72.6	Jan 27, 2020			
Cohort 1		NQE-5321	Male	67	168	77.1	May 19, 2020			
		QTY-1674	Male	25	191	72.6	Jan 27, 2020			
Cohort 2		UBA-2759	Male	25	170	88.9	Mar 17, 2020			
රි o files		URQ-1459	Male	25	173	86.2	Mar 18, 2020			
Cohort 2		YJD-2154	Male	67	168	77.1	May 19, 2020			
o files										
Cohort 4 පි o files										
Cohort 5										
		[↓] Import Files	Select Fi	les						

#### 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 monitor suite of products provides hemodynamic parameters through the Acumen IQ sensor, FloTrac sensor, TruWave disposable pressure transducer, Acumen IQ finger cuff, ClearSight finger cuff, Swan-Ganz cathether, and ForeSight tissue oximetry sensor. 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.

#### Title and Settings Bar

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

**Acumen Analytics** 

#### **Primary Toolbar**

File List		Qs Comparison	PGDT	BTinT	<b></b> Customize	PDF
-----------	--	---------------	------	-------	-------------------	-----

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.

#### **Cohort Sidebar**

Cohort 2	
Cohort 3	<
Cohort 4	
Cohort 5	

Figure 1-2 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.

#### **Main Viewing Pane**

Description		MAP: Hypotension Statistics	
Number of Files Number of Files without MAP	1 0	Gender	ນີ້ 100 % (male) ຜຼື້ 0 % (female)
Number of Files Analyzed	1	Age	× 67 ± 0
First Case Start Timestamp	May 19, 2020, 11:07:28 AM	Weight	₹ 77.1 ± 0 kg
	may 19, 2020, 1107.20 Put	Height	× 170 ± 0 lbs × 168 ± 0 cm × 66 ± 0 in
		Total monitoring time of the cohort	233.67 minute(s)
MAP: Total Number of Hypoten	sive Events in Cohort	Monitoring time per patient	
(su)		Number of patients with hypotension	1 of 1 100%
E °		Total number of hypotensive events in dataset	2 event(s)
4 eusio	2	Average number of hypotensive events per patient	X 2 ± 0 [2, 2, 2] event(s)
		Total duration of hypotension in cohort	6.33 minute(s)
<b>É</b> <b>5</b> 0 100 15	0 200 250 Events	Average duration of each hypotensive event	X 3.17 ± 2.59 [1.33, 3.17, 5] minute(s)
E Procedure Time Elapsed (mins)		Mean MAP under 65 mmHg per patient	x 60.43 ± 0 [60.43, 60.43, 60.43] mmHg
MAP: Percent of Patients with Hypotension Total Patient(s) 1 Patient(s) 1 100%		Area under 65 mmHg for MAP per patient (AUT)	
		Time Weighted Average of Area under Threshold (MAP < 65 mmHg) per patient	X 0.14 ± 0 [0.14, 0.14, 0.14] mmHg
		% of patients that experience an event under 50 mmHg	0 of 1 0%
		Total number of events when a patient is under 50 mmHg	o event(s)
		Lowest MAP among all patients	54 mmHg

# Figure 1-3 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.

#### Individual File Trend Analysis

Clinicians can review recorded data on available parameters on the EV1000 clinical platform and on the HemoSphere monitor suite of products.

#### Individual File PGDT Analysis

The individual file Perioperative Goal Directed Therapy (PGDT) screen allows GDT sessions within an individual file to be reviewed and analyzed.

#### Individual File TinT Analysis

The individual file TinT screen allows users to analyze time out of target data for the following parameters in a session: MAP, CI, SVI, SVRI, SVV, and dP/dt.

#### **PGDT Summary**

The customizable PGDT cohort summary screen allows GDT sessions of multiple files to be analyzed at a cohort level.

#### TinT

The customizable TinT cohort summary screen displays data collected for the chosen patient or patient group, for any of the selected TinT parameters.

#### **Cohort Comparison**

The cohort comparison screen allows clinicians to compare data from two cohorts.

Symbol	Description	
Title and Settings Bar		
	Settings	
မိုမို	User Preferences	
?	Help	
Primary Tool	bar	
	File List	
Do	Cohorts Summary Comparison	
6	PGDT	
Ð	TinT	
	Customize	
	Trend Analysis	
-	Filter	
$\bigcirc$	Annotate	
$\Leftrightarrow$	Pan	
+	Zoom In	
Q	Zoom Out	
	Autoscaling	
ē	PDF	

#### Table 1-2 User Interface Symbols

Symbol	Description
$\langle \!$	Back
Secondary T	oolbar
	Import Files
	Export Files
00	Remove from Cohort
Ē	Delete
	Select Files
G	GDT Report
С	Case Report
Cohort Side	bar
00	Cohorts
	Edit
+	Add Cohort
Ŵ	Delete
Ľ×	Close
Main Viewing	g Pane
	Modify (GDT targets)

#### Table 1-2 User Interface Symbols (continued)

	• •
Symbol	Description
$\nabla$	Intervention Event
$\leftrightarrow$	Combine Graphs

#### Table 1-2 User Interface Symbols (continued)

## **1.5 Clinical Platform Parameters**

 Table 1-3 EV1000 Clinical Platform, HemoSphere, HemoSphere Vita, and HemoSphere

 Alta monitor 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	
Diastolic pressure (DIA)	Diastolic blood pressure	
Systolic Slope (dP/dt)	Change in pressure over time	
Dynamic Arterial Elastance (Ea <sub>dyn</sub> )	Ratio of pulse pressure variation (PPV) to stroke volume variation (SVV)	
Hypotension Prediction Index (HPI)	Prediction value for hypotension. Higher values indicate greater probability of ensuing hemodynamic stability.	
Mean arterial pressure (MAP)	Averaged systemic blood pressure over one cardiac cycle	
Pulse pressure variation (PPV)	Quantifies the changes in arterial pulse pressure during mechanical ventilation	
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	
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 <sub>2</sub> )	Venous oxygen saturation as measured in the superior vena cava	
Mixed venous oximetry (SvO <sub>2</sub> )	Venous oxygen saturation as measured in the pulmonary artery	
Systolic pressure (SYS)	Systolic blood pressure	
Tissue Oximetry (StO <sub>2</sub> )	Absolute tissue oxygen saturation as measured at anatomical surface below sensor locatoin	

### 1.6 Cybersecurity

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 should take measures to ensure the security of any shared network Acumen Analytics software is 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 endpoint detection and response 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 Role Based Access Control (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 National Institute of Standards and Technology (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 10 or Windows 11 Memory: 8 GB RAM (minimum) Hard disk: 32 GB hard drive (minimum) with 3 GB of available disk space **Note:** Minimum screen resolution supported is 1366 x 768 pixels with 100% scale and layout.

# 2.2 Software Installation and Updates

Acumen Analytics software can be downloaded as follows:

- 1 Reach out to your local Edwards representative for a download link and license key.
- **2** Download and double-click the Acumen Analytics software .msi file to launch the installation wizard.
- 3 Follow the steps outlined in the installation wizard.
- 4 Enter the license key.

Please contact your Edwards representative or Technical Support for additional information on how to download the application, if needed (tech\_support@edwards.com).



Figure 2-1 Acumen Analytics software .msi installation wizard window

#### 2.2.1 Software Updates

Acumen Analytics software can be upgraded from 1.0 or 2.0.0 to version 3.0.0, using the same .msi file as above. Files loaded onto previous versions of Acumen Analytics software will be preserved in the new version.

The steps to upgrade a previous version of Acumen Analytics software are as follows:

- 1 Reach out to your local Edwards representative for a download link
- 2 Double-click on the .msi file to launch the installation wizard.
- 3 Follow the steps outlined in the installation wizard.
- 4 Acumen Analytics software will be updated to the latest 3.0.0 version, while maintaining all prior data.

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

# 2.3 System Settings

The Systems Settings menu contains features that allows you edit and review the following: Parameter Thresholds, Procedure List, Clinician List, Audit History, and Technology Priority.



Figure 2-2 System Settings drop down menu options

#### 2.3.1 Parameter Thresholds

Modify the global threshold value for TinT parameters (MAP, CI, SVI, SVRI, SVV, and dP/dt) after importing files into Acumen Analytics software.

drumeter		
MAP		
CI	Madify Threehold Value	
SVI	Modity Threshold Value	
SVRI		Canad
SVV		Cancel

SVRI 🗸		
	Modify Threshold Value	
Original Current		1970 1970
		Cancel Done

Figure 2-3 Parameter Threshold pop-up gives the user the option to modify the threshold value for all 6 TinT parameters.

The allowable range of threshold values for each parameter as well as the default value set is shown below:

Parameter	Minimum Value	Maximum Value	Default Value
MAP	50	100	65
CI	0.1	20.0	2.0
SVI	1	200	30
SVRI	1	9950	1970
SVV	1	99	13
dP/dt	1	3000	480

Table 2-	1
----------	---

After a TinT Parameter threshold value is modified, all statistical calculations and chart visualizations for the respective TinT parameter will update to reflect the new threshold value.

SVI: Below Target Statistics	
Monitoring time	233.67 minute(s)
Total number of below target events in dataset	7 event(s)
Total duration of below target events in dataset	23 minute(s)
Average duration of each below target event	₹ 3.29 ± 2.64 [1.08, 2, 5.33] minute(s)
Mean SVI under 30 mL/b/m <sup>2</sup>	27.61 mL/b/m <sup>2</sup>
Area under 30 mL/b/m <sup>2</sup> for SVI (AUT)	59 mL/b/m <sup>2</sup> x minute(s)
Time Weighted Average of Area under Threshold (SVI < 30 mL/b/m <sup>2</sup> )	0.25 mL/b/m <sup>2</sup>

SVI: Below Target Statistics	
Monitoring time	233.67 minute(s)
Total number of below target events in dataset	13 event(s)
Total duration of below target events in dataset	182.33 minute(s)
Average duration of each below target event	X 14.03 ± 28.76 [2.25, 4.33, 6.58] minute(s)
Mean SVI under 40 mL/b/m <sup>2</sup>	33.61 mL/b/m <sup>2</sup>
Area under 40 mL/b/m <sup>2</sup> for SVI (AUT)	1175.67 mL/b/m <sup>2</sup> x minute(s)
Time Weighted Average of Area under Threshold (SVI < 40 mL/b/m <sup>2</sup> )	5.03 mL/b/m <sup>2</sup>

Figure 2-4 Example of SVI statistical calculations changing depending on the threshold value set by the user in the Parameter Thresholds pop-up.

#### 2.3.2 Procedure List

Edit the list of procedures available with patient files. Acumen Analytics software comes preloaded with a list of procedures, which the user may customize by adding or deleting procedures. It is recommended to customize the available procedures before importing files. When a procedure is deleted from the list it is removed from all patient files.

Procedure List	Close
Add or remove procedures available in the application	
New Procedure Name	Add Procedure
Abdominal hysterocolpectomy and excision of periuterine tissue	Ê
Abdominoperineal excision of rectum and end colostomy	â
Abdominoperineal resection of the rectum, not otherwise specified	面
Allotransplantation of kidney from cadaver heart beating	â
Allotransplantation of kidney from cadaver heart non-beating	Ô
Allotransplantation of kidney from cadaver NEC	Ê
Allotransplantation of kidney from live donor	Ê
Anastomosis of ileum to anus and creation of pouch HFQ	â
Anastomosis of ileum to caecum	Ê
Anastomosis of ileum to colon NEC	Ê
Anastomosis of ileum to rectum	Ê
Anastomosis of ileum to transverse colon	Ê
Anastomosis of pancreatic duct to duodenum	Ê
Anastomosis of pancreatic duct to jejunum NEC	Ê
Anastomosis of pancreatic duct to stomach	â ,

Figure 2-5 List of clinical procedures that can be tagged to files.

### 2.3.3 Clinician List

Edit the list of clinicians available to associate 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.

	Acumen Analytics		٢	ti ()
≣ File List	Clinician List	Close		
All files	Add or remove the clinicians available in the application			
1 file	Dr. First Name Last Name	Add Clinician		
Cohorts	Dr. Evan Lim	ŵ		
+ Add Cohort	Dr. Sam Dalton	<del></del>		
	Dr. Zihong Peng	盦		
hpi sto2				
_				
	El mitra mez Ez sene una			

Figure 2-6 List of clinicians that can be tagged to files.

#### 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 and editing GDT targets.

#### 2.3.5 Technology Priority

Clicking on the "Technology Priority" button opens the Technology Priority window. The modifications made in this window will only affect HemoSphere Alta monitor files with multi-tech enabled, where multiple technology types were used to monitor the same hemodynamic parameter at the same time. For instance, if both Acumen IQ sensor and Acumen IQ cuff were collecting data at the same time for a HemoSphere Alta monitor panel, there would be two CO data values recorded.

If there are two or more technology types monitoring the same hemodynamic parameter at a given time, the data value used at each time point for all plots and calculations in Acumen Analytics software will be determined by the priority order set by the user in this window.

Upon changing this technology priority order, all statistical calculations and chart visualizations for HemoSphere Alta monitor files with multi-tech will update to reflect the new priorities.

Technology Priority		
Select priority order <ol> <li>Non Invasive •</li> </ol>	of data, if there are mu 2 Min Invasive •	ultiple technologies: 3 Invasive ▼
		Cancel Done

Figure 2-7 The technology priority window

#### 2.3.6 User Preferences

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

**ہ**|ہ



Figure 2-8 User Preferences drop down menu options

#### 2.3.7 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.

					Acumo	en Analy	tics
🗮 File List	<u>୦</u> ୧ Sumr	mary <u>२</u> ९८	omparison				
All files		Cohort 02					
5 files		Patient ID▲	Gender	Age	Height (cm)	Weight (kg)	Start
Oo Cohorts	T.	DEW-6197	Male	67	168	77.1	May 19, 2020
		FBG-3214	Male	67	168	77.1	May 19, 2020
+ Add Cohort							
					Acume	n Analyti	ics
🗮 File List	<u>଼</u> ୁ ୧୪୦୦୮	nary <u></u> ccc	omparison		Acume	n Analyti	ics
File List	୍ରି Sumn	nary ्रिट्ट Cohort 02	omparison		Acume	n Analyti	cs
File List	<u> </u> Sumn	nary 🔍 Co Cohort 02 Patient ID	omparison Gender	Age	Acume	n Analyti <sup>Weight (kg)</sup>	<b>CS</b> Start
File List	୍ ୧ Sumn	nary 오오co Cohort 02 Patient ID DEW-6197	omparison Gender Male	Age 67	Acume Height (cm) 168	n Analyti Weight (kg) 77.1	CS Start May 19, 2020
File List	Qe Sumn ▲	nary Qo Co Cohort 02 Patient ID DEW-6197 FBG-3214	omparison Gender Male Male	Age 67 67	Acume Height (cm) 168 168	n Analyti Weight (kg) 77.1 77.1	CS Start May 19, 2020 May 19, 2020

Figure 2-9 Light and dark theme colors

#### 2.3.8 Language

Select your preferred language of Acumen Analytics software. Acumen Analytics software is available in English, French, Italian, German, Spanish, Portuguese (Brazilian), Japanese, and Mandarin Chinese (Simplified).

# 2.4 Help

This menu contains access to the application welcome tutorial, the user guide, contact information, data access sharing, and application information.





Figure 2-10 Help drop down menu options

#### Welcome

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

#### **User Guide**

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

#### **Contact Us**

Share feedback via email by clicking the Contact Us link.

#### **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.

#### About

View the version of your Acumen Analytics software and legal licensing information.

# **Chapter 3**

# **Importing and Organizing Files**

Acumen Analytics software imports and displays monitoring session data saved from EV1000 monitor software version 1.9 or higher, HemoSphere monitor software version 1.01.000.025 or higher, HemoSphere Vita monitor software version 3.02.000.006 or higher, and HemoSphere Alta monitor software version 2.0.0 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 400 10 MB files can be stored in Acumen Analytics software.
- A maximum of 50 10 MB files can be imported at one time.
- A maximum of 25 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.
- Files should contain monitoring data.
- MAP data in the Excel file is not required for import. Sessions without pressure data (using Swan-Ganz or ForeSight tissue oximetry sensors only) can be imported.
- .xls, .xlsx, and .ew files are the only file types supported by Acumen Analytics software.
- For EV1000 and HemoSphere monitor files, .xls files exported in English (US), Spanish, French, German, or Italian can be imported.
- For HemoSphere Vita monitor files, .xls files exported in English (US) can be imported.
- For HemoSphere Alta monitor files, .xlsx files exported in English (US) can be imported.

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

To import files:

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

File List



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

Individual files can be imported into Acumen Analytics software using the Import Files button or by drag and drop. Before the file is imported, the File Import pop-up will appear with the following tiles:

- In the **Description** tile, patient demographic data and start/end times for the selected monitoring session will be displayed.
- In the Add to Cohort tile, you can select a Cohort with which the file will be categorized.
- In the **Print PDF Report** tile, you can export the file as a Case Report or GDT Report. See Chapter 6 for more information on this option.
- In the **Add Details** tile, you can associate the imported files to a clinician(s), a procedure(s), and/or add comments.

Description		Add Details
Patient ID Gender Age Weight Height	XLG-4853 Male 25 88.9 kg / 196 lbs 170 cm / 67 in	Select Clinician Enter clinician name
BSA Start End	2.00 m <sup>2</sup> Mar 17, 2020, 1:52:30 PM Mar 17, 2020, 2:19:10 PM	Select Procedure Enter procedure name
Add to Coho	<b>rt</b> ohorts available.	Comment
Print PDF Re Case GDT	port	•

Figure 3-1 File import pop-up window for single file import

#### 3.1.2 Multiple File Import

In addition to single file import, multiple files can be imported at a time into Acumen Analytics software using the same Import Files button or via drag and drop. Before the files are imported, the File Import pop-up will appear:

Importing 5 files	
Files Selected HPI StO2 MAP (3) - no GDT sheet.xls HPI StO2 MAP (3).xls HPI StO2 MAP (4) - Copy.xls HPI StO2 MAP (4) high SVV.xls HPI StO2 MAP (3) - Copy.xls	Add Details Select Clinician Enter clinician name
Add to Cohort Cohort 01 Cohort 02	Comment
	Cancel Import Files

#### Figure 3-2 File import pop-up window for multiple files

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.

# 3.2 Organizing Files

Acumen Analytics							0	ţţţ	?				
File List	QqSL	ımm	ary Occ	omparison					Q Find	×	= Filter	ē	PDF
			All files										
9 files			Patient ID 🛦	Gender	Age	Height (cm)	Weight (kg)	Start	Clinician	Proce	edure		
Os Cohorts	Γ <i>Ω</i> .		AGD-7516	Male	25	173	86.2	Mar 18, 2020					
	<u> </u>		AJO-1945	Male	25	191	72.6	Jan 15, 2020					
+ Add Cohort			CUE-2567	Male	25	173	86.2	Mar 17, 2020					
			KED-8472	Male	25	191	72.6	Jan 27, 2020					
Cohort 1			NQE-5321	Male	67	168	77.1	May 19, 2020					
			QTY-1674	Male	25	191	72.6	Jan 27, 2020					
Cohort 2			UBA-2759	Male	25	170	88.9	Mar 17, 2020					
යි o files			URQ-1459	Male	25	173	86.2	Mar 18, 2020					
Cobort 2			YJD-2154	Male	67	168	77.1	May 19, 2020					
as o files													
Cohort 4													
Cohort 5													

Import Files Select Files

#### Figure 3-3 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

Click the **Import Files** icon to import additional data files. See "Importing Files" on page 19.

#### Select Files



Click the **Select Files** icon to select multiple files for cohort editing. See "Organizing Cohorts" on page 23.

#### 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. **Note**: Cohort names can only include alphanumeric characters.



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 3-4.



Figure 3-4 Select files screen

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

In figure 3-4, 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.



# **Individual File Analysis**

# 4.1 Navigation and Toolbars

111	c usc		can chic		iuai ii	ic analys	is by circ	king into a	The listed in			3010	101
Acumen Analytics											_		$\times$
						Acume	n Analyt	ics			٢	<b>†</b> ↓†	?
Eile List	<u> </u> ୧୧ Su	mm	nary <u>O</u> ooco	omparison					Q Find	×	\Xi Filter	<b>₽</b>	PDF
All files			All files										
9 files			Patient ID ▲	Gender	Age	Height (cm)	Weight (kg)	Start	Clinician	Proc	edure		
Os Cohorts	Γ <i>Ω</i>		AGD-7516	Male	25	173	86.2	Mar 18, 2020					
	<u> </u>		AJO-1945	Male	25	191	72.6	Jan 15, 2020					
+ Add Cohort			CUE-2567	Male	25	173	86.2	Mar 17, 2020					
			KED-8472	Male	25	191	72.6	Jan 27, 2020					
Cohort 1			NQE-5321	Male	67	168	77.1	May 19, 2020					
C1 O mes			QTY-1674	Male	25	191	72.6	Jan 27, 2020					
Cohort 2			UBA-2759	Male	25	170	88.9	Mar 17, 2020					
o files			URQ-1459	Male	25	173	86.2	Mar 18, 2020					
Cohorto			YJD-2154	Male	67	168	77.1	May 19, 2020					
So files													
Cohort 4													
Cohort 5													
		[	Import Files	Select Fil	es								

The user can enter individual file analysis by clicking into a file listed in the File List screen.



Figure 4-1 After clicking into a file on the file list screen, the individual file screen appears

The individual file screen allows users to view and analyze the data of a single file. Within the individual file screen, there are the following 3 ways to visualize data:

- 1 Trend Analysis
- 2 PGDT
- 3 TinT

#### 4.1.1 Primary Toolbar

The individual file screen displays the following toolbar at the top of the screen:

Acumen Analytics					
€ HPI StO2 MAP.xls	🗠 Trend Analysis 💿 PGD	T 🗞 TinT	않 Cohorts		PDF

#### Figure 4-2 Individual File Screen navigation and toolbar

The Primary toolbar contains the following features and functions:

	View the trends data in full screen by clicking the <b>Trend Analysis</b> icon.
6	View the PGDT data by clicking the PGDT icon.

View time in target data of MAP, CI, SVI, SVRI, SVV, or dP/dt in full screen by clicking the **TinT** 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.

#### 4.1.2 Secondary Toolbar

Within the PGDT and TinT tabs, there is a secondary toolbar at the bottom of the screen:

Case Report GDT Report

Delete

#### Figure 4-3 Individual File Screen secondary toolbar

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

## 4.2 Trend Analysis Tab

Trend Analysis

The Trend Analysis tab allows users to visualize the trends of hemodynamic parameters from clinical monitoring platforms. Clicking the "Trend Analysis" button will open the Trend Analysis screen.

#### 4.2.1 Trend Analysis Plotting

The Trend Analysis screen displays a separate tile for each hemodynamic parameter plot.



Figure 4-4 Trend Analysis screen

The Trend Analysis screen displays the following parameters if the file contains data for them:

- MAP (Mean Arterial Pressure)
- SVV (Stroke Volume Variation)
- SV (Stroke Volume)
- SVI (Stroke Volume Index)
- CO (Cardiac Output)
- CI (Cardiac Index)
- SVR (Systemic Vascular Resistance)
- SVRI (Systemic Vascular Resistance Index)
- SYS (Systolic Brachial Pressure)
- DIA (Diastolic Brachial Pressure)
- PR (Pulse Rate)
- StO2 A1 (Tissue Oximetry)
- StO2 A2 (Tissue Oximetry)
- StO2 B1 (Tissue Oximetry)
- StO2 B2 (Tissue Oximetry)
- HPI (Hypotensive Predictive Index)
- PPV (Pulse Pressure Variation)
- dP/dt (Systolic Slope)

- Eadyn (Dynamic Arterial Elastance)
- CVP (Central Venous Pressure)

Each parameter is given its own tile, and each parameter is plotted for the entire duration of the case. For select parameters, there is green, yellow, and red background shading shown behind the trend line. The colors of the background shading show the target threshold bounds for each parameter set on the clinical monitoring platform. The colors are defined as follows:

Green background shading defines where the parameter is within target range.

Yellow background shading defines where the parameter is outside of target but within physiological range.

Red background shading defines where the parameter is in the alarm range.

 $StO_2A1$  and A2 parameters are plotted together on the same  $StO_2A$  plot, and  $StO_2B1$  and B2 parameters are plotted together on the same StO2B plot. Ea<sub>dyn</sub> does not contain any background shading: The trend analysis screen has the following features:

StO <sub>2</sub> A (%)								StO <sub>2</sub> A1
75 -								
25	▼		andre Version		. 🔻	<b>.</b> T	and men	
	11:37 am	12:07 pm	12:37 pm	1:07 pm	1:37 pm	2:07 pm	2:37 pm	3:07 pm
StO <sub>2</sub> B (%)								■StO <sub>2</sub> B1 ■StO <sub>2</sub> B2
75							mi -1 M	Samo
50 · 25 ·						_	in the second se	V
0	11:37 am	12:07 pm	12:37 pm	1:07 pm	1:37 pm	2:07 pm	2:37 pm	3:07 pm
Ea dvn								
10								
5								
0					~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~			
	11:37 am	12:07 pm	12:37 pm	1:07 pm	1:37 pm	2:07 pm	2:37 pm	3:07 pm

#### Figure 4-5 StO2 A, StO2B, and Ea\_dyn trend analysis plots

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.

#### **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.

#### 4.2.2 Trend Analysis Toolbar

The Trend Analysis screen contains its own individual toolbar to allow for customizable visualization of parameter data.

\*Collapse 💿 Annotate 🔍 Zoom In 📝 Autoscaling

#### Figure 4-6 Trend Analysis toolbar (default view)

When a graph is zoomed in using the "Zoom In" button, the Trend Analysis toolbar becomes the following:

\*Collapse 💿 Annotate 💠 Pan 🔍 Zoom In 🔍 Zoom Out 🗹 Autoscaling

#### Figure 4-7 Trend Analysis toolbar (expanded view)

#### Collapse/Expand



The collapse and expand icons allow users to toggle between viewing 4 or 2 plots at one given 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.

#### 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.

# 4.3 PGDT Tab

# 🛞 PGDT

The PGDT Tab allows users to analyze GDT sessions performed on the clinical monitoring platform during the session. The user can also tag the file with clinician names, procedure names, and comments. The GDT session must be initiated on the monitor prior to case start for the PGDT tab to function.

#### 4.3.1 Description Tile

Description	
Patient ID	XBQ-9164
Gender	Male
Age	67
Weight	77.1 kg / 170 lbs
Height	168 cm / 66 in
BSA	1.87 m <sup>2</sup>
Start	May 19, 2020, 11:07:28 AM
End	May 19, 2020, 3:09:48 PM

#### Figure 4-8 The description tile display

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

#### 4.3.2 Add Details Tile

Add Details	
Select Clinician	
Dr. Evan Lim	× Enter clinician name
Select Procedure	
Conversion from previou	s × Enter procedure name
Comment	
This is a comment	

Figure 4-9 Add Details Tile

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*.

#### 4.3.3 Event Review Tile

05/19/2020 11:07:01 am Tissue Oximetry: StO2 A1 Sensor Location: Left Brain
05/19/2020 11:07:01 am Tissue Oximetry: StO <sub>2</sub> A2 Sensor Location: Right Brain
05/19/2020 11:07:01 am Tissue Oximetry: StO <sub>2</sub> B1 Sensor Location: Left Calf
05/19/2020 11:07:01 am Tissue Oximetry: StO₂ B2 Sensor Location: Right Calf
05/19/2020 11:07:01 am Tissue Oximetry: Patient Mode: Adult
05/19/2020 11:07:01 am Tissue Oximetry: StO₂ A1/A2 Averaging: Normal
05/19/2020 11:07:01 am Tissue Oximetry: StO <sub>2</sub> B1/B2 Averaging: Normal
05/19/2020 11:07:01 am Tissue Oximetry: Patient Mode: Adult
05/19/2020 11:07:01 am Tissue Oximetry: StO <sub>2</sub> B1/B2 Averaging: Normal

Figure 4-10 Event Review Tile

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.

### 4.3.4 GDT Sessions Tile



Figure 4-11 GDT Sessions Tile

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.

DT Target				
Modify GDT Session 1 -	SV (mL/b)			
Start Time	End Time	Original		Current
05/19/2020 11:22:21 am	05/19/2020 3:10:23 pm	≥ 56	≥ ₹	56
		C	ancel	Done

Figure 4-12 GDT Target pop-up window allows users to modify the GDT session

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.

#### 4.3.5 Trends Tile

This tile displays graphical trends of the parameters shown in the Trend Analysis screen. Each trend plot is autoscaled to show the entire monitoring session of a parameter. The first four plots displayed are those of the key parameters selected during monitoring. For each parameter, the GDT session number and the percent time in target is displayed.

Scroll down to view trend data for all parameters.



Figure 4-13 Trends tile in the PGDT tab

Parameter values are plotted as a solid line. Background shading indicates the presence of a GDT session for that specific parameter. There are 3 colors of background shading that could be shown:

#### Blue



Blue background shading indicates an active GDT session for the parameter.

12:07 pm

#### Grey



Background shading indicates a paused GDT session for the parameter.

12:37 pm

#### Turquoise



Turquoise background shading indicates an edited GDT session for the parameter.

12:07 pm

**Note**: For HemoSphere Alta monitor files, GDT-specific data (donut charts and shading on plots) is not available.

### 4.4 TinT Tab



The TinT Tab allows users to analyze time out of target events that occurred for the following parameters: MAP, CI, SVI, SVRI, SVV, and dP/dt.

In the global Parameter Thresholds setting (see Chapter 2), the user can set threshold values for each TinT parameter. For MAP, CI, SVI, SVRI, and dP/dt parameters, an out of target event is defined as one minute (3 consecutive data points) below the set threshold. For SVV only, an out of target event is defined as one minute above the set threshold.

For labeling purposes, the phrase "out of target event" is translated differently across the various TinT screen, depending on the parameter:

- MAP: Hypotensive event
- CI, SVI, SVRI, dP/dt: Below target event
- SVV: Above target event

When the TinT button is clicked, a dropdown appears listing all the TinT parameters. The user can choose which TinT parameter they would like to have displayed.



Figure 4-14 TinT parameter dropdown

Once a selection is made, the individual file TinT screen for the parameter chosen will appear:

		Acumer	n Analytics	😌 ili 🔇
) HPI StO2	2 MAP.xls		🗠 Trend Analysis 🔘 PGDT  용 TinT 않	Cohorts 🛱 PD
Description			SVI: Total Number of Below Target Events	
Patient ID Gender Age Weight Height BSA Start End	XBQ-9164 Male 67 77.1 kg / 170 lbs 168 cm / 66 in 1.87 m <sup>2</sup> May 19, 2020, 11:07:28 AM May 19, 2020, 3:09:48 PM		10         50         100         150         200         2           Procedure Time Elapsed (mins)         200         2	13 Events
SVI: Below Targ Monitoring time Total number of bel Total duration of be Average duration of Mean SVI under 34 II Area under 34 mL/b Time Weighted Aver mL/b/m <sup>2</sup> )	get Statistics low target events in dataset elow target events in dataset if each below target event mL/b/m <sup>2</sup> y/m <sup>2</sup> for SVI (AUT) rage of Area under Threshold (SVI < 34	233.67 minute(s) 13 event(s) 84.33 minute(s) X 6.49 ± 10.56 [1.67, 2.33, 4] minute(s) 30.61 mL/b/m <sup>2</sup> 299.67 mL/b/m <sup>2</sup> x minute(s) 1.28 mL/b/m <sup>2</sup>	SVI: Time Below Target during Procedure	34.3 min 36.09%
SVI           75         1           50         34           25         0	2 3 4 11:37 am 12:07 pm	5 6.7 12:37 pm 1:07 f	<sup>0</sup> 10 11 1213 10	3:07 pm
Case Report	GDT Report			

Figure 4-15 Individual file TinT screen. SVI is shown in this example.

#### 4.4.1 Description Tile

Description	
Patient ID	XBQ-9164
Gender	Male
Age	67
Weight	77.1 kg / 170 lbs
Height	168 cm / 66 in
BSA	1.87 m <sup>2</sup>
Start	May 19, 2020, 11:07:28 AM
End	May 19, 2020, 3:09:48 PM

#### Figure 4-16 Description Tile

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

#### 4.4.2 Trends Tile

The Trends Tile displays a plot of the selected TinT parameter. The plot is autoscaled for visualization of all data points. A horizontal dashed line is plotted to indicate the threshold value set by the user for the displayed TinT parameter.

For MAP, CI, SVI, SVRI, and dP/dt parameters, values above and below this threshold line are plotted as green and red, respectively. Below target events for these parameters are highlighted with a pink shaded box, and each box is numbered for visualization of the number of below target events in the case.



#### Figure 4-17 TinT MAP trends tile.

#### Threshold value of 68 is shown as the black dashed horizontal line. MAP values above 68 are plotted in green, and values below are plotted in red. Hypotensive events are indicated with a numbered pink box.

For SVV, values below and above the threshold are plotted as green and red, respectively. Above target events are highlighted with a pink shaded box, and each box is numbered for visualization of the number of above target events in the case.

For the MAP parameter only, HPI is also plotted in the Trends Tile, if the file contains HPI data. A horizontal dashed line is plotted at 85. HPI values above and below 85 are plotted in red and green, respectively.



#### Figure 4-18 TinT SVV trends tile.

Threshold value of 15 is shown as the black dashed horizontal line. SVV values above 15 are plotted in red, and values below are plotted in green. Above target events are indicated with a numbered pink box.

#### 4.4.3 Events Scatter Plot



#### Figure 4-19 Events Scatter Plot

The events scatter plot displays the total number of out of target events for a TinT parameter in the case. Each event for a parameter is plotted as a scatter point, where the x-value is the minute in the case the event occurred, and the y-value is the amount of time the event lasted for.

#### 4.4.4 Statistics Table

MAP: Hypotension Statistics		
Monitoring time	233.67 minute(s)	
Total number of hypotensive events in dataset	8 event(s)	1.1
Total duration of hypotensive events in dataset	18.33 minute(s)	
Average duration of each hypotensive event		
Mean MAP under 68 mmHg	64.92 mmHg	
Area under 68 mmHg for MAP (AUT)	91.33 mmHg x minute(s)	
Time Weighted Average of Area under Threshold (MAP < 68 mmHg)	0.39 mmHg	
Total number of events when a patient is under 50 mmHg	o event(s)	*

Figure 4-20 Statistics Table

The statistics table shows various calculations to quantify the time out of target for a TinT parameter.

The table below describes the meaning of each row in the TinT MAP individual file statistics table. For all other TinT parameters, analogous row labels and calculations are applied.

Row Name	Numerical value meaning
Monitoring time	The total length of time the selected TinT parameter was monitored for (ignores missing data points)
Total number of hypotensive events in dataset	The number of hypotensive events that occurred
Total duration of hypotensive events in dataset	The length of hypotension experienced
Average duration of each hypotensive event	Mean, standard deviation, and 25th / 50th / 75th percentiles of the distribution of the length of hypotensive events experienced in the file
Mean MAP under <threshold> mmHg</threshold>	Mean value of all MAP values less than the threshold
Area under <threshold> mmHg for MAP (AUT)</threshold>	Area of the MAP curve under the threshold value

Table 4-1 TinT individual file statistics table rows

Row Name	Numerical value meaning
Time Weighted Average of Area under Threshold (MAP < <threshold> mmHg) per patient</threshold>	Area under threshold divided by the monitoring time
Total number of events when a patient is under 50 mmHg (MAP parameter only)	Number of times in the cohort a patient experienced at least one minute of MAP below 50 mmHg

#### Table 4-1 TinT individual file statistics table rows

#### 4.4.5 Donut Chart



#### Figure 4-21 Donut Chart

The donut chart quantifies the percentage of the total procedure time that the patient was out of target for a TinT parameter.

The value inside the donut chart refers to the total procedure time of the case. The values outside the donut chart refer to the total and percentage of time the patient was out of target for the selected TinT parameter.

# **Chapter 5**

# **Cohort Summary and Comparison**

# 5.1 Navigation and Toolbars

The user can enter cohort summary or cohort comparison analysis by clicking into the "Summary" or "Comparison" buttons at the top of the home screen.

C Acumen Analytics											_	
						Acume	n Analyt	ics			٢	tli ()
E File List	Qqsı	ımm	nary Qoc	omparison					Q Find	×	- Filter	PDF
			All files									
5 files			Patient ID▲	Gender	Age	Height (cm)	Weight (kg)	Start	Clinician	Proc	edure	
OS Cohorts	T.		BQY-3485	Male	25	191	72.6	Jan 27, 2020	Dr. Evan Lim			
			MAQ-2364	Male	65	180	76.2	Apr 18, 2024				
+ Add Cohort			NBZ-4536	Male	67	168	77.1	May 19, 2020				
			PAU-6359	Male	25	173	86.2	Mar 18, 2020				
Cohort 01			TJQ-5624	Male	25	191	72.6	Jan 15, 2020				
Cohort 02 Cohort 03 Cohort 03												
			Import Files	Select F	iles							

Figure 5-1 Home Screen

		Acumen Analyt	ics	© # ⑦
🗮 File List ्रि Sum	mary <u>२</u> ९ Comparison		SPGDT 🛞 Tin 1	T 🖉 Customize 🛱 PDF
□ All files	All files			
10 files	Description		MAP: Hypotensions Statistics	
🔗 Cohorts 📝	Number of Files Number of Files without MAP	10 1	Gender	ນີ້ 77.78 % (male) ຜີ້ 22.22 % (female)
	Number of Files Analyzed	9	Age	₹ 55.56 ± 24.42
+ Add Cohort	First Case Start Timestamp	Jan 15, 2020, 3:31:12 AM	Weight	₹ 65.02 ± 20.66 kg
	Last Case Start Timestamp	Mar 26, 2024, 4:55:07 PM		× 143.33 ± 45.53 lbs
Cobort 01			Height	× 179.67 ± 11.54 cm
00 1 file				₹ 70.67 ± 4.53 in
			Total monitoring time of the cohort	500.33 minute(s)
Cohort 02	MAP: Total Number of Hypote	ensive Events in Cohort	Monitoring time per patient	x 55.59 ± 70.75 [12.67, 34.67, 68.67] minute(s)
2 files	(sui		Number of patients with hypotension	3 of 9 33.33%
	E 60		Total number of hypotensive events in dataset	10 event(s)
Cohort 03		10	Average number of hypotensive events per patient	
	20		Total duration of hypotension in cohort	123 minute(s)
gdt march 2024		• Events	Average duration of each hypotensive event	▼ 12.3 ± 22.87 [1.33, 1.83, 7] minute(s)
S files	E Procedure Time El	apsed (mins)	Mean MAP under 68 mmHg per patient	
	Figure 5.2 After c	licking into "Summ	arv" or "Comparison"	

Figure 5-2 After clicking into "Summary" or "Comparison", the Cohort Summary or Comparison screen appears.

The cohort summary and comparison screens allow users to view and analyze the data of cohorts. Within the cohort summary and comparison screens, there are the following 2 ways to visualize data:

- 1 PGDT
- 2 TinT

#### 5.1.1 Toolbar

The cohort summary and comparison screens display the following toolbar at the top of the screen:

			Acumen Analytics			٢	ŧţŧ	?
Eile List	Qe Summary	Qo Comparison		🛞 PGDT	<b>®</b> TinT	🖉 Customize	Ē	PDF

#### Figure 5-3 Cohort Summary and Comparison Screen navigation and toolbar

The toolbar contains the following features and functions:

:==

While viewing cohort summary or comparison data, click on the **File List** button to return to the main Acumen Analytics software screen.



Enter cohort summary mode with the **Cohort Summary** icon.



Enter cohort summary mode with the **Cohort Comparison** icon.



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.



View time in target data of MAP, CI, SVI, SVRI, SVV, or dP/dt in full screen by clicking the TinT icon.



Customize which tiles are visible on the screen.



Click the Print to PDF button to generate a PDF copy of the currently displayed screen.

#### 5.1.2 Cohort Sidebar

To select which cohort to analyze in Cohort Summary or Comparison mode, select a cohort on the left side of the screen. The cohort that is selected in the cohort sidebar will be the cohort that is displayed. See chapter 2 for more information on creating and managing cohorts.

File List 오오Sum	mary ्रि Comparison		
All files	Cohort 03		
4 files	Description		
😤 Cohorts 🗹	Number of Files		
	Number of Files without MAP		
+ Add Cohort	Number of Files Analyzed		
	Last Case Start Timestamp		
Cohort 01			
Cohort 02	MAP: Total Number of Hypote		
a files	(suus) 8		
Cohort 03	6 4 4 6 6 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8 7 8		
Long cohort name example text	Procedure Time I		
and the	MAP: Percent of Patients with		

Figure 5-4 User has selected "Summary" mode at the top of the screen. To choose which cohort to view in Summary mode, the user can select any of the available cohorts they have created.

#### 5.1.3 Customize View

In Cohort Summary and Comparison modes, the user can customize which data tiles are visible.



To select which data tiles appear on the screen, click on the Customize View icon and a dialog will display your choices. In Cohort Summary and Comparison modes, the user can customize which data tiles are visible. When an option is selected, its corresponding tile will be visible. If an option is unselected, its corresponding tile will not be visible.

	© PGDT ලි	TinT 🧕	🖉 Customize	
Customize View				1
Demographic Histogra	ams		o	
Age Heigh	t Weight			
Parameter Mean vs Ti	ime Graphs			- 1
SVV				- 1
GDT Plots	_			
Duration of GDT	Files with GD	г	24	
Time in Target				
250 -				
	🛞 PGDT 🍕	TinT	🖉 Customiz	ze 🖨
Customize View				
Time in Hypotens	sion Statistic	cs		
Events Pat	tients with Hypoter	ntion		
		ç	22.22 % (female	)

# Figure 5-5 Customize View setting in cohort summary and comparison screens for PGDT (top) and TinT data (bottom)

When the user exports a PDF from a cohort summary or comparison screen, only the tiles that are currently displayed will be included in the PDF file.

## 5.2 Cohort Summary

<u>୧</u>Summary

The cohort summary screen displays an overview of all patient monitoring data contained within the cohort. Clicking the Summary button allows the user to enter Cohort Summary mode.

Within Cohort Summary mode, the user can view PGDT or TinT data. In Cohort Summary, the user can customize which data tiles are visible.

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.

#### 5.2.1 PGDT Cohort Summary

```
    PGDT
```

Clicking the PGDT button while in Cohort Summary mode will open the PGDT Cohort Summary screen.



#### Figure 5-6 PGDT Cohort Summary screen

#### 5.2.1.1 Patient Demographic Tiles



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

#### 5.2.1.2 GDT Session Duration



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.

#### 5.2.1.3 Patient Files with GDT Session



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

#### 5.2.1.4 Pooled Time in Target

1			
5			_
			Н
;			-

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.

#### 5.2.1.5 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 TinT Cohort Summary



Clicking the TinT button while in Cohort Summary mode will open a dropdown prompting the user to select a specific TinT parameter to analyze in Cohort Summary mode.



Figure 5-7 TinT dropdown menu in cohort summary mode.

Selecting a specific TinT parameter in the dropdown will result in that parameter being displayed in Cohort Summary mode:

	Acumen Analy	tics	🐵 🚻 🕐
≣ File List ्र 2ू९ Sur	nmary QC Comparison	🕲 PGDT 🛛 🏷 Ti	nT 🖉 Customize 🗧 PDF
	All files		í.
10 files	Description	MAP: Hypotensions Statistics	
😤 Cohorts 🗹	Number of Files 10 Number of Files without MAP 1	Gender	
+ Add Cohort	Number of Files Analyzed 9 First Case Start Timestamp Jan 15, 2020, 3:31:12 AM List Case Start Timestamp Into 52 2021, 4:5727 DM	Age Weight	× 55.50 = 24.42 × 65.02 ± 20.60 kg
Cohort on	Last case statis interstantly mail 20, 2024, 4-35.07 Pm	Height	× 143-33 ± 45-53 los × 179-67 ± 11.54 cm × 70-67 ± 4.53 in
Cohort 02	MAP: Total Number of Hypotensive Events in Cohort	Total monitoring time of the cohort Monitoring time per patient	500.33 minute(s) × 55.59 ± 70.75 [12.67, 34.67, 68.67] minute(s)
25 2 files	24	Number of patients with hypotension	3 of 9 33 33%
	5 M	Total number of hypotensive events in dataset	10 event(s)
Cohort 03 St 1 file	10 § 4°.	Average number of hypotensive events per patient	X 1.11 ± 4.04 (1, 1, 6.25) event(s)
	2 20	Total duration of hypotension in cohort	123 minute(s)
gdt march 2024	g 0 50 100 150 200 250	Average duration of each hypotensive event.	# 12.3 ± 22.87 [1.33, 1.83, 7] minute(s)
St 5 files	Procedure Time Elapsed (mins)	Mean MAP under 68 mmHg per patient	E 66.65 = 30.16 [22.25, 59, 63.44] mmHg x minute(s)
Long cohort name example text	MAP: Percent of Patients with Hypotension	Area under 68 mmHg for MAP per patient (AUT)	X 499-56 ± 1353.47 (0, 0, 145] mmilg x minute(s)
SS + file		Time Weighted Average of Area under Threshold (MAP < 68 mmHg) per patient	X 7.34 ± 19.16 [0, 0, 2.22] mmHg
	Total Patient(s) 3 Patient(s)	% of patients that experience an event under 50 mmHg	1 of 9 11.11%
	9 33-33%	Total number of events when a patient is under 50 mmHg	1 event(s)
		Lowest MAP among all patients	10 mmilg
	35-33 4	Towe memory or events when a patient is under 50 mmHg Lowest MAP among all patients	1 eveni(s) 10 mmilig

Figure 5-8 TinT Cohort Summary screen. In this example, MAP data is shown.

The purpose of TinT Cohort Summary is to allow users to analyze out of target event data for all TinT parameters. For MAP, CI, SVI, SVRI, and dP/dt parameters, an out of target event is defined as one minute (3 consecutive data points) below the set threshold. For SVV only, an out of target event is defined as one minute above the set threshold.

For labeling purposes, the phrase "out of target event" is translated differently across the various TinT screen, depending on the parameter:

- MAP: Hypotensive event
- CI, SVI, SVRI, dP/dt: Below target event
- SVV: Above target event

For all TinT cohort summary screens, only the files in the cohort that contain data for the selected TinT parameter are accounted for the displayed calculations and graphs.

The TinT Cohort Summary screen contains several tiles to display out of target event data for each parameter:

#### **Description Tile**

Number of Files	10
Number of Files without MAP	1
Number of Files Analyzed	9
First Case Start Timestamp	Jan 15, 2020, 3:31:12 AM
Last Case Start Timestamp	Mar 26, 2024, 4:55:07 PM

The description tile displays the number of files in the cohort, the number of files that do not contain the selected TinT parameter in the cohort, the number of files in the cohort that were analyzed for the selected TinT parameter, the first case start timestamp, and the last case start timestamp. Files in the cohort that do not contain the selected TinT parameter data are excluded from the analysis.

#### **Events Scatter Plot**



This is a visual representation of the total occurrences of out of target events during a procedure. The Y-axis of the graph demonstrates the length in time of each out of target event, while the X-axis demonstrates the procedure time. Each scatter point indicates an individual out of target event, so you can track when events are occurring across procedures.

#### **Percent of Patients Donut Chart**



This is a visual representation of the number of patients in a cohort that experienced an out of target event for a certain TinT parameter. The value inside the donut refers to the number of patients analyzed in the cohort. The values outside refer to the number and percentage of patients that experienced at least one event during its case.

#### Average Time Donut Chart



This data shows how much time each patient in the cohort spends, on average, out of target for the selected parameter. The value inside the donut chart refers to the total procedure time of cohort. The values outside refer to the average time spent out of target per patient as absolute and percentage values.

#### **Statistics Table**



A list of key calculations to quantify time spent out of target for a specific TinT parameter for a cohort.

The table below describes the meaning of each row in the TinT MAP Cohort Summary statistics table. For all other TinT parameters, analogous row labels and calculations are applied.

Row Name	Numerical value meaning
Gender	Percentage of male and female patients in the cohort
Age	Mean and standard deviation of age distribution in the cohort
Weight	Mean and standard deviation of weight distribution in the cohort
Height	Mean and standard deviation of height distribution in the cohort
Total monitoring time of the cohort	The sum of the individual monitoring times of each file in the cohort
Monitoring time per patient	Mean, standard deviation, and 25th / 50th / 75th percentiles of the distribution of monitoring times for each patient for the selected parameter
Number of patients with hypotension	Number and percentage of patients in the cohort that experienced at least one hypotensive event
Total number of hypotensive events in dataset	The sum of the number of hypotensive events experienced by each patient in the cohort
Average number of hypotensive events per patient	Mean, standard deviation, and 25th / 50th / 75th percentiles of the distribution of number of hypotensive events experienced by each patient in the cohort
Total duration of hypotension in cohort	The sum of the duration of hypotension experienced by each patient in the cohort
Average duration of each hypotensive event	Mean, standard deviation, and 25th / 50th / 75th percentiles of the distribution of the length of hypotensive events experienced in the cohort
Mean MAP under <threshold> mmHg per patient</threshold>	Mean, standard deviation, and 25th / 50th / 75th percentiles of the distribution of mean MAP values under the threshold value per patient
Area under <threshold> mmHg for MAP per patient (AUT)</threshold>	Mean, standard deviation, and 25th / 50th / 75th percentiles of the distribution of the area of the MAP curve under the threshold value per patient
Time Weighted Average of Area under Threshold (MAP < <threshold> mmHg) per patient</threshold>	Mean, standard deviation, and 25th / 50th / 75th percentiles of the distribution of the time weighted average area of the MAP curve under the threshold value per patient
% of patients that experience an event under 50 mmHg (MAP parameter only)	Number and percentage of patients in the cohort that experienced at least one minute of MAP below 50 mmHg
Total number of events when a patient is under 50 mmHg (MAP parameter only)	Number of times in the cohort a patient experienced at least one minute of MAP below 50 mmHg
Lowest MAP among all patients	Lowest MAP value across the cohort

Table	9 5-1

# 5.4 Cohort Comparison

The cohort comparison screen displays an overview of patient monitoring data of two cohorts. Clicking the Comparison button allows the user to enter cohort comparison mode.

Use the cohort comparison screen to view a side-by-side summary of two cohorts. The main viewing pane is divided in half lengthwise. Within cohort comparison mode, the user can view PGDT or TinT data. The cohort comparison screen displays the exact same tiles as would be displayed in cohort summary mode. Similar to cohort summary, the user can customize which data tiles are visible.

				A	cumen An	alytics	;			Ô	ili ()
₩ File List	<u>୦୧</u> Sun	nmary	<u> ୧</u> ୧Compariso	in				PGDT	® TinT	🖉 Customize	e 🛱 PDF
All files		Baseli	ne Cohort: Coh	ort 03 <del>-</del>						All files -	*
Cohorts				7.84%	T ا <b>(</b>	ime spent hypotensio	in on	23%	b	Ø.	
+ Add Cohort			$\mathbf{\cdot}$	0	MAP	events un mmHg	der 50	1		G	
Cohort 01		Desc	cription				Description				
යි 1 file		Coho	ort Name	Cohort 03		1	Cohort Name		All files		<b>^</b>
6 h		Num	ber of Files	1			Number of Files		12		
2 files		Num	ber of Files without MA	AP O		_	Number of Files with	out MAP	1		
		Num	ber of Files Analyzed	1			Number of Files Anal	yzed	11		
Cohort 03		First	Case Start Timestamp	May 19, 202	0, 11:07:28 AM		First Case Start Time	stamp	Jan 15, 202	0, 3:31:12 AM	
1 file		Last	Case Start Timestamp	May 19, 202	0. 11:07:28 AM	<b>•</b>	Last Case Start Times	stamp	Apr 10, 202	4, 11:33:00 AM	*
Long cohort name example text 3 1 file	2	Time in Hypotension (mins)	P: Total Number of	Hypotensive Events	in Cohort	s	MAP: Total Numb	100 Trocedure Time Ela	150 20 apped (mins)	in Cohort	<b>2</b> nts

Figure 5-9 Cohort comparison mode

The cohort comparison screen has the following features.

#### Select Cohort



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. When the user exports a PDF from a cohort summary or comparison screen, only the tiles that are currently displayed will be included in the PDF file.

#### **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.



Figure 5-10 Tiles that display cohort description and percentage of cases with GDT sessions cannot be clustered.

### 5.4.1 PGDT Cohort Comparison



Clicking the PGDT button while in cohort comparison mode will open the PGDT cohort comparison screen.



#### Figure 5-11 PGDT Cohort Comparison screen

All tiles described in section 5.2.1 PGDT Cohort Summary are also visible in PGDT Cohort Comparison screen.

#### 5.4.2 TinT Cohort Comparison

```
® TinT
```

Clicking the TinT button while in Cohort Comparison mode will open a dropdown prompting the user to select a specific TinT parameter to analyze in Cohort Comparison mode.



# Figure 5-12 TinT dropdown menu in cohort comparison mode.

Selecting a specific TinT parameter in the dropdown will result in that parameter being displayed in Cohort Comparison mode:

Acumen Analytics					_	
		Acumen A	nalytic	:s	<b>@</b>	ili ()
≣ File List _ 옷 Sur	mmary ्रि Comparison			💿 PGD	)T 🤏 TinT 📝 Customize	🖨 PDF
☐ All files	Baseline Cohort: Cohort	03 -			All files -	*
12 files		7.84%	Time sper hypotens	ion 23°	%	
+ Add Cohort	$\odot$	0	AP events u mmHန္	nder 50 g <b>1</b>	U	
Cohort 01	Description Cohort Name	Cohort 03	•	Description Cohort Name	All files	
Cohort 02	Number of Files Number of Files without MAP	1		Number of Files Number of Files without MAP	12	
Cohort 03	First Case Start Timestamp	1 May 19, 2020, 11:07:28 AM May 19, 2020, 11:07:28 AM		First Case Start Timestamp	Jan 15, 2020, 3:31:12 AM Apr 10, 2024, 11:33:00 AM	·
Long cohort name example text 쏭 1 file	MAP: Total Number of Hyp (sili) 6 4 2 50 100 Frocedure Tin	e lapsed (mins)	<b>3</b> ents	MAP: Total Number of Hypot	tensive Events in Cohort 150 200 250 Elapsed (mins)	<b>2</b> ts

#### Figure 5-13 TinT Cohort Comparison screen. In this example, MAP data is shown for two cohorts.

The TinT Cohort Comparison screen will display the following header:

Baseline Cohort:	Cohort 03 -		All files -	
	7.84%	Time spent in hypotension	22.99% 👰	
	0	MAP events under 50 mmHg	1	

Figure 5-14 TinT Cohort Comparison header for MAP

The header displays the percentage of time a cohort was out of target for a TinT parameter. For MAP only, the header will also display the number of events where MAP was below 50 mmHg in a cohort.

All tiles described in section 5.2.2 TinT Cohort Summary are also visible in TinT Cohort Comparison screen.

# **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.

The following screens can be exported as a PDF:

- File List screen
- Individual File Trend Analysis screen
- Individual File PGDT screen
- Individual File TinT screen (for each TinT parameter)
- Cohort Summary PGDT screen
- Cohort Summary TinT screen (for each TinT parameter)
- Cohort Comparison PGDT screen
- Cohort Comparison TinT screen (for each TinT parameter)



Figure 6-1 PDF report examples: Individual File Trend Analysis and Individual File TinT MAP

# 6.2 Exporting GDT Reports

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	L

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 6-2.
- 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.

Report Content				
Include				
Session 1	05/19/2020	11:22:21 AM		(4 hours)
De-identify			Cancel	Print

Figure 6-2 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.



Figure 6-3 GDT report PDF example

# 6.3 Exporting Case Reports

С	

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 6-4.
- 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.



Figure 6-4 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.



Figure 6-5 Case report PDF example

# 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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