

Acumen Analytics Software

User Guide



Edwards

Acumen Analytics Software User Guide

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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 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	<i>Introduction</i>
2	<i>Setup and Customization</i>
3	<i>Importing and Viewing Files</i>
4	<i>File Organization</i>
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Chapter 1

Introduction

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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 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 are shown in Table 1-1, on page 2.

Table 1-1 : Acronyms and Abbreviations

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
MAP	Mean Arterial Pressure
PDF	Portable Document Format
PGDT	Perioperative Goal Directed Therapies
PR	Pulse Rate
StO ₂	Tissue Oximetry
SV	Stroke Volume
SVI	Stroke Volume Index
SVR	Systemic Vascular Resistance
SVRI	Systemic Vascular Resistance Index
SVV	Stroke Volume Variation
SYS	Systolic Pressure
USB	Universal Serial Bus
TWA	Time Weighted Average

1.4 User Interface

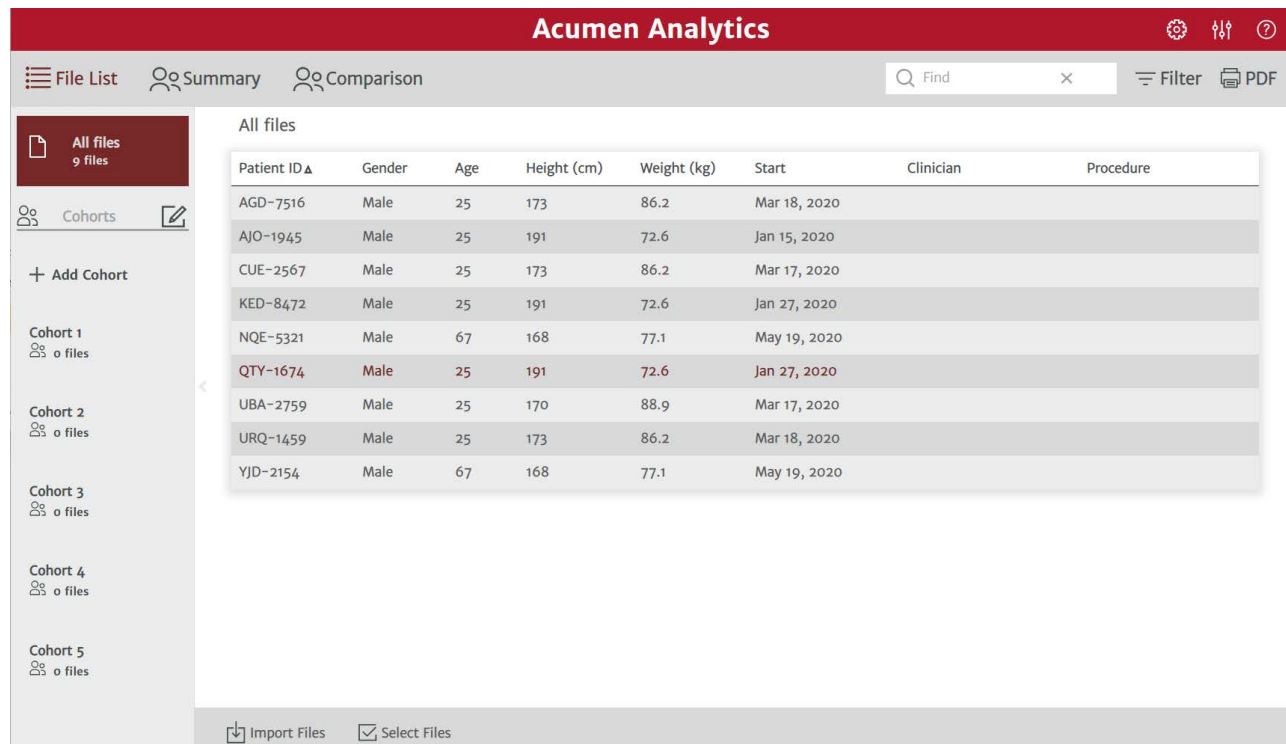


Figure 1-1 : Primary screen

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.

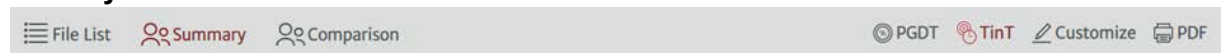
Data files can be imported into Acumen Analytics software and organized into cohorts. The primary screen appears as shown in Figure 1-1, on page 3. This interface allows the user to analyze data within and between cohorts. With a streamlined tile layout, the main viewing page organizes a list of all 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.

Primary Toolbar



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 Individual File Analysis and Cohort Summary and Comparison for cohort and cohort comparison views.

Main Viewing Pane

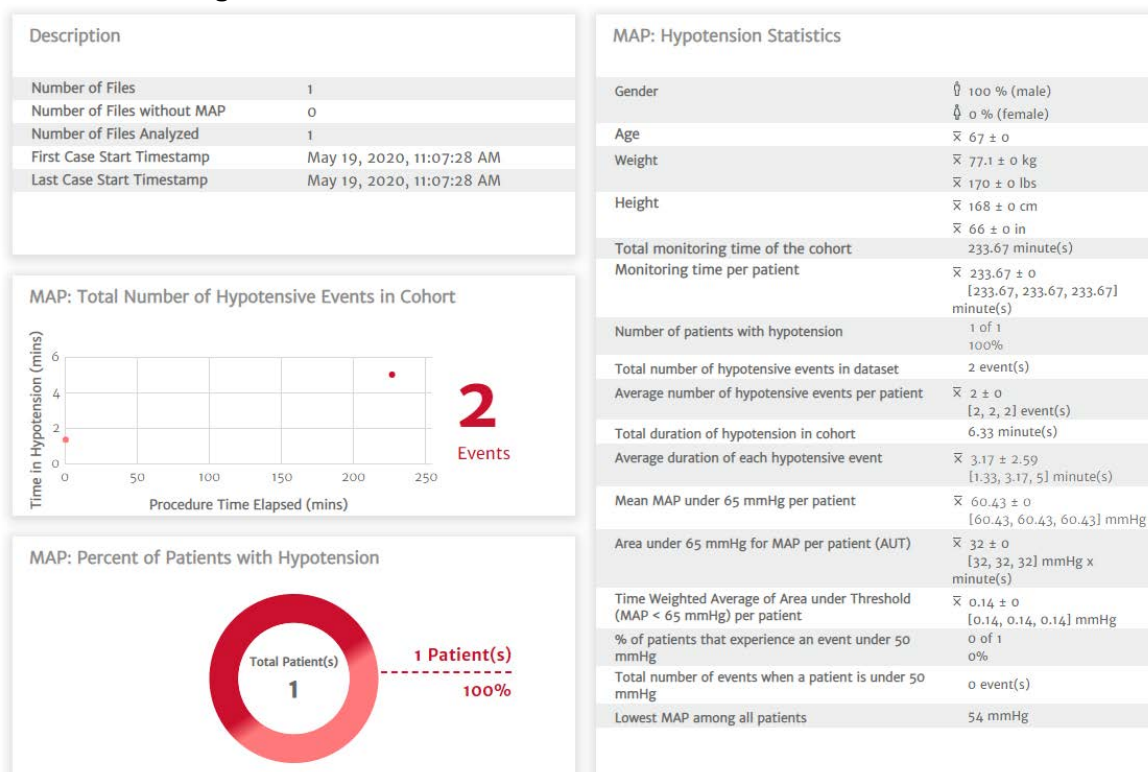


Figure 1-2: Main viewing pane

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 Summary

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.

Cohort Sidebar



Figure 1-3 : 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.

Table 1-2 User Interface Symbols

















Symbol	Description
Title and Settings Bar	
	Settings
	User Preferences
	Help
Primary Toolbar	
	File List
	Cohorts Summary Comparison
	PGDT
	TinT
	Customize
	Trend Analysis
	Filter
	Annotate
	Pan
	Zoom In
	Zoom Out
	Autoscaling
	Print to PDF

Table 1-2 User Interface Symbols (continued)

















Symbol	Description
	Back
Secondary Toolbar	
	Import Files
	Export Files
	Remove from Cohort
	Delete
	Select Files
	GDT Report
	Case Report
Cohort Sidebar	
	Cohorts
	Edit
	Add Cohort
	Delete
	Close
Main Viewing Pane	
	Modify (GDT targets)

Table 1-2 User Interface Symbols (continued)

Symbol	Description
	Intervention Event
	Combine Graphs

1.5 Clinical Platform Parameters

Acumen Analytics software displays parameters from the following compatible monitoring platforms: EV1000 clinical platform and HemoSphere, HemoSphere Vita, and HemoSphere Alta advanced monitoring platforms,

Table 1-3 : Compatible 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
Systolic Slope (dP/dt)	Change in pressure over time
Dynamic Arterial Elastance ($E_{a_{dyn}}$)	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 (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 location

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 cybersecurity 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

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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.

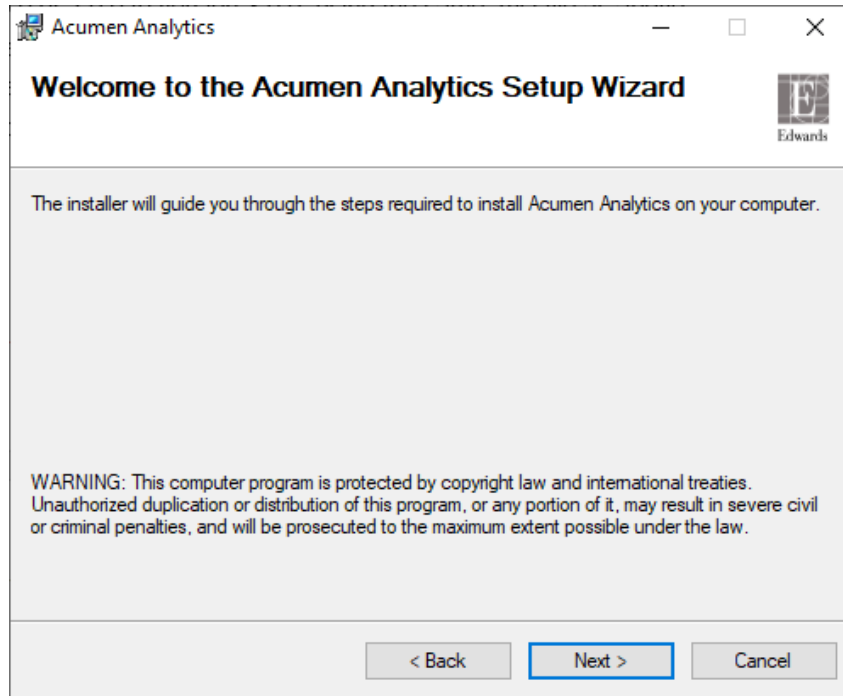


Figure 2-1 : Acumen Analytics software .msi installation wizard window

- 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).

2.2.1 Software Updates

If the current version of Acumen Analytics is 3.0, a pop-up will appear upon each launch of the application to prompt the software update to Acumen Analytics 3.1. Simply click “Update now” to proceed with installation. The software will automatically update. Multiple restarts of the Acumen Analytics application may occur. Files previously loaded in Acumen Analytics will be preserved in the new version. License key will be preserved.

If the current version is 1.0 or 2.0, upgrade the software to Acumen Analytics 3.0 first before upgrading to 3.1.

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, Technology Priority, and Non-Pulsatile Mode.

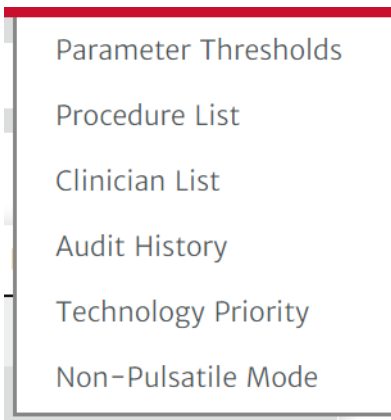


Figure 2-2 : System Settings drop down menu options

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.

The parameter thresholds pop-up gives the user the option to modify the threshold value for all six TinT parameters.

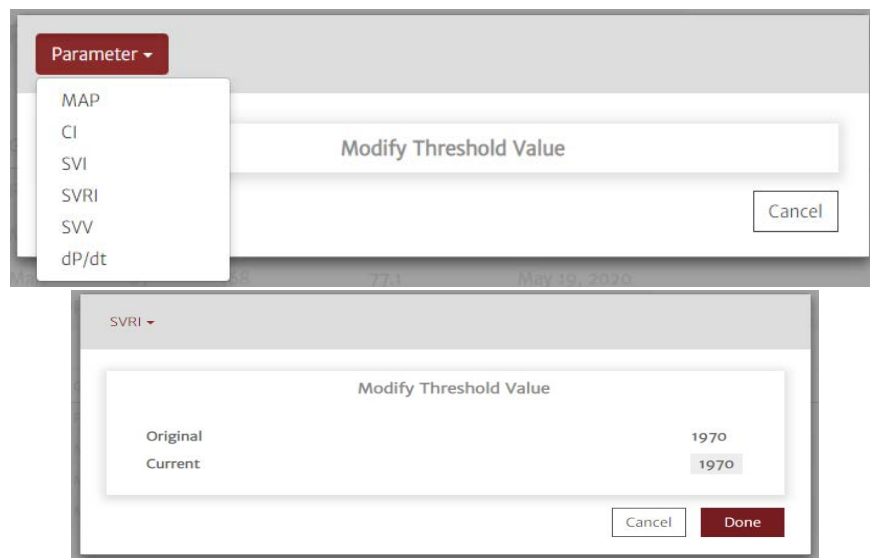


Figure 2-3 : Parameter thresholds pop-up

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

Table 2-1 : Parameter threshold allowable range

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

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.

Figure 2-4, on page 15 shows examples of SVI statistical calculations that are changing depending on the threshold value set by the user in the parameter thresholds pop-up.

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	\bar{x} 3.29 ± 2.64 [1.08, 2, 5.33] minute(s)
Mean SVI under 30 mL/b/m ²	27.61 mL/b/m ²
Area under 30 mL/b/m ² for SVI (AUT)	59 mL/b/m ² x minute(s)
Time Weighted Average of Area under Threshold (SVI < 30 mL/b/m ²)	0.25 mL/b/m ²

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	\bar{x} 14.03 ± 28.76 [2.25, 4.33, 6.58] minute(s)
Mean SVI under 40 mL/b/m ²	33.61 mL/b/m ²
Area under 40 mL/b/m ² for SVI (AUT)	1175.67 mL/b/m ² x minute(s)
Time Weighted Average of Area under Threshold (SVI < 40 mL/b/m ²)	5.03 mL/b/m ²

Figure 2-4 : SVI statistical calculations

2.3.2 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.

Figure 2-5, on page 16 shows a list of clinical procedures that can be tagged to files.

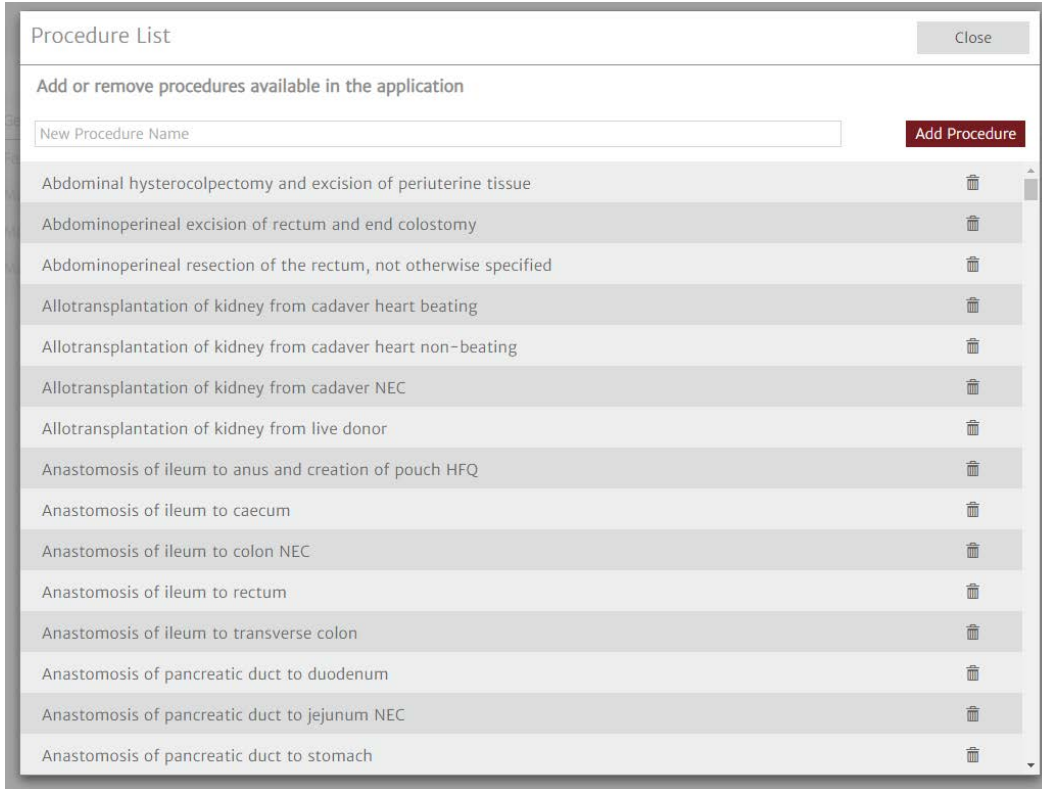


Figure 2-5 : Procedure list

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.

Figure 2-6 on page 17 shows a list of clinicians that can be tagged to files.

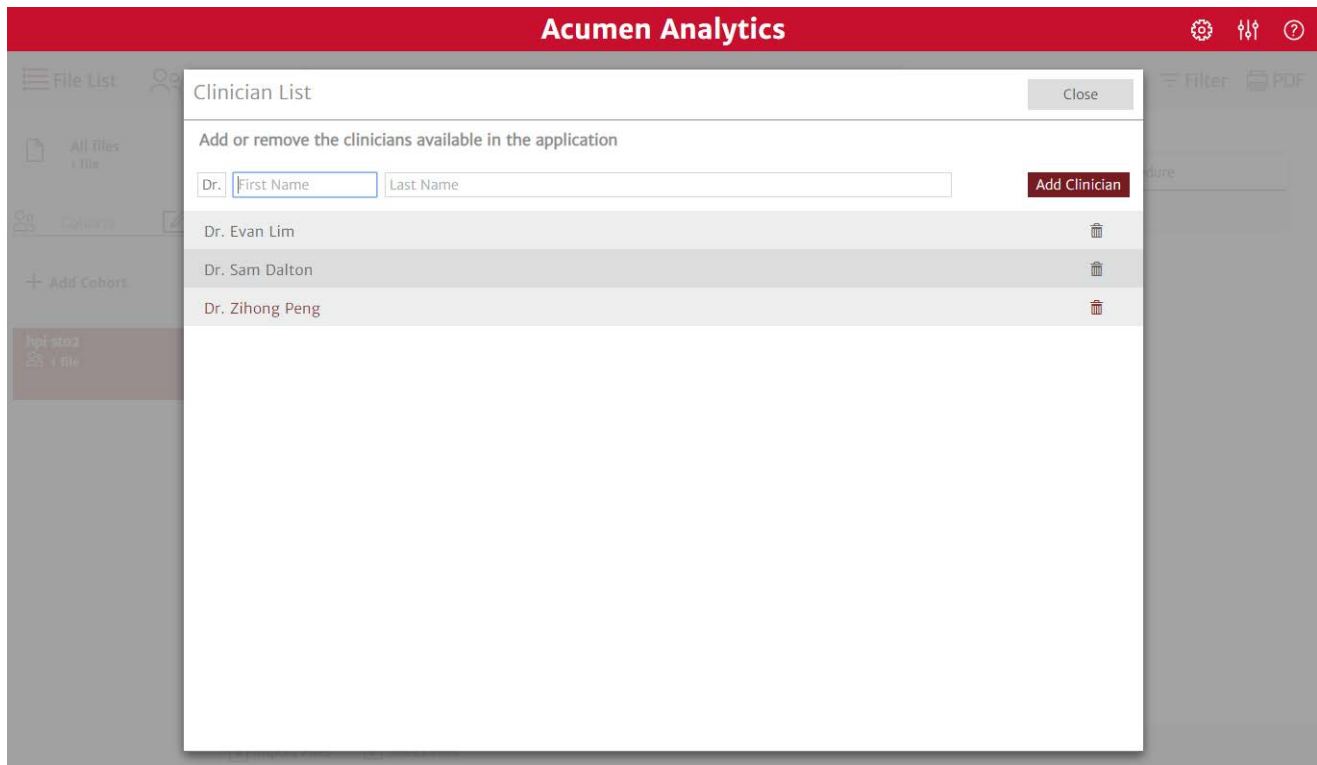


Figure 2-6 : Clinician list

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 menu option 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.

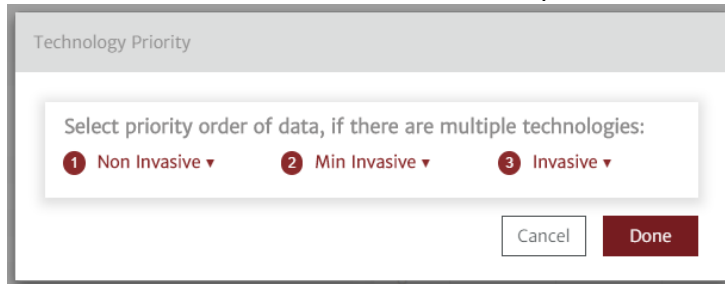


Figure 2-7 : Technology priority

2.3.6 Non-Pulsatile Mode

Clicking the Non-Pulsatile Mode menu option opens the Non-Pulsatile Mode pop-up. In this window, the user is given the option to include or exclude MAP, SYS, and DIA parameter data collected during non-pulsatile mode from all statistical calculations and graphs for all HemoSphere and HemoSphere Alta files.

NOTE For the Acumen Analytics 3.1 software, this pop-up is only available in English.

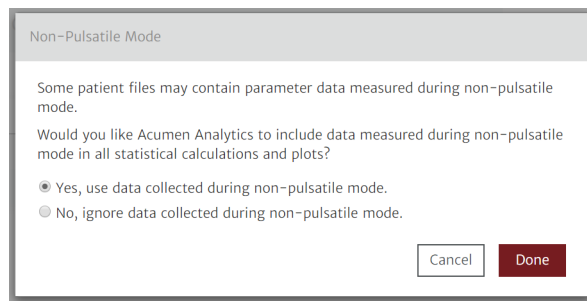


Figure 2-8 : Non-Pulsatile Mode

2.4 User Preferences



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

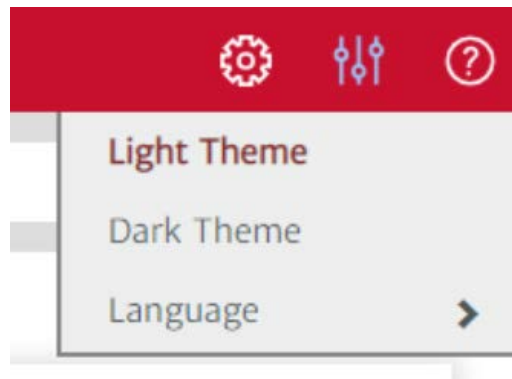


Figure 2-9 : User preferences drop-down menu options

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.

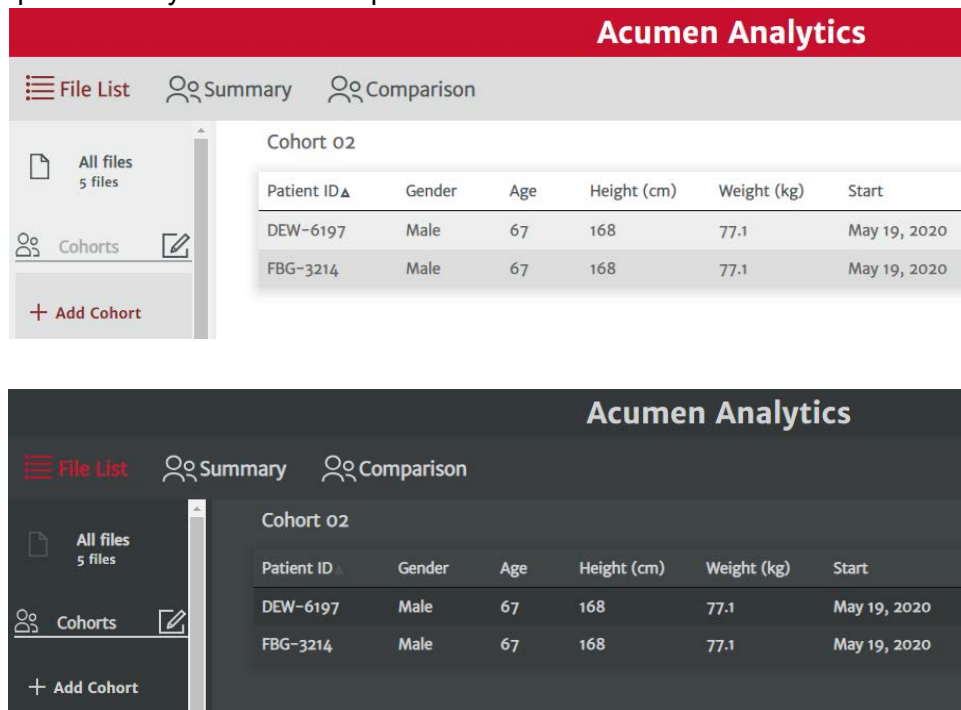


Figure 2-10 Light and dark theme colors

2.4.2 Language

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

2.5 Help

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

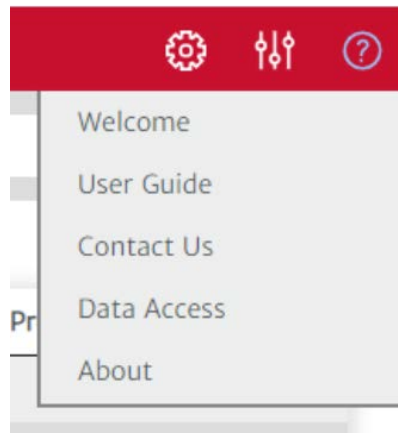


Figure 2-11 : Help drop-down menu options

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 of your Acumen Analytics software and legal licensing information.

Chapter 3

Importing and Organizing Files

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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.

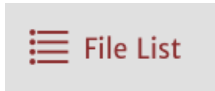
3.1 Importing Files

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 HemoSphere files can be stored in Acumen Analytics software.
- A maximum of 50 10 MB files can be imported at one time.
- A maximum of 50 HemoSphere Alta files (24 hours of monitoring data) can be stored in Acumen Analytics software.
- A maximum of 25 cohorts can be created at one time.
- Supported Excel files contain data points at 20-second time intervals.
- 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.



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

Importing EV1000_1.9_IA_GDT_CUFF_ENGLISH.xls

Description	
Patient ID	XLG-4853
Gender	Male
Age	25
Weight	88.9 kg / 196 lbs
Height	170 cm / 67 in
BSA	2.00 m ²
Start	Mar 17, 2020, 1:52:30 PM
End	Mar 17, 2020, 2:19:10 PM

Add to Cohort

There are no cohorts available.

Print PDF Report

- Case
- GDT

Add Details

Select Clinician

Select Procedure

Comment

Figure 3-1 : Single file import pop-up window

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:

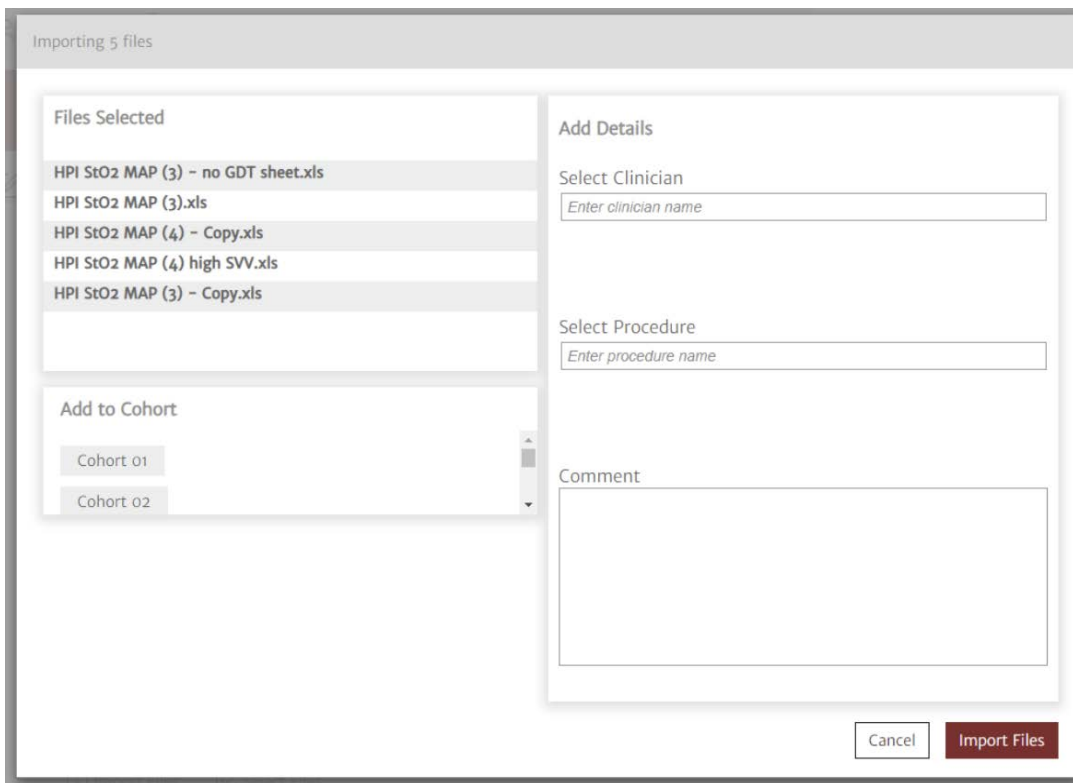


Figure 3-2 : Multiple file import pop-up window



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

The screenshot shows the Acumen Analytics File List screen. The interface includes a red header with the application name and navigation icons. Below the header is a toolbar with tabs for 'File List', 'Summary', and 'Comparison', a search bar, and buttons for 'Filter' and 'PDF'. A sidebar on the left lists 'All files (9 files)' and five cohorts. The main area displays a table of patient data with columns for Patient ID, Gender, Age, Height (cm), Weight (kg), Start, Clinician, and Procedure. The row for Patient ID QTY-1674 is highlighted in red. At the bottom, there are 'Import Files' and 'Select Files' buttons.

Patient ID	Gender	Age	Height (cm)	Weight (kg)	Start	Clinician	Procedure
AGD-7516	Male	25	173	86.2	Mar 18, 2020		
AJO-1945	Male	25	191	72.6	Jan 15, 2020		
CUE-2567	Male	25	173	86.2	Mar 17, 2020		
KED-8472	Male	25	191	72.6	Jan 27, 2020		
NQE-5321	Male	67	168	77.1	May 19, 2020		
QTY-1674	Male	25	191	72.6	Jan 27, 2020		
UBA-2759	Male	25	170	88.9	Mar 17, 2020		
URQ-1459	Male	25	173	86.2	Mar 18, 2020		
YJD-2154	Male	67	168	77.1	May 19, 2020		

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

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

Import Files



Click the **Import Files** icon to import additional data files. See “Importing Files”.

Select Files



Click the **Select Files** icon to select multiple files for cohort editing. See “Organizing Cohorts”.

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 on page 26.

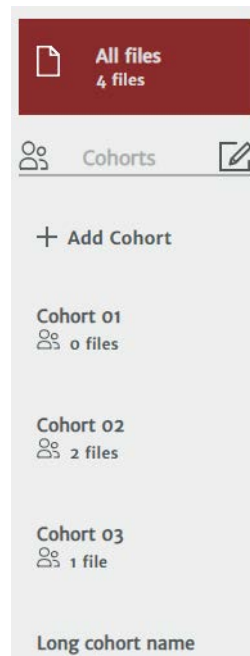


Figure 3-4 : Select files screen

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



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



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

Click **Done** to exit the select file screen.

Chapter 4

Individual File Analysis

Contents

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4.1 Navigation and Toolbars

The user can enter individual file analysis by clicking into a file listed in the file list screen. After clicking on a file on the file list screen (see Figure 4-1 on page 27), the individual file screen appears (see Figure 4-2 on page 28).

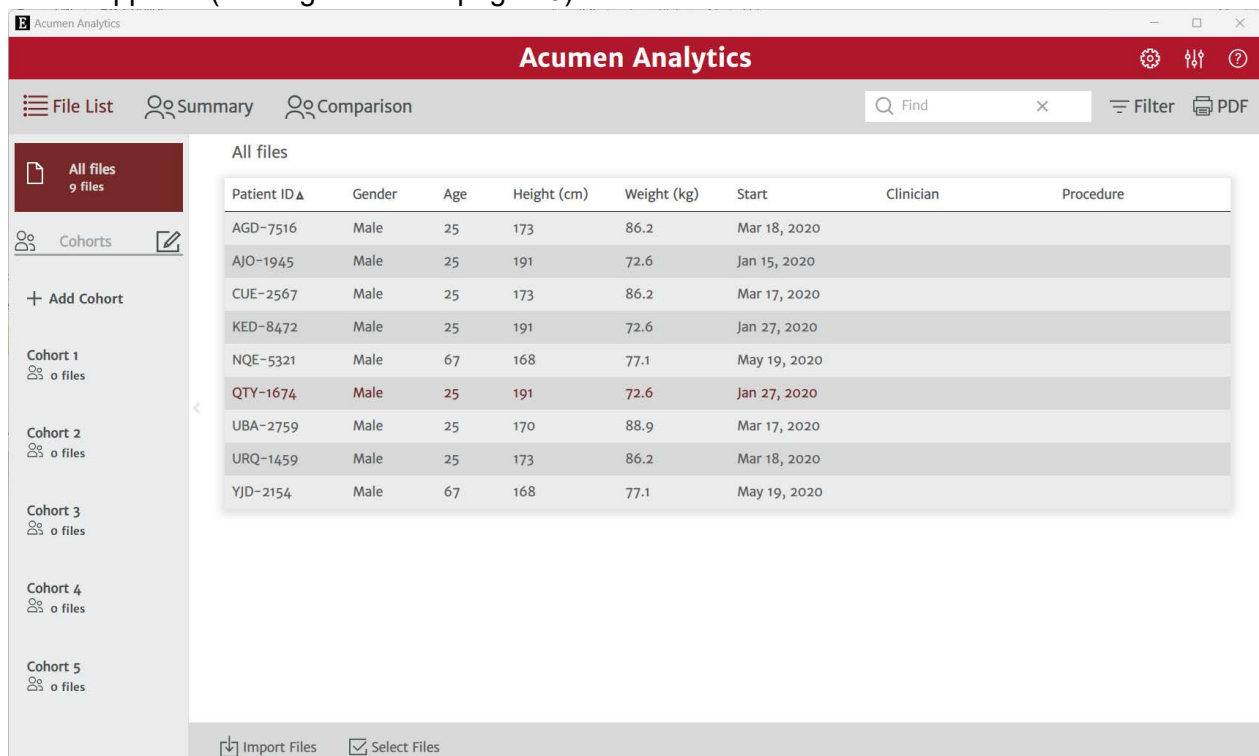


Figure 4-1 : File list screen

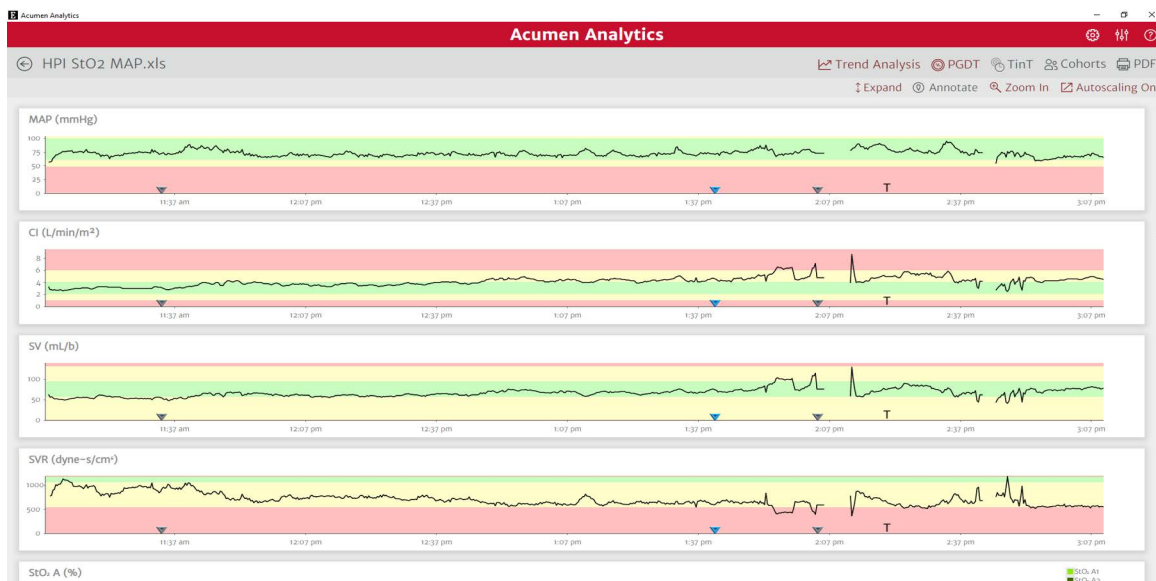


Figure 4-2 : Individual file screen

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:



Figure 4-3 : Individual file screen primary toolbar

The Primary toolbar contains the following features and functions:



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



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



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



While viewing an individual patient file, click on the **Back** icon 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:



Figure 4-4 : Individual file screen secondary toolbar

From the toolbar you can create reports, export or delete a file. See Exporting and Saving Data for more information.

4.2 Trend Analysis Tab



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.

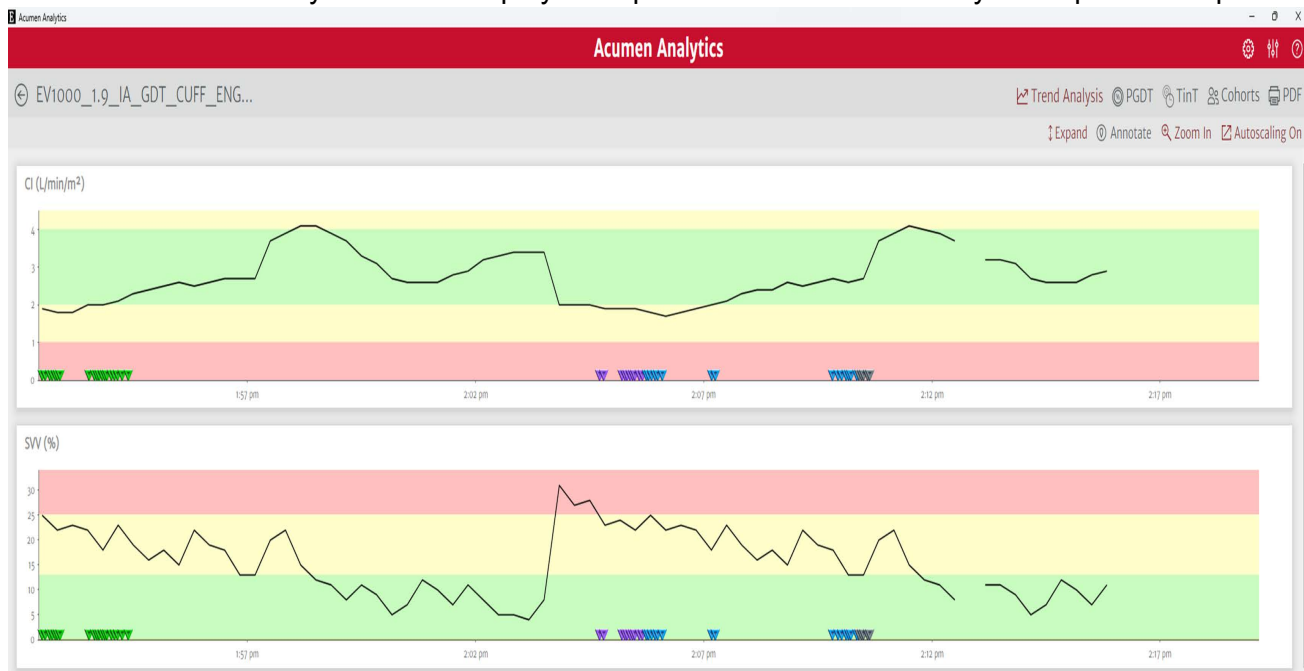





Figure 4-5 : Trend analysis screen

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)

- Ea_{dyn} (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_2 A1 and A2 parameters are plotted together on the same StO_2 A plot, and StO_2 B1 and B2 parameters are plotted together on the same StO_2 B plot. Ea_{dyn} does not contain any background shading. The trend analysis screen has the following features:

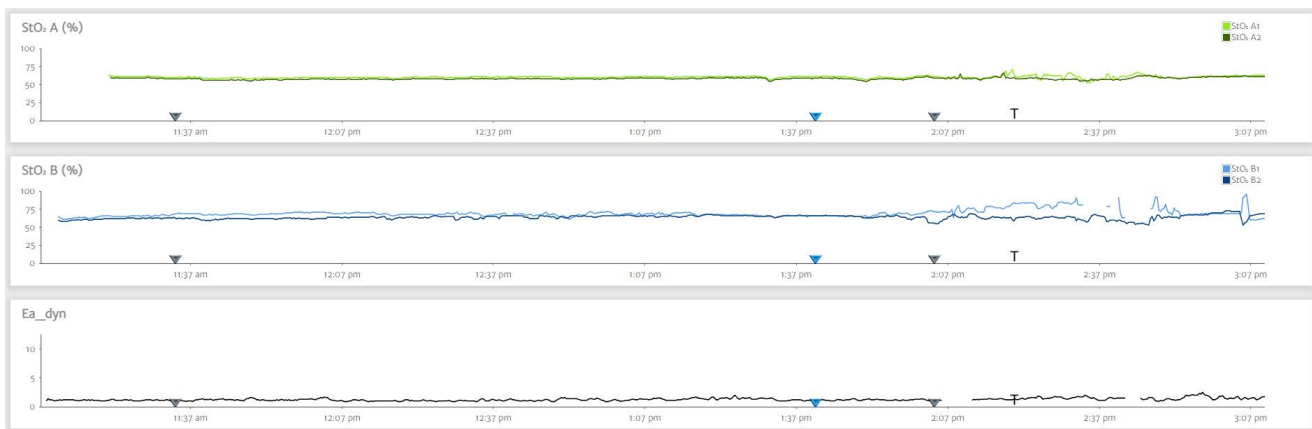


Figure 4-6 : StO_2 A, StO_2 B, and Ea_{dyn} trend analysis plots

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.



Figure 4-7 : Trend analysis toolbar (default view)

When a graph is zoomed in using the **Zoom In** icon, the trend analysis toolbar becomes the following:



Figure 4-8 : Trend analysis toolbar (expanded view)

Collapse/Expand



The **Collapse** and **Expand** icons allow users to toggle between viewing four or two 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** icon 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



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

A screenshot of a 'Description' tile from a software interface. The tile has a light gray border and a white background. It contains a table with patient demographic and session data.

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

Figure 4-9 : 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

4.3.2 Add Details Tile

Figure 4-10 : 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. Chapter 2.

4.3.3 Event Review Tile

Event Review		
05/19/2020	11:07:01 am	Tissue Oximetry: StO: A1 Sensor Location: Left Brain
05/19/2020	11:07:01 am	Tissue Oximetry: StO: A2 Sensor Location: Right Brain
05/19/2020	11:07:01 am	Tissue Oximetry: StO: B1 Sensor Location: Left Calf
05/19/2020	11:07:01 am	Tissue Oximetry: StO: 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: StO: A1/A2 Averaging: Normal
05/19/2020	11:07:01 am	Tissue Oximetry: StO: 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: B1/B2 Averaging: Normal

Figure 4-11 : 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

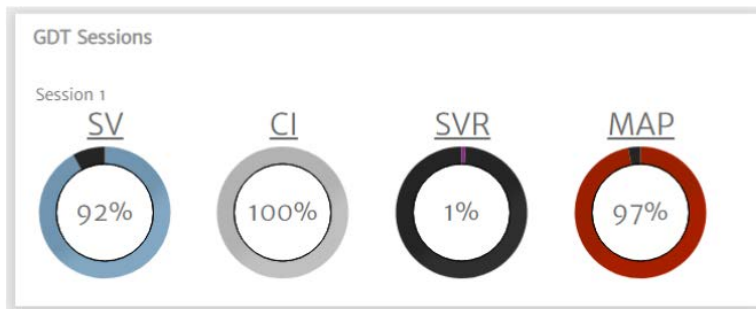


Figure 4-12 : GDT Sessions tile

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



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

A GDT Target pop-up 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.

The GDT Target pop-up window allows users to modify the GDT session.

The figure shows a 'GDT Target' pop-up window titled 'Modify GDT Session 1 - SV (mL/b)'. It contains a table with the following data:

Start Time	End Time	Original	Current
05/19/2020 11:22:21 am	05/19/2020 3:10:23 pm	≥ 56	≥ 56

At the bottom right of the window are 'Cancel' and 'Done' buttons.

Figure 4-13 : GDT Target pop-up window

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.

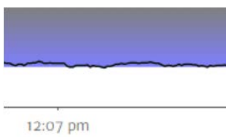
Scroll down to view trend data for all parameters.



Figure 4-14 : Trends tile in the PGDT tab

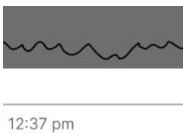
Parameter values are plotted as a solid line. Background shading indicates the presence of a GDT session for that specific parameter. There are 3 colors of background shading that could be shown:

Blue



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

Grey



Gray background shading indicates a paused GDT session for the parameter.

Turquoise



12:07 pm

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

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 drop-down appears listing all the TinT parameters. The user can choose which TinT parameter they would like to have displayed.

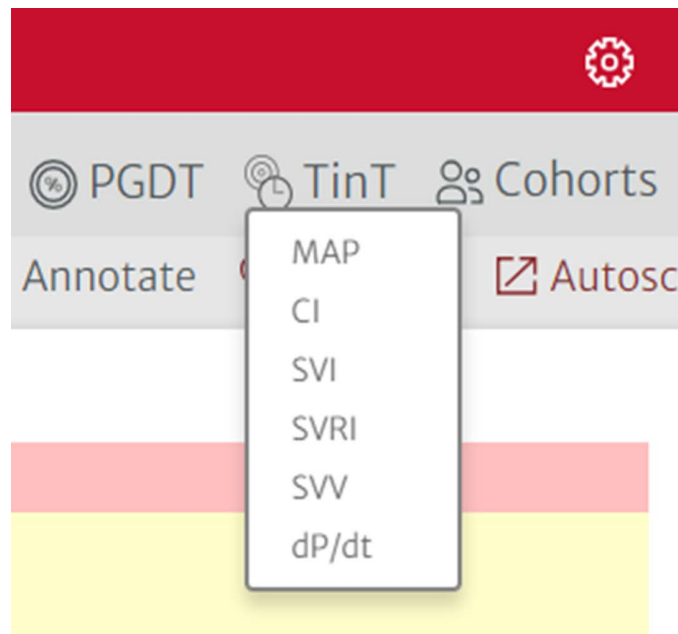


Figure 4-15 TinT parameter drop-down

Once a selection is made, the individual file TinT screen for the parameter chosen will appear. Figure 4-16 on page 39 shows SVI parameter as an example.

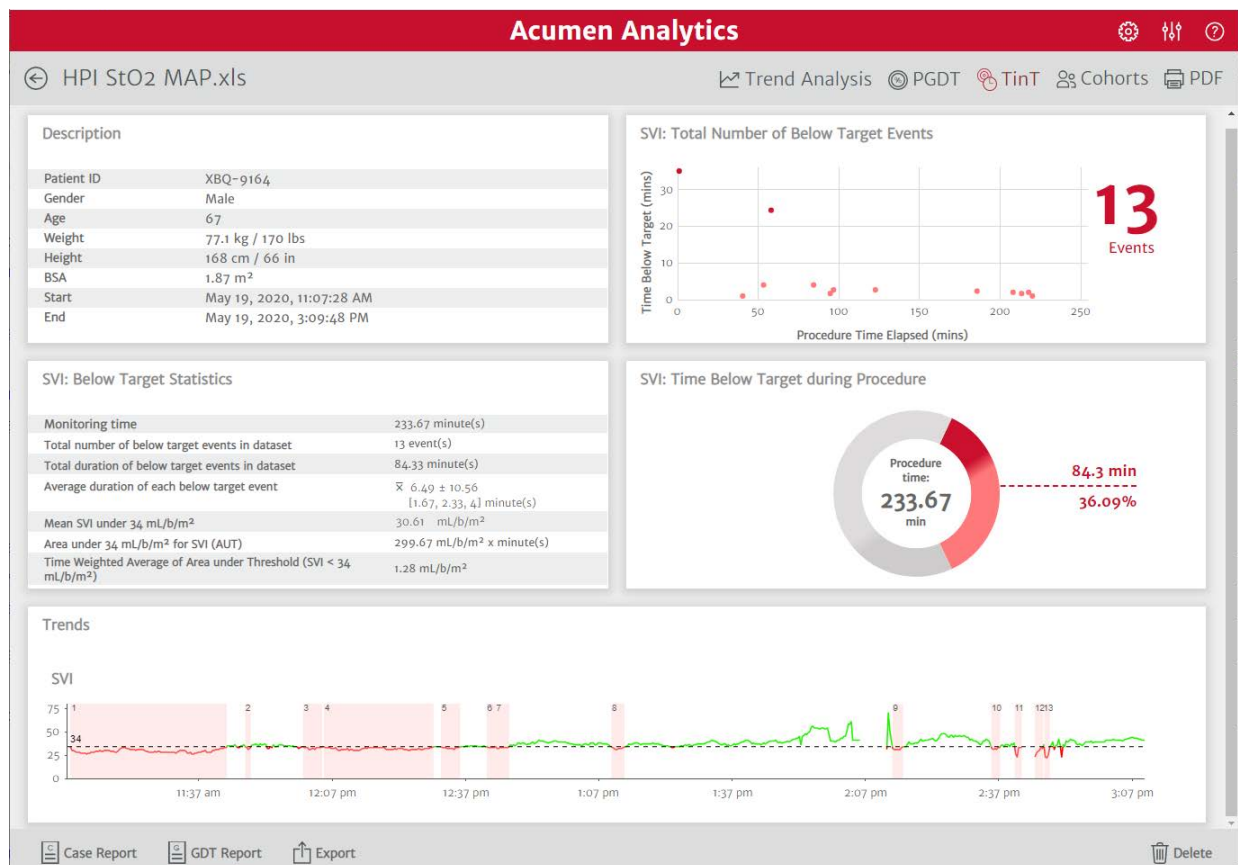


Figure 4-16 Individual file TinT screen

4.4.1 Description Tile

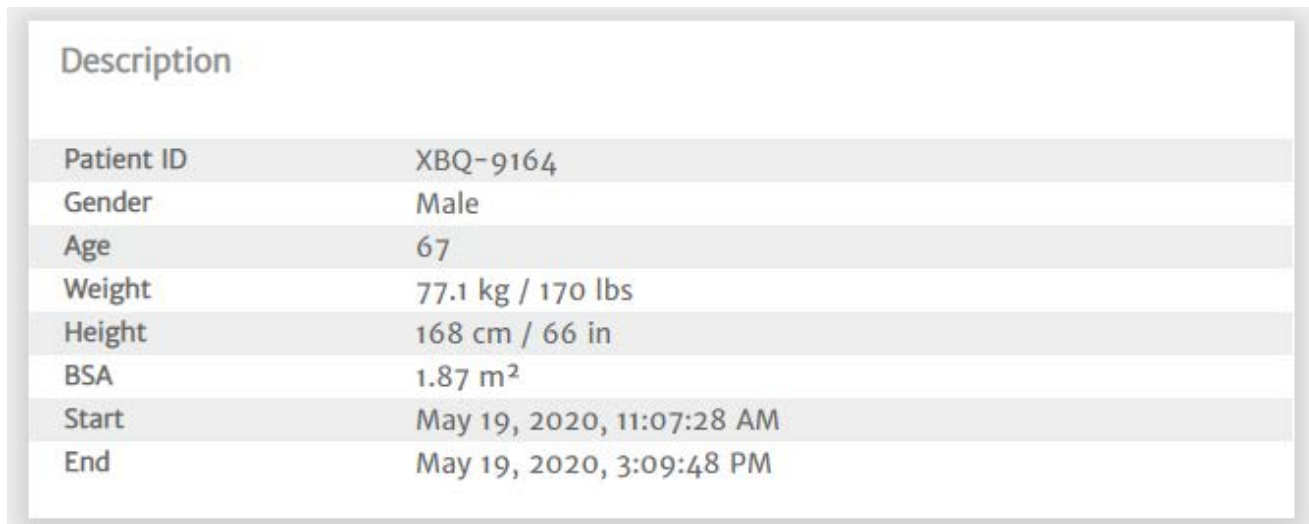


Figure 4-17 : Description tile

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.

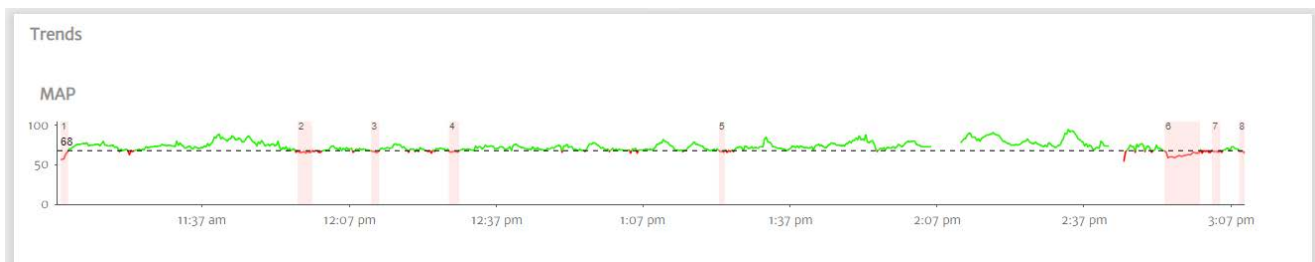


Figure 4-18 : TinT MAP trends tile

Threshold value of 68 is shown in Figure 4-18 on page 40 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.

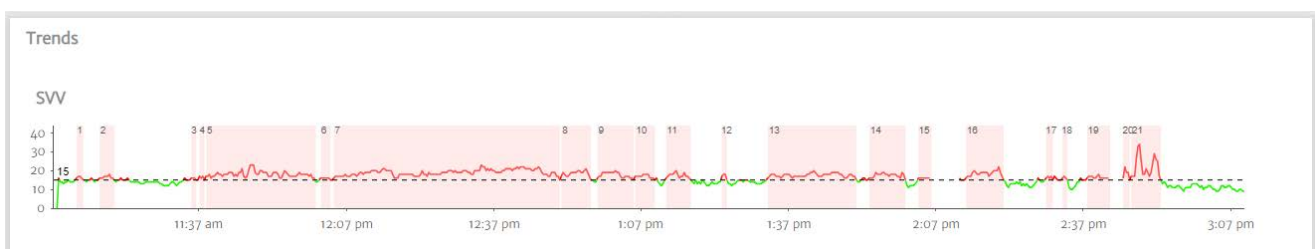


Figure 4-19 : TinT SVV trends tile

Threshold value of 15 is shown in Figure 4-19 on page 40 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

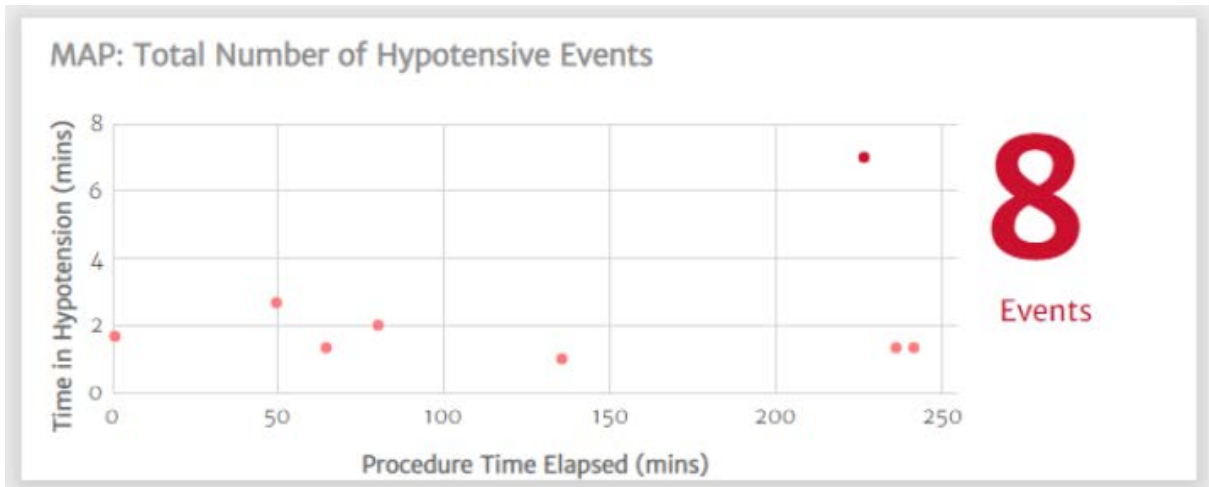


Figure 4-20 : Events scatter plot

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.

4.4.4 Statistics Table

Monitoring time	233.67 minute(s)
Total number of hypotensive events in dataset	8 event(s)
Total duration of hypotensive events in dataset	18.33 minute(s)
Average duration of each hypotensive event	\bar{x} 2.29 ± 1.97 [1.33, 1.5, 2.33] minute(s)
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	0 event(s)

Figure 4-21 : 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.

Table 4-1 TinT individual file statistics table rows

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	Mean value of all MAP values less than the threshold
Area under <Threshold> mmHg for MAP (AUT)	Area of the MAP curve under the threshold value
Time Weighted Average of Area under Threshold (MAP < <Threshold> mmHg) per patient	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

4.4.5 Donut Chart

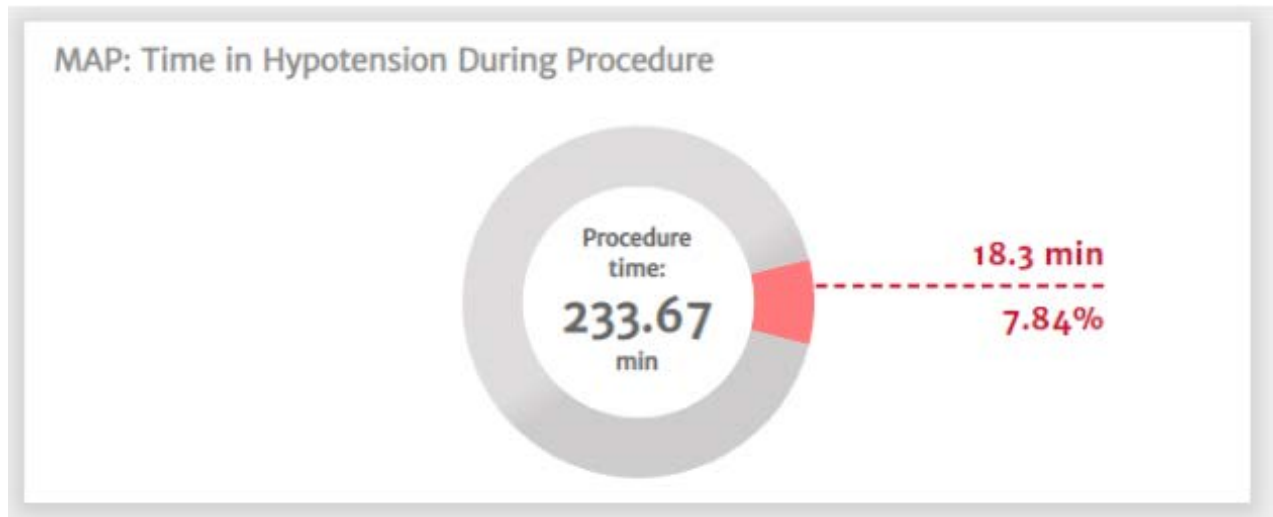


Figure 4-22 : Donut Chart

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

Contents

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Cohort Summary	55
Cohort Comparison	60

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.

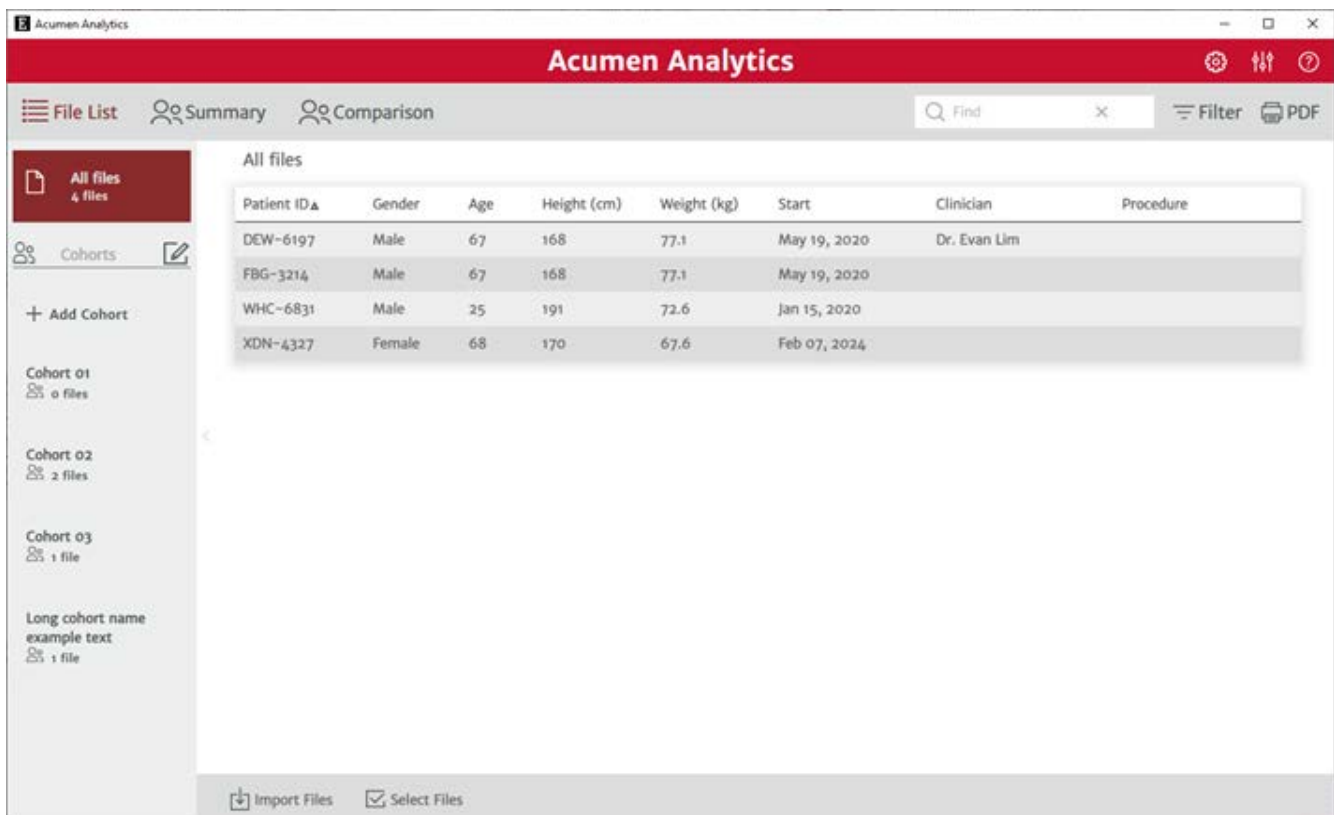


Figure 5-1 : Home Screen

The cohort summary or comparison screen appears as shown in Figure 5-2 on page 45.

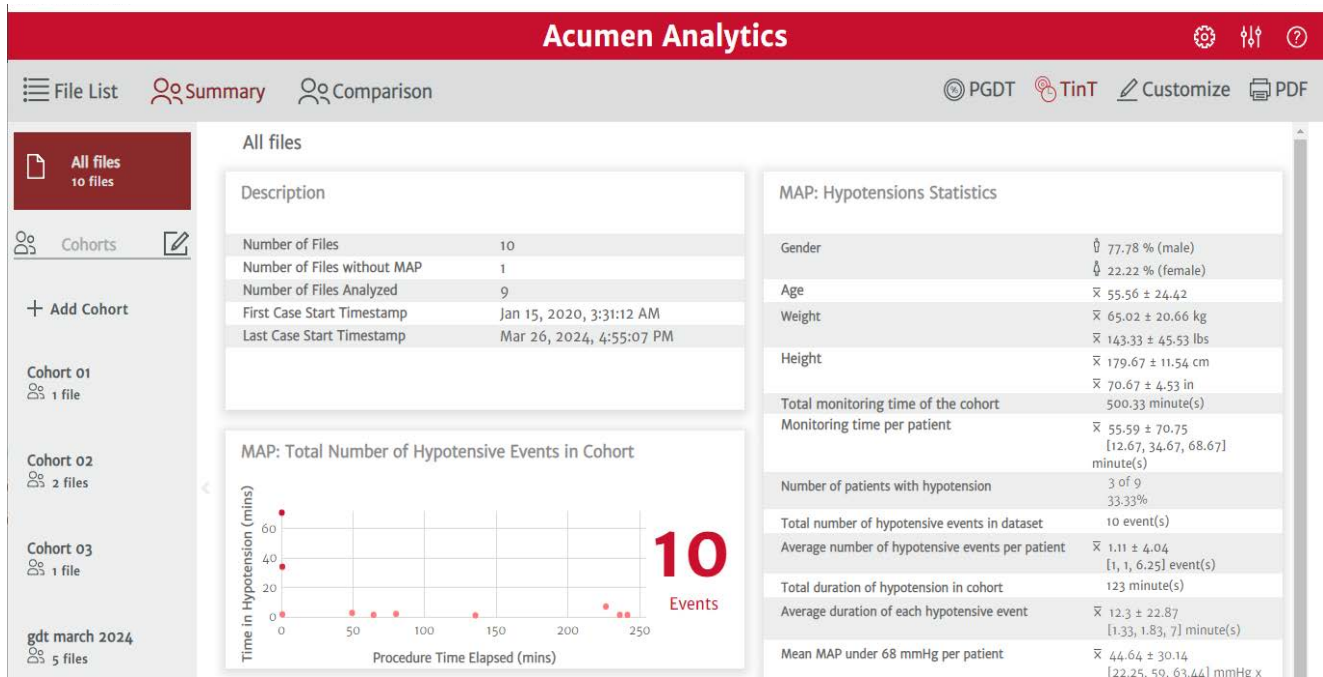


Figure 5-2 : Cohort summary screen

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 two 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:



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** tab to return to the main Acumen Analytics software screen.



Click on the **Summary** icon to enter cohort summary mode.



Click on the **Cohort Comparison** icon to enter cohort comparison mode.



View the PGDT data in full screen 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.



Customize which tiles are visible on the screen.



Click the **PDF** icon to generate a printed 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 “Organizing Files” on page 24 for more information on creating and managing cohorts.

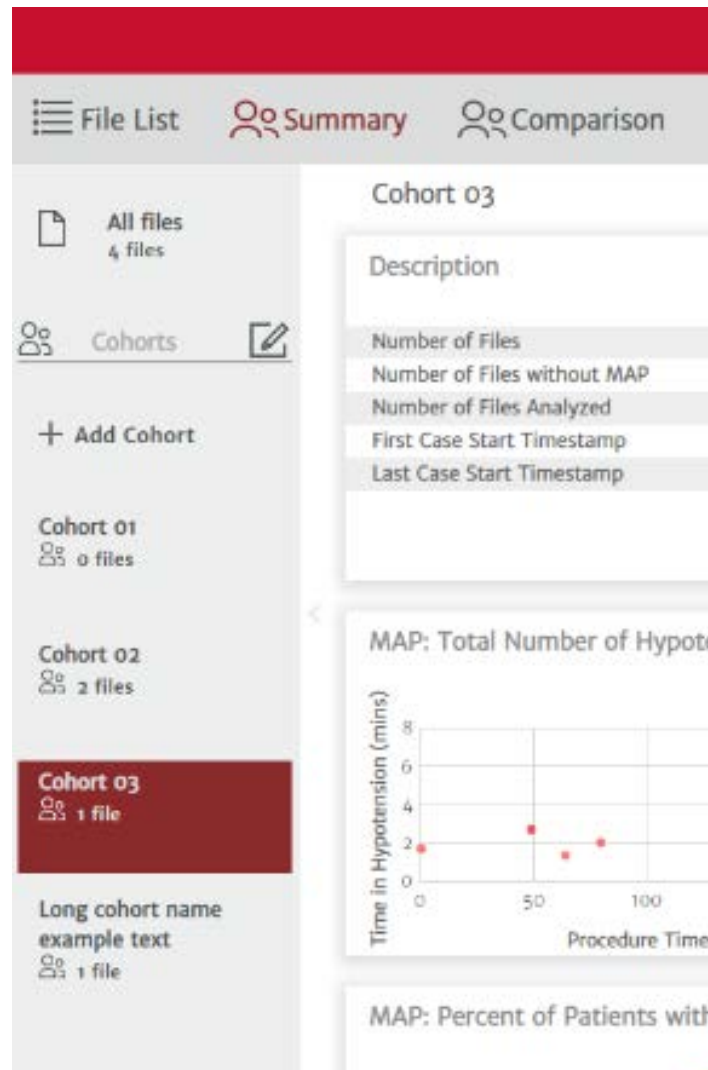


Figure 5-4 : Cohort summary sidebar

Figure 5-4 on page 47 displays cohort summary mode. Select any of the available cohorts from the sidebar to view them on the cohort summary screen.

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.

When an option is selected, the button is highlighted and its corresponding tile will be visible on the cohort summary or comparison screen.

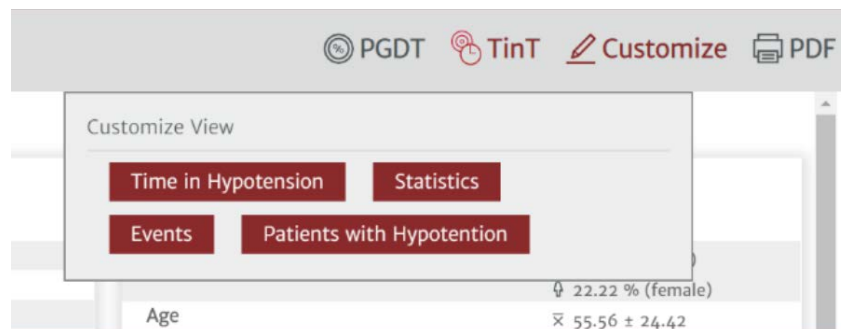
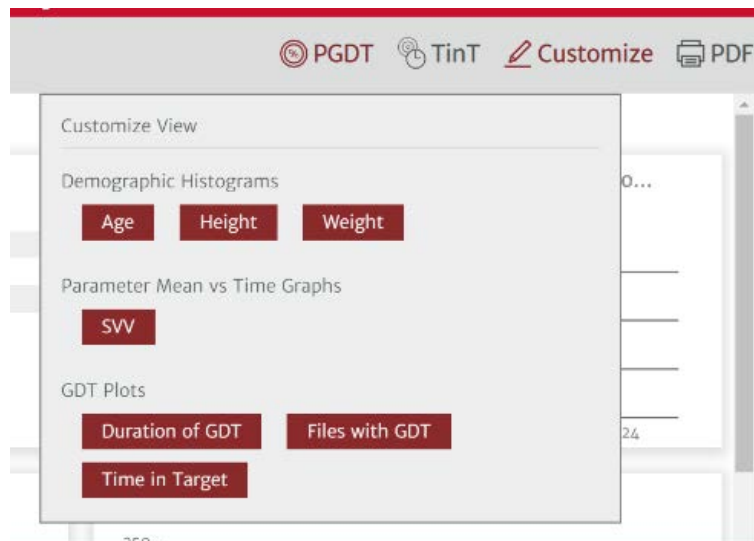


Figure 5-5 : Customize view for PGDT (top) and TinT data (bottom)

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



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

Within cohort summary mode, the user can view PGDT or TinT data and 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



Clicking the **PGDT** icon while in cohort summary mode will open the PGDT cohort summary screen.

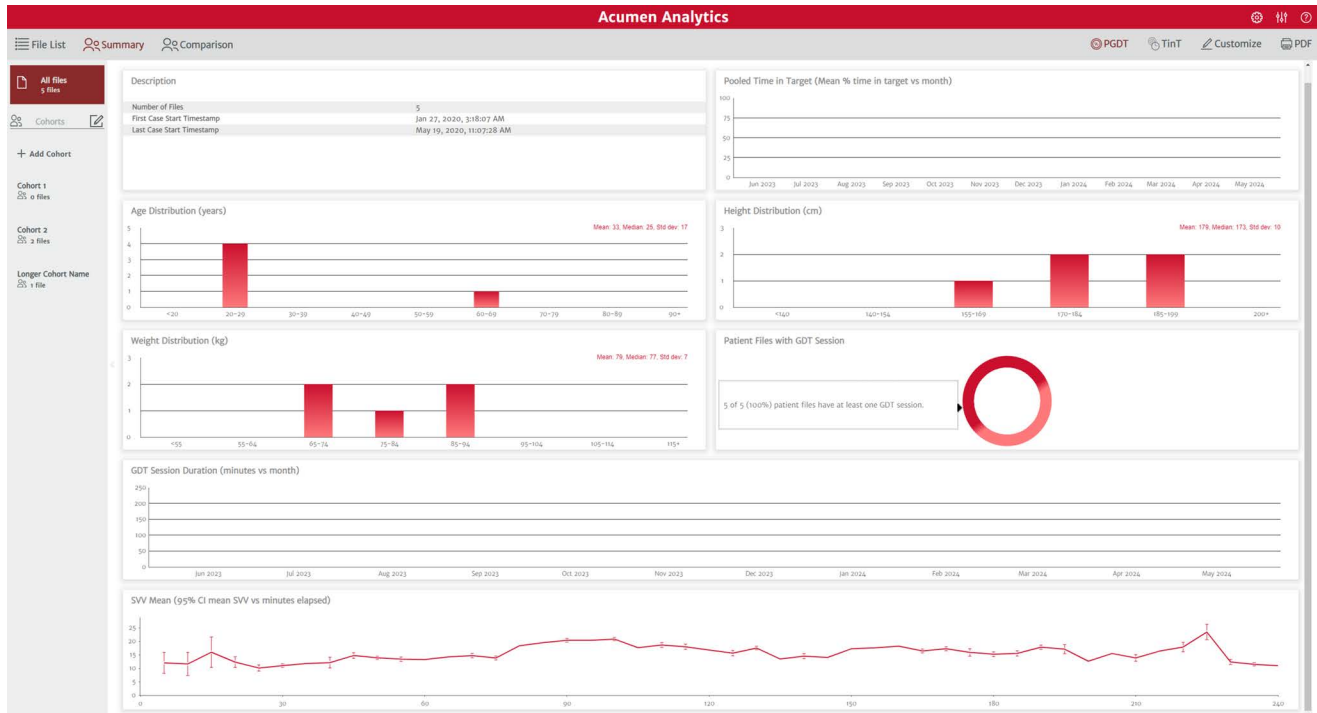
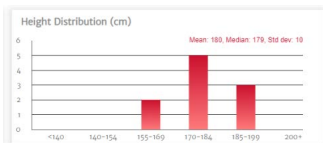


Figure 5-6 : PGDT cohort summary screen

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.

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.

Patient Files with GDT Session



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

Pooled Time in Target



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.

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.

5.2.2 TinT Cohort Summary



Clicking the TinT icon while in cohort summary mode will open a drop-down menu prompting the user to select a specific TinT parameter to analyze in cohort summary mode. See Figure 4-15 on page 38.

Selecting a specific TinT parameter in the drop-down menu will result in that parameter being displayed in cohort summary mode. MAP parameter data shown in Figure 5-7.

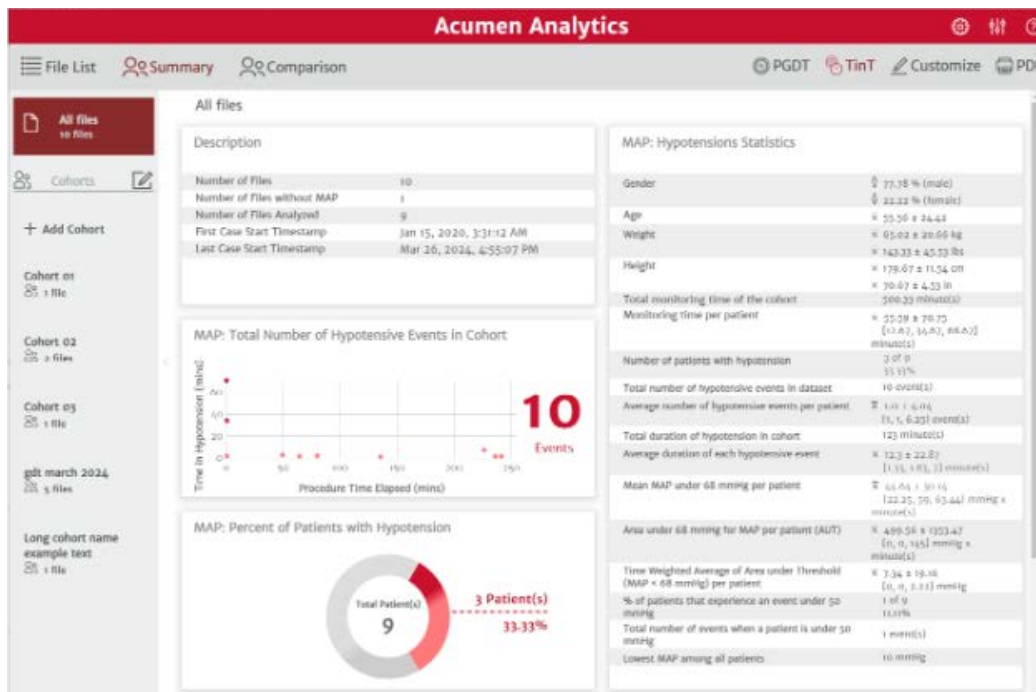


Figure 5-7 : TinT cohort summary screen

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 (three 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 displayed 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.

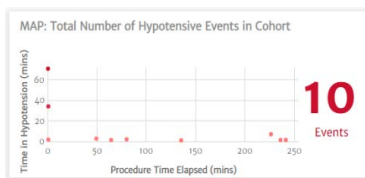
The TinT cohort Summary screen contains several tiles to display out of target event data for each parameter:

Description Tile

Description	
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

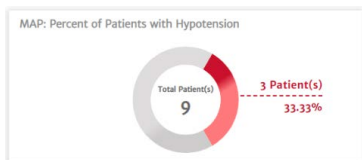
The description tile displays the following: number of files in the cohort, the number of files that do not contain the selected TinT parameter in the cohort, the number of files in the cohort that were analyzed for the selected TinT parameter, the first case start timestamp, and the last case start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

Events Scatter Plot



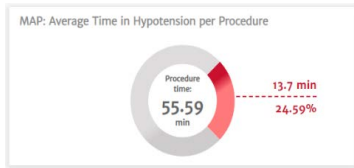
This is a visual representation of the total occurrences of out of target events during a procedure. The Y-axis of the graph demonstrates the length in time of each out of target event, while the X-axis demonstrates the procedure time. Each scatter point indicates an individual out of target event, so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

MAP: Hypotensions Statistics	
Gender	♂ 77.78 % (male) ♀ 22.22 % (female)
Age	55.59 ± 24.12
Weight	65.02 ± 20.66 kg
Height	179.67 ± 11.54 cm 70.67 ± 4.53 in
Total monitoring time of the cohort	300.33 minute(s)
Monitoring time per patient	55.59 ± 20.75 (12.67, 34.67, 68.67) minute(s)
Number of patients with hypotension	3 of 9 33.33%
Total number of hypotensive events in dataset	10 event(s)
Average number of hypotensive events per patient	1.11 ± 4.04 (1, 1, 6.25) event(s)
Total duration of hypotension in cohort	123 minute(s)
Average duration of each hypotensive event	12.3 ± 22.87 (1.33, 1.83, 7) minute(s)
Mean MAP under 68 mmHg per patient	44.04 ± 30.14 (22.25, 59, 63.44) mmHg x minute(s)
Area under 68 mmHg for MAP per patient (AUT)	499.56 ± 1353.47 (0, 0, 143) mmHg x minute(s)
Time Weighted Average of Area under Threshold (MAP < 68 mmHg) per patient	7.34 ± 19.16 (0, 0, 2.21) mmHg
% of patients that experience an event under 50 mmHg	1 of 9 11.11%
Total number of events when a patient is under 50 mmHg	1 event(s)
Lowest MAP among all patients	10 mmHg

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.

Table 5-1 : TinT MAP cohort summary statistics

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

Table 5-1 : TinT MAP cohort summary statistics

Row Name	Numerical value meaning
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	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)	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	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

5.3 Cohort Comparison

The cohort comparison screen displays an overview of patient monitoring data of two cohorts. Clicking the **Comparison** tab 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.

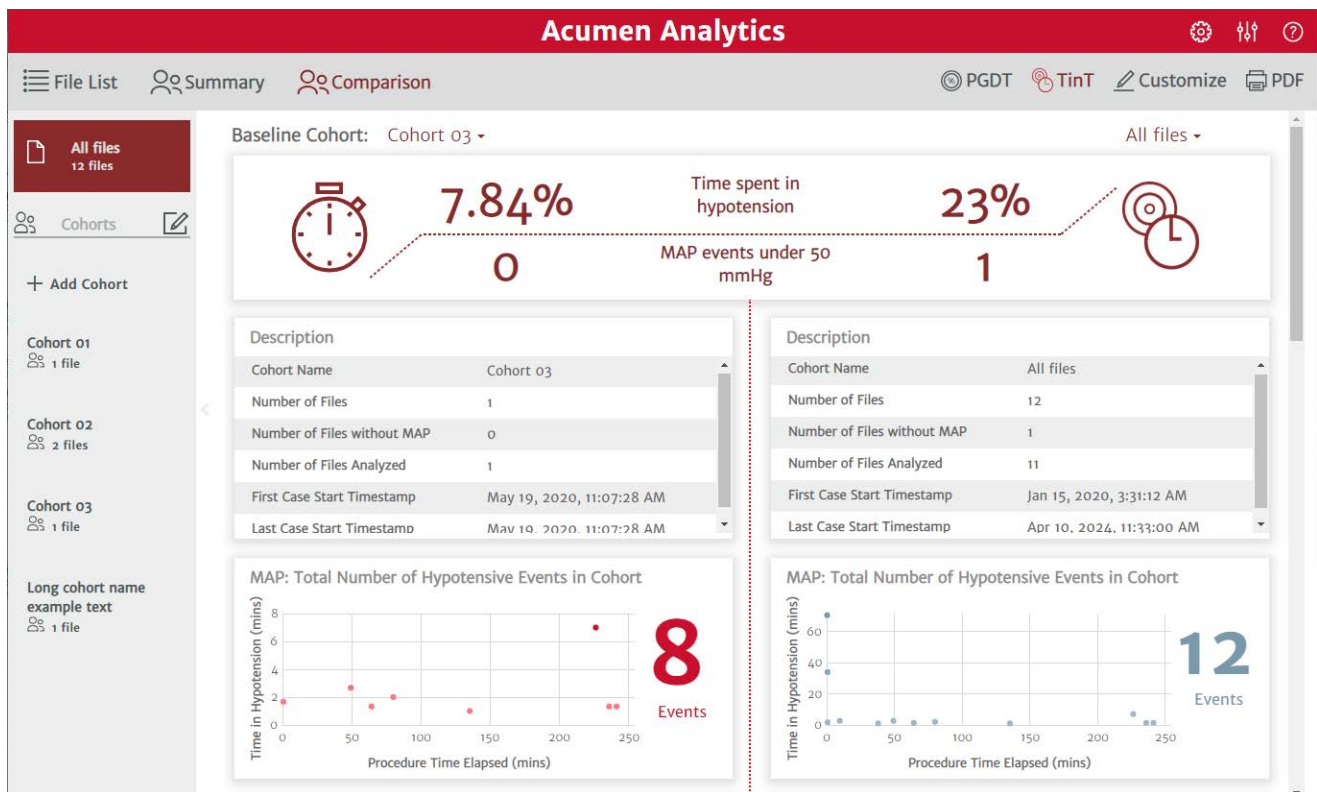
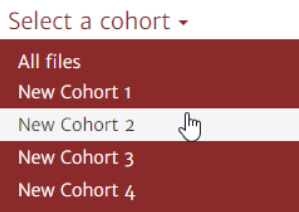


Figure 5-8 : Cohort comparison screen

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.

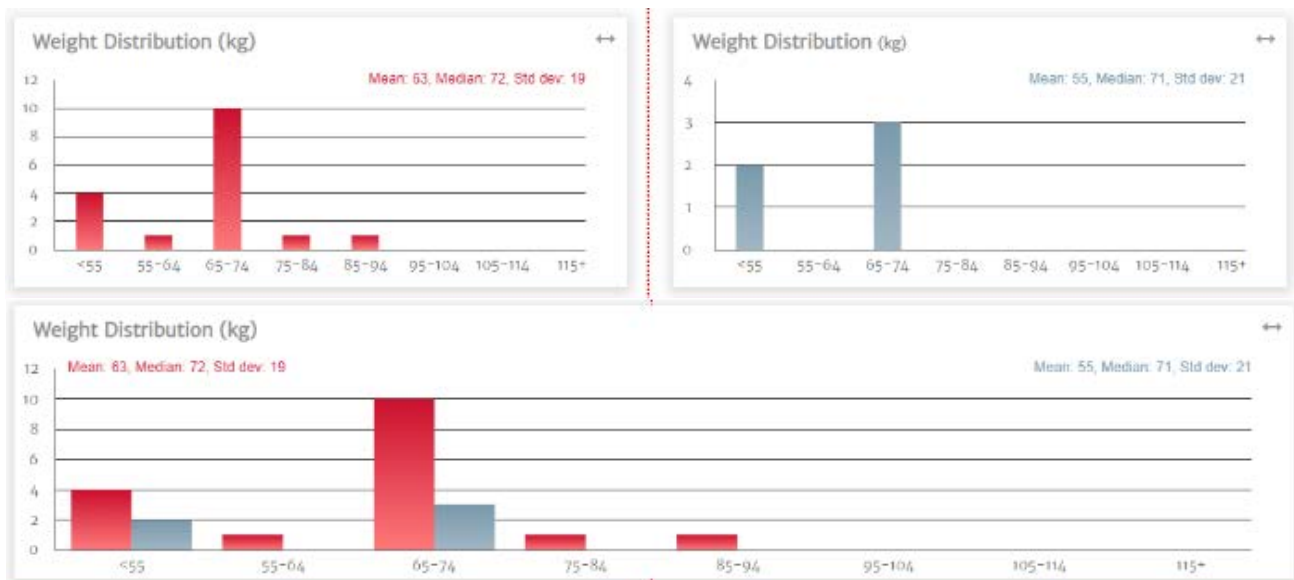


Figure 5-9 : Individual and Combined Graphs

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

5.3.1 PGDT Cohort Comparison



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

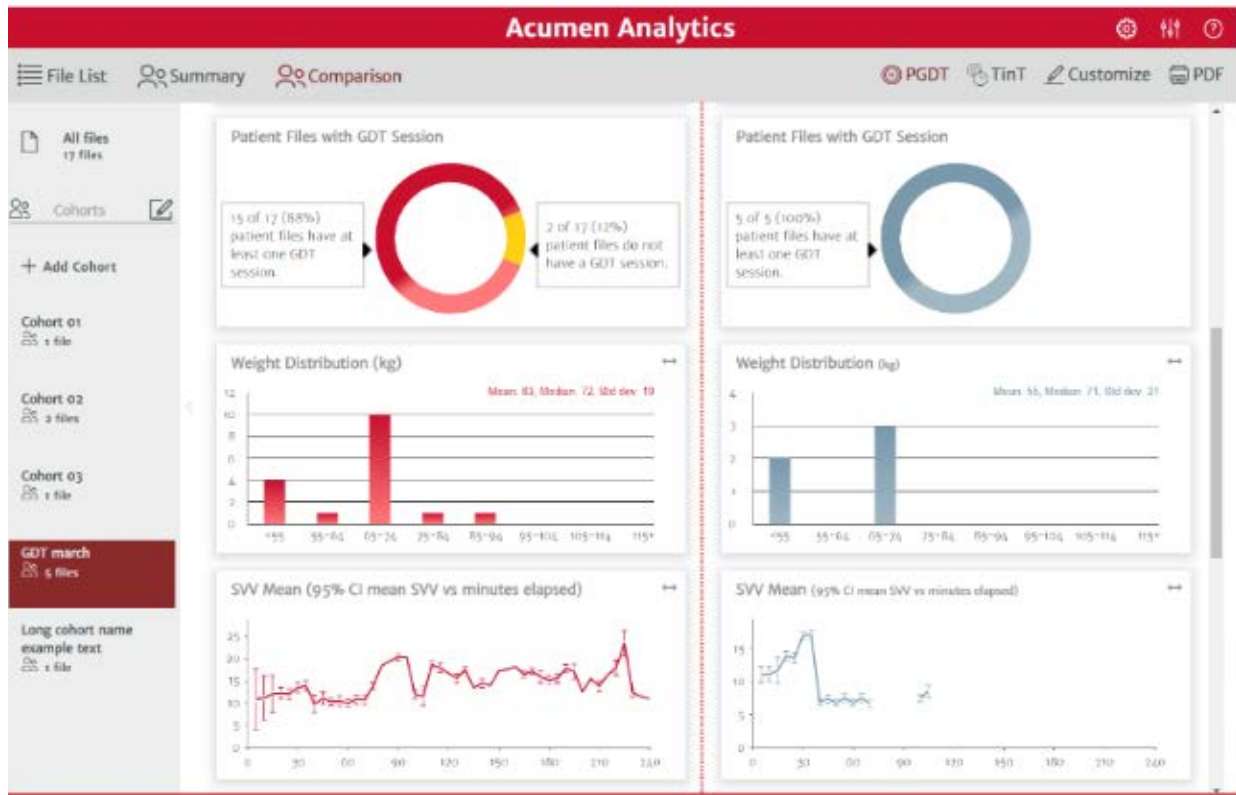


Figure 5-10 : PGDT Cohort comparison screen

All tiles described in “PGDT Cohort Summary” on page 48 are also visible in PGDT Cohort Comparison screen.

5.3.2 TinT Cohort Comparison



Clicking the **TinT** icon while in cohort comparison mode will open a drop-down menu prompting the user to select a specific TinT parameter to analyze in cohort comparison mode. See Figure 4-15 on page 38.

Selecting a specific TinT parameter in the drop-down will result in that parameter being displayed in cohort comparison mode. MAP parameter is shown for two cohorts in Figure 5-11 on page 57.

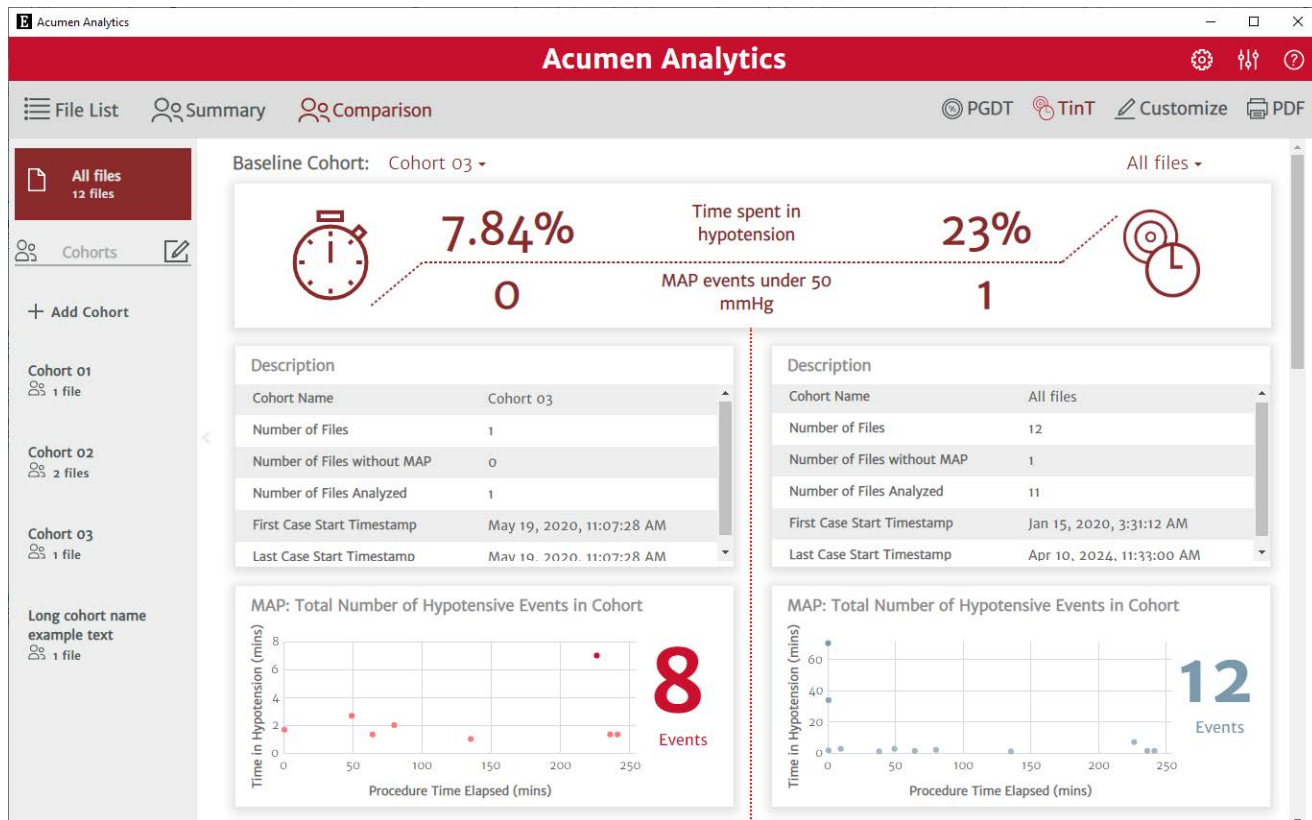


Figure 5-11 : Cohort comparison screen for MAP

The TinT cohort comparison screen will display the following header:

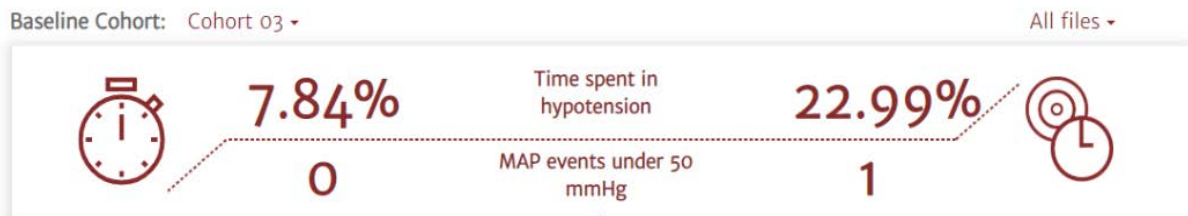


Figure 5-12 : TinT cohort comparison header for MAP

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 “TinT Cohort Summary” on page 50 are also visible in TinT cohort comparison screen.

Chapter 6

Exporting and Saving Data

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6.1 Print to PDF



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

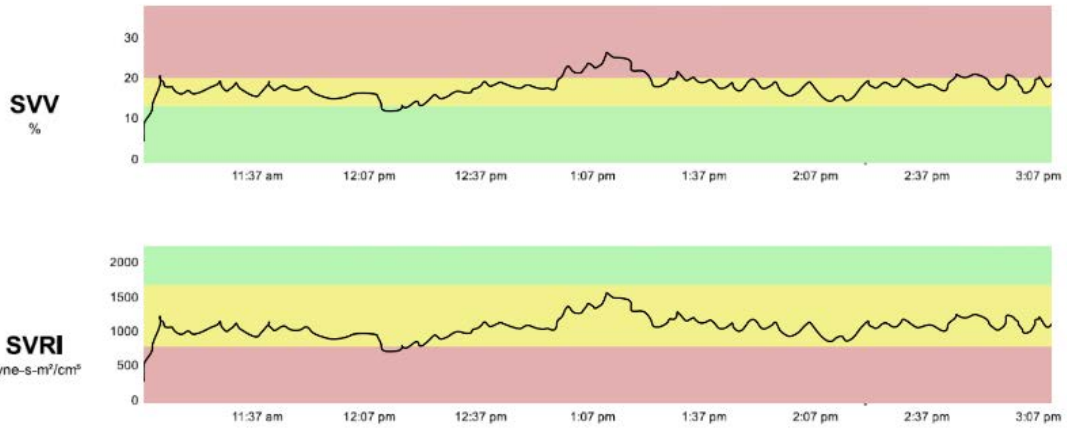
Exported PDFs will list the data in the same order as it appeared on the screen at the time of export. PDFs have a white background and a header listing summary information pertinent to the type of screen displayed at the time.

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)

**Acumen Analytics
Trend Analysis**

Gender	Male	BM/BSA	27.3 kg/m ² / 1.87 m ²
Age	67	Start	May 19, 2020, 11:07:28 AM
Weight	77.1 kg / 170 lbs	End	May 19, 2020, 3:09:48 PM
Height	168 cm / 66 in	Cohorts	New Cohort 2, hpi sto2



HPI SIO2 MAP (1).xls
Page 5 of 9 (CONFIDENTIAL)
Report generated on 04/01/2024 1:18:53 pm

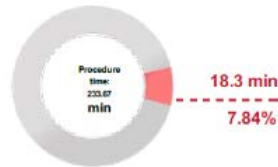


Figure 6-1 : PDF report example - Individual File Trend Analysis

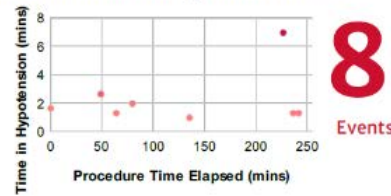
Acumen Analytics
File Overview

Gender	Male	BMI/BSA	27.3 kg/m ² / 1.87 m ²
Age	67	Start	May 19, 2020, 11:07:28 AM
Weight	77.1 kg / 170 lbs	End	May 19, 2020, 3:09:48 PM
Height	168 cm / 66 in	Cohorts	Cohort 03

MAP: Time in Hypotension During Procedure



MAP: Total Number of Hypotensive Events



HPI SIO2 MAP.xls
Page 2 of 4 (CONFIDENTIAL)
Report generated on 04/17/2024 11:32:35 am



Figure 6-2 : PDF report example - Individual File TNT Analysis for MAP

6.2 Exporting GDT Reports



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 pop-up menu will appear. See Figure 6-3 on page 68.
- 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.

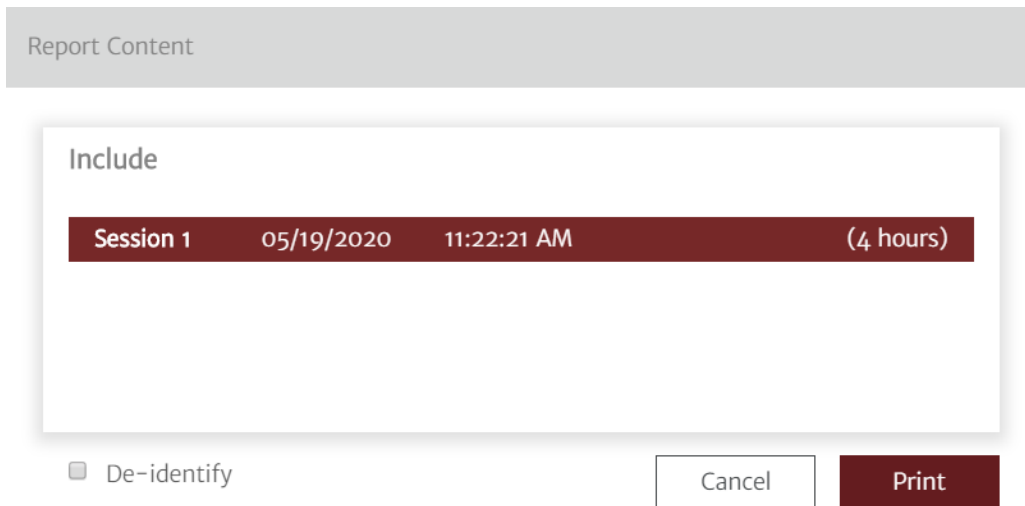


Figure 6-3 : GDT report pop-up menu

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.

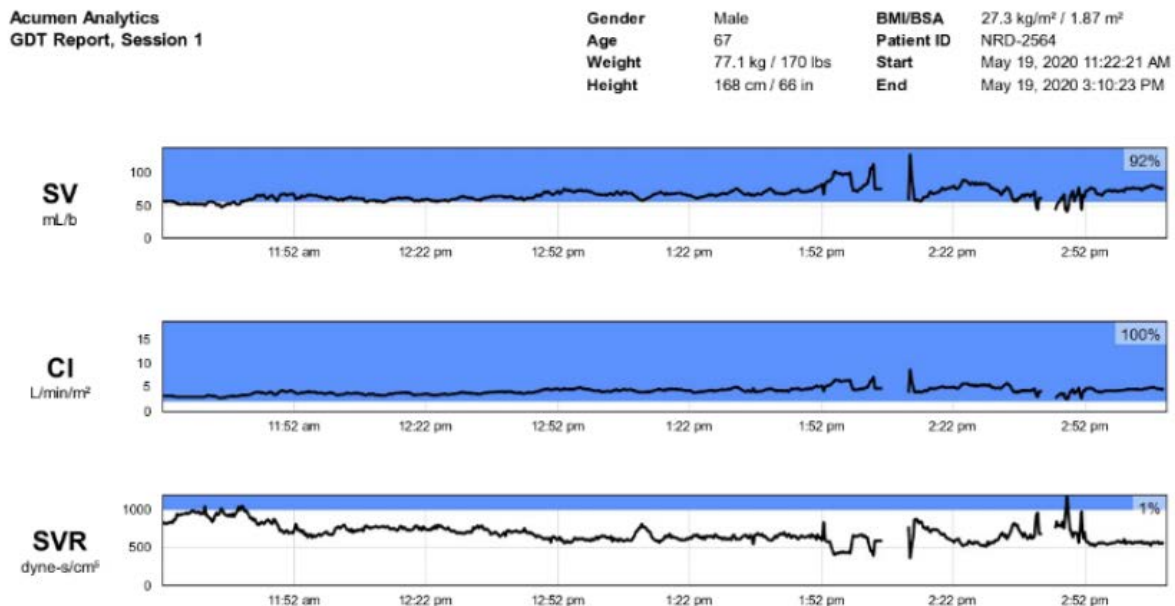


Figure 6-4 : GDT report PDF example

6.3 Exporting Case Reports



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 6-5 on page 69.
- 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.

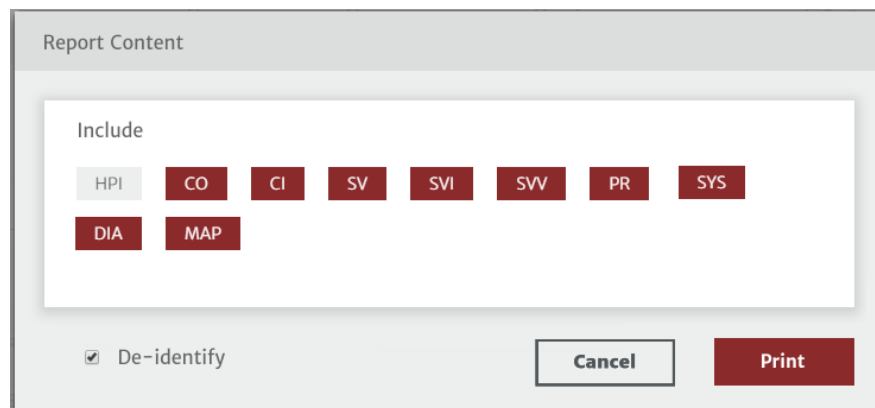


Figure 6-5 : Case report pop-up menu

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 6-6 : 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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