Extubation Advisor

Therapeutic Monitoring Systems Licensed Technology

Version 1

Clinical User Guide

OBS Medical
Data for Life

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Contents

Introduction

This guide contains all the information you need to operate Extubation Advisor (EA).

EA is intended for use by trained medical personnel and assumes prior knowledge of the operation of multi-parameter patient monitors and the various tasks involved in the documenting and reporting of a spontaneous breathing trial (SBT).

The configuration and system administration of EA is detailed in the Administration and Configuration User Guide. ***(Part No. 011-1015-LMAN).***

Extubation Advisor (EA) Overview

Expeditious, safe extubation is vitally important in the care of Intensive Care Unit (ICU) patients as prolonged mechanical ventilation harms patients, and failed extubation (i.e. re-intubation within 48 hours) is associated with increased morbidity, mortality & costs.

Extubation Advisor (EA) is a clinical decision support tool developed to provide prediction of extubation outcomes and standardize the assessment of extubation readiness, to mitigate and prevent extubation failure. It is a tool to assist in the complex decisions made in assessing extubation readiness as part of a spontaneous breathing trial (SBT).

EA produces a respiratory rate variability (RRV) derived predictive model of the risk of extubation failure called the WAVE score which is then delivered via a generated extubation report along with the rapid shallow breathing index (RSBI), clinical impression of extubation failure risk, and a standardized extubation readiness checklist for clinical decision making.

Extubation Advisor can be run multiple times, providing updated SBT performance, prediction of extubation failure reports and clinical assessment, to be used when considering extubation.

This combination of standardized SBT performance and reporting, along with optimal prediction of extubation outcomes aims to minimize extubation failure and enhance care. It does not replace the clinical judgment of a Clinician.

Weaning and Variability Evaluation (WAVE) Score

EA uses respiratory waveforms recorded during an SBT to calculate respiratory rate variability (RRV) metrics and uses a predictive model to provide a probabilistic estimate of the risk of extubation failure (defined as the need for re-intubation within 48 hours after extubation). That risk is called the Weaning and Variability Evaluation (WAVE) score.

Values of the WAVE score closer to zero indicate a lower probability of extubation failure and values closer to one indicate a higher probability of extubation failure. In the EA user interface, the risk estimate from the WAVE score is summarized as low, average or high-risk categories.

Low Risk	Average Risk	High Risk

The low-risk category corresponds to patients who have a risk estimate below the average population risk of 16%. Both average and high-risk categories have a risk estimate above the average population risk, with an incidence of extubation failures higher than 24% for the high-risk group.

Note: The WAVE score is based on respiratory rate variability (RRV) derived from interbreath intervals obtained from capnography waveforms recorded during the SBT; RRV is thought to reflect the patient's capacity to tolerate an increased respiratory workload.

Rapid Shallow Breathing Index (RSBI)

The rapid shallow breathing index (RSBI) has been incorporated into the standardized report generated by EA using the data inputted by the Respiratory Therapist during the SBT.

The RSBI is defined as the ratio of respiratory frequency to tidal volume (f/VT).

- A RSBI score of less than 65 indicating a relatively low respiratory rate compared to tidal volume is generally considered as an indication of weaning readiness.
- A patient with a rapid shallow breathing index (RSBI) of less than 105 has an approximately 80% chance of being successfully extubated, whereas an RSBI of greater than 105 has a high chance of weaning failure.

Low Risk	Average Risk	High Risk
RSBI < 60	**RSBI is between 60 to 110**	**RSBI > 110**

Respiratory Therapist's Clinical Impression

As clinical domain experts intimately involved in the process of assessing patients' readiness for liberation from mechanical ventilation, Respiratory Therapists are uniquely positioned to provide insight into a patient's risk of extubation failure.

As part of the EA clinical workflow, respiratory therapists are asked to provide their best professional assessment of the perceived risk of extubation failure for the patient undergoing an SBT.

- Risk estimates are based on an RT user's clinical judgment and should broadly reflect the following risk categories: higher than average > %20 risk of extubation failure, average 5-20%, lower than average < 5%.
- Our studies showed that the combination of RT's clinical impression combined with the WAVE score offered the best prediction of extubation outcomes.
- The inclusion of RT impression is intended to empower the RT to provide their best professional assessment, as their experience and impressions are valuable yet often inadequately communicated to MDs. EA is intended to enhance RT MD communication.

Lower than Average Risk	Average Risk	Higher than Average Risk
RT perceived risk of extubation failure **less than 5%**	RT perceived risk of extubation failure is between **5 to 20%**	RT perceived risk of extubation failure **greater than 20%**

Note: The RT risk estimates are based on existing clinical literature, and the WAVE risks are based on quartiles of population. Both risk scores will appear different and never align perfectly.

Intended Patient Population

Extubation Advisor (EA) is intended for adult patients on ventilation within the hospital ICU.

Intended Use

The intended Use of the Extubation Advisor software is to provide

- Non-invasive monitoring of breathing rate variation in adult patients receiving mechanical ventilation in the Intensive Care Unit (ICU).
- On demand open-loop advice in mechanically ventilated adult patients regarding risk of extubation failure.

The device is intended for use by trained clinicians. Extubation Advisor is for prescription use only.

Intended Use Environment

Extubation Advisor (EA) is intended to be used within the hospital ICU.

Indications for Use

Extubation Advisor (EA) is to be used on ventilated patients to provide repeatable standardized assessment of extubation readiness, estimate of extubation failure risk, and personalized extubation risk mitigation strategies, all derived from assessment and monitoring during a Spontaneous Breathing Trial (SBT).

Contraindications

Extubation Advisor (EA) is not intended for use in the following situations or patient populations:

- Patients outside of the Intensive Care Unit (ICU).
- Paediatric or Neonatal Patients.
- Patients not ready for a Spontaneous Breathing Trial (SBT).
- Patients with Do-Not-Resuscitate (DNR) or Comfort Care Status.

Safety Information

OBS Medical products are designed to meet stringent safety standards. Users should read and adhere to all Contra-indications, Warnings, Cautions and Notes listed here and in the associated sections throughout this manual.

Do not use EA before reading these instructions

Warnings and Cautions

Warnings:

⚠ EA is a tool to assist in the complex decisions made in assessing extubation readiness of ventilated patients. It does not replace the clinical judgment of a Clinician.

Cautions:

⚠ When connected to a Patient Monitor, the device running EA cannot be connected to mains power.

⚠ When not in use, the device running EA should be kept on charge to ensure it can be used on battery when connected to a Patient Monitor.

⚠ Please note, if you attempt to connect mains power during an SBT recording, all recording data to that point will be lost.

⚠ While WAVE was derived for patients undergoing their first extubation, the physiologic basis for the prediction would be unchanged when assessing readiness for subsequent extubations (if the first extubation failed), and thus can be helpful when assessing a patient's readiness for a second extubation. However, the reasons for failing the first extubation need to be addressed in planning a second extubation vs. tracheostomy.

Data Protection/ Privacy

Clinicians and other users of EA should be aware that, in collecting and recording patient names and data, they are responsible for complying with all applicable data protection and/or privacy law and regulation.

Note: All patient names and data used throughout this guide are fictitious. Images used within this manual are provided for reference purposes only. Screens may differ based on system configuration and available parameters.

Symbols

Symbol	Title	Description
	Manufacturer	Indicates the medical device manufacturer
	Build Date	Indicates the date the Lot / Batch / Software Version was released
	Batch Code	Batch code so the lot or batch can be identified
	Catalogue Number	Catalogue number so product can be identified
	Consult Instructions for Use	Indicates the need for user to refer to instructions for use
	Prescription Use Only (USA only)	Device is prescription use only by a healthcare professional
	Medical Device	Identifies the product as an approved Medical Device
	EU Authorised Rep	OBS Medical Authorised Representative in the EU market

Licensing

EA uses a licensing system that provides copy protection and security and allows registered clinical users to login and use the system as indicated on an activated computer.

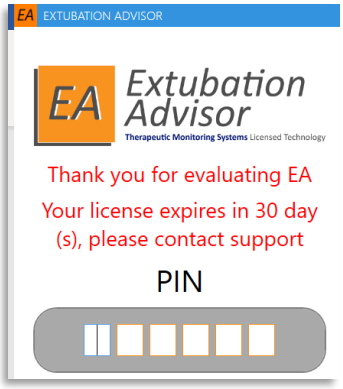
EA comes preinstalled with a 30-day trial license to facilitate set-up and configuration before requiring activation using a license key. The license key is specific to a given computer and cannot be used on any other computer.

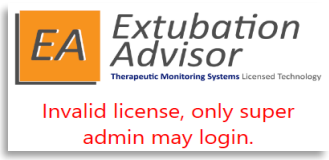
The license key allows the software to be used for the duration purchased and must be updated at each renewal period. It is important to ensure the EA system has enough computers and associated activated licenses to meet the needs of your particular unit size.

If your system admin has not yet activated the software license, clinical users will not be able to login to view the patient roster and document an SBT, after the initial 30-day trial license has expired.

A notification will be displayed in red via the login screen, indicating the number of days remaining for the preinstalled trial license, and again 14 days prior to expiration of an activated license.

After the license has expired, the login screen will show a message indicating the license is invalid. Only Admin users will be able to login to manage the license key and restore the EA Systems full functionality.





Note: Please contact your system admin when receiving a license expiration notification to minimize disruptions and to renew the license key as required for your computer.

Getting Started

Logging In

Depending on your organization's IT security policy, the device or devices running EA will be primarily governed by the local security settings applied.

Once successfully logged into the device, you will then be able to access EA and input your unique PIN code.

Your unique PIN code is defined by you during the creation of a new user account.

1. Start the EA Application.
2. Input your PIN using the device's keyboard.

You should now be able to access the system and its various features as per the User Role assigned to you. If you incorrectly input your PIN code, simply repeat step 2. You can Logout of the system at any time by selecting the logout button, located at the top right of every dashboard.

Note: If you have forgotten your PIN code, you will need to inform your System Administrator to remind you what it is or to set you a new unique PIN.

User Roles

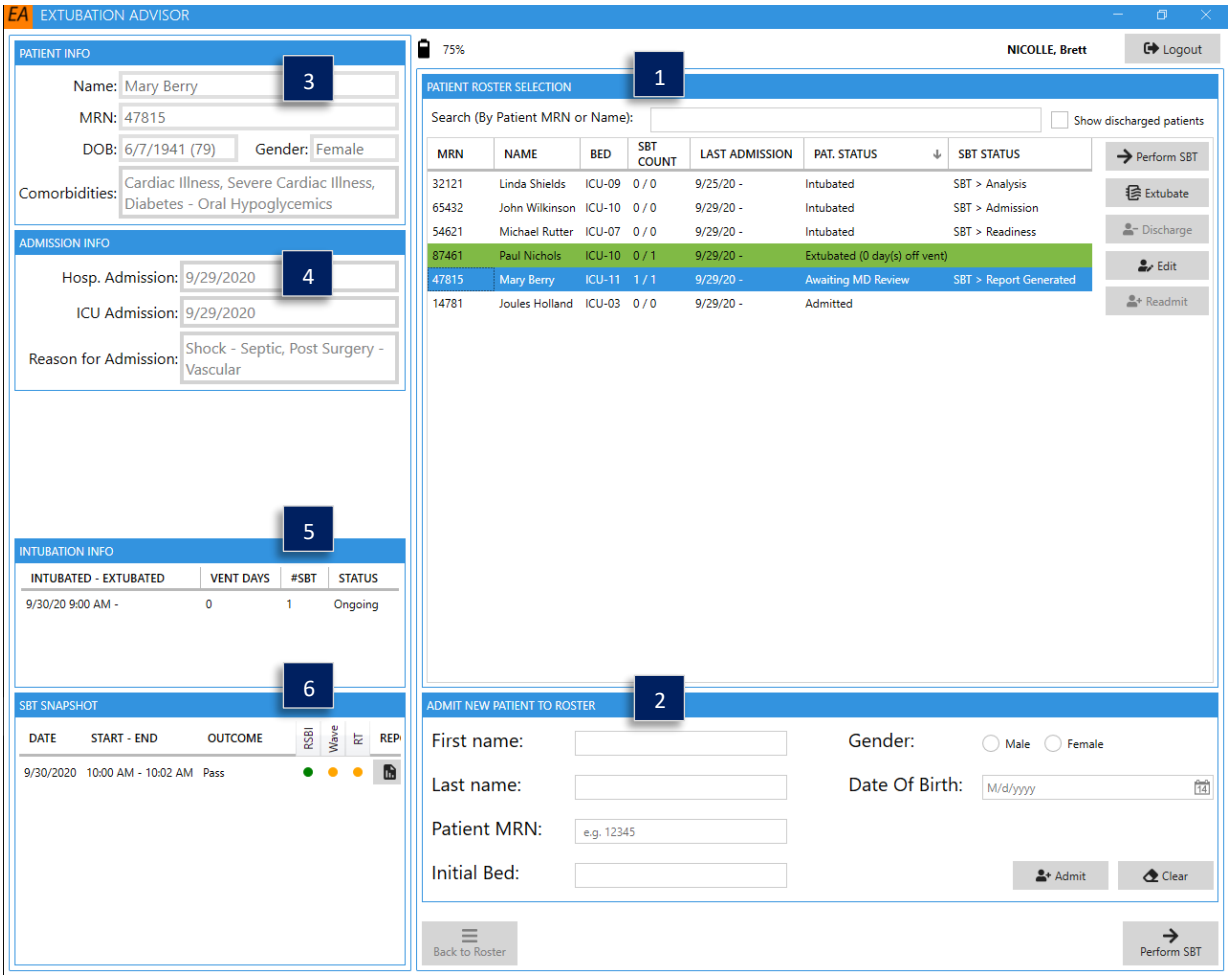
All system Users are allocated a role which controls the level of access they have to the various functions and scope of the system.

Role	Scope
Administration: (Part No. 011-1015-LMAN)	
Admin / Super Admin / Data Manager**	Manages the overall installation and configuration of the systems Global or Local settings and its Users and exporting data. - Adding, Editing or Deleting of Users - Patient Monitor Settings - Clinical Documentation Settings - EA Generated Report Settings - Exporting anonymized data** **Note:** All functions of the data manager role can be performed by Administrator users. The data manager role allows a dedicated user who is not an Administrator to perform these functions.
Clinical: (Part No. 011-1014-LMAN)	
Respiratory Therapist (RT) / Report Viewer	Completes the various tasks associated with the documentation and reporting of an SBT. Items marked with * are not available to the Report Viewer role. - Navigating the Patient Roster - Admit*, Extubate*, Discharge*, Start / Continue SBT* - Adding / Editing Admission and Comorbidities Info* - Adding / Editing the Extubation Readiness Checklist* - Recording of Waveform Data for WAVE Score and Patient Monitor Vital Signs during SBT* - SBT Outcome* - Generating the SBT Synoptic Report* - Reviewing and printing historic reports

EA Clinical Information Dashboard

The EA clinical information dashboard forms the control center for all EA monitored patients and their progress towards liberation from a ventilator. The EA clinical information dashboard consists of the following:

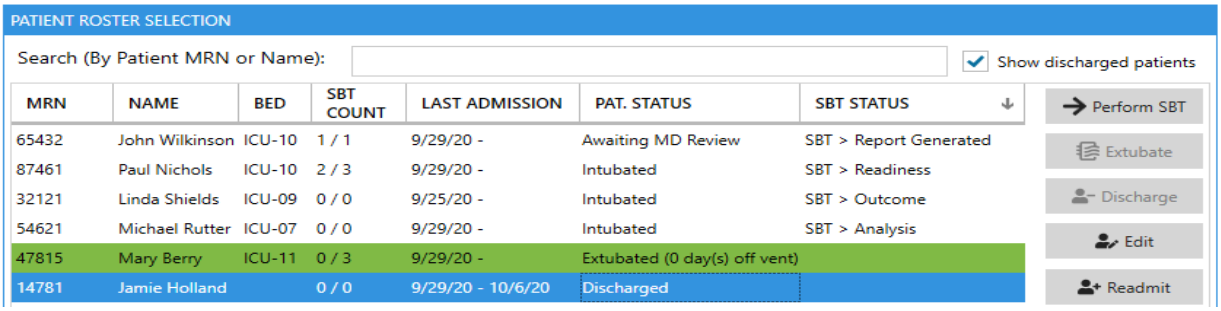
1. **Patient Roster**
   - With the option to **Perform** or **Continue SBT**
   - Document an **Extubation**
   - **Discharge** or **Readmit** a Patient in the Roster
   - **Edit** a Patients Demographic information
2. **Patient Admit form**
3. **Patient Demographic and Comorbidity information**
4. **Admission Reason and associated dates information**
5. **Intubation information**
   - Date the Patient was intubated
   - Date the Patient was extubated
   - Number of days on a ventilator
   - Number of SBT's performed
   - Ventilation Liberation Status
6. **SBT Snapshot information**
   - SBT Outcome
   - Risk Scores
     - **RSBI**
     - **WAVE**
     - **RT Impression**
   - EA Generated SBT Synoptic Report



Note: Report Viewers will only have access to sections 3,4,5,6 along with a list of patients via 1.

Patient Roster

The **Patient Roster** displays all monitored patients and their progress in terms of ventilator liberation via the columns **Patient Status** and **SBT Status** for the current admission.



Select a patient to view previously documented information via the surrounding clinical information dashboards. The options to **Perform SBT** or **Continue SBT** as well as **Extubate** and **Discharge** will become available depending on the **Patient Status** and **SBT Status**.

	Progress:	Details:
Patient Status	**Admitted**	Confirms the patient is admitted to EA, however the intubation date has not yet been inputted. ○ Use the Perform SBT button to start the workflow.
	Intubated	Confirms the intubation date has now been inputted. ○ Use the SBT Status column to determine weaning progress.
	Awaiting MD Review	Confirms an SBT Synoptic Report has been generated. Awaiting MD review and decision regards extubation. ○ Use Perform SBT button to restart the workflow.
	Extubated	Confirms the patient has been extubated and the number of days they have been ventilator free. ○ Use Perform SBT button to restart the workflow and to document a re-intubation as required.
	Discharged	Confirms the patient has been discharged from EA. Only shown if "Show discharged patients" is enabled. ○ Use Readmit button to re-admit the patient to ICU and to document a re-intubation as required.
SBT Status	**SBT > Admission**	Awaiting the Intubation, Hospital, and ICU Admission Dates to be documented, along with the patients Comorbidity Information.
	SBT > Readiness	Awaiting the Extubation Readiness Checklist to be documented.
	SBT > Analysis	Awaiting the connection of the configured patient monitor and for the SBT Recording to be started.
	SBT > Outcome	Awaiting the SBT Outcome information to be documented and for the SBT Synoptic Report to be generated.
	SBT > Report Generated	Awaiting MD Review and decision regards extubation to be documented.

Note: The various columns that make up the **Patient Roster** table can be sorted by selecting the column heading in question. The above example shows the patient roster sorted by **SBT Status**.

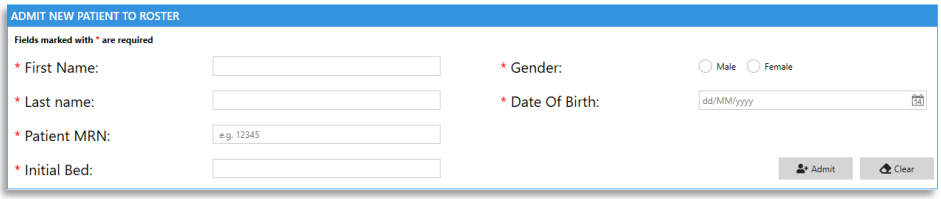
Admitting a Patient to the Roster

Complete the **Admission information** form as required.

1. Select the **Admit** button to begin the patient's ventilation liberation journey.

Once admitted, the patient will appear in the **Patient Roster** above.

2. Select the **Clear** button, to reset the form as and when required.



Note: All fields are required to be completed to allow you to proceed.

Note: All dates will need to be entered in your local format. i.e. **M/d/yyyy** or **dd/MM/yyyy**

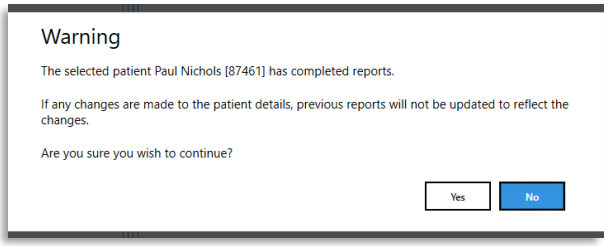
Note: The format of the **Patient MRN** is a configurable option. Your EA Administrator can choose to display the **watermark** as a reminder to you of the expected MRN format used by your organization.

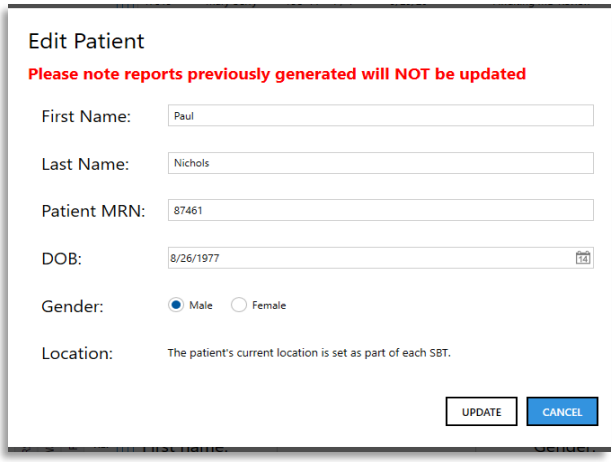
Note: The patient's location (Unit/Bed) can be updated whenever a new SBT is performed.

Warnings	
	▲ EA must not be used outside of its intended use.
	▲ EA is not for use for patients under the age of 18 years
	▲ EA is a tool to assist in the complex decisions made in assessing extubation readiness of ventilated patients. It does not replace the clinical judgment of a Clinician.

Editing Patient Demographic Information

You can **Edit** a patient's demographic information at any time by selecting the **Edit** button, located in the **Patient Roster**, and completing the associated form.



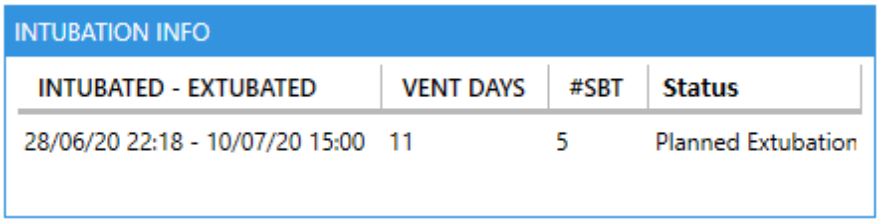


Note: Any amendments to the demographic information will not be applied to previously generated SBT Synoptic Reports. A **warning message** is displayed when attempting to update patient demographic information in this instance. Select **Yes to proceed** or **No to leave unchanged**.

Intubation Information

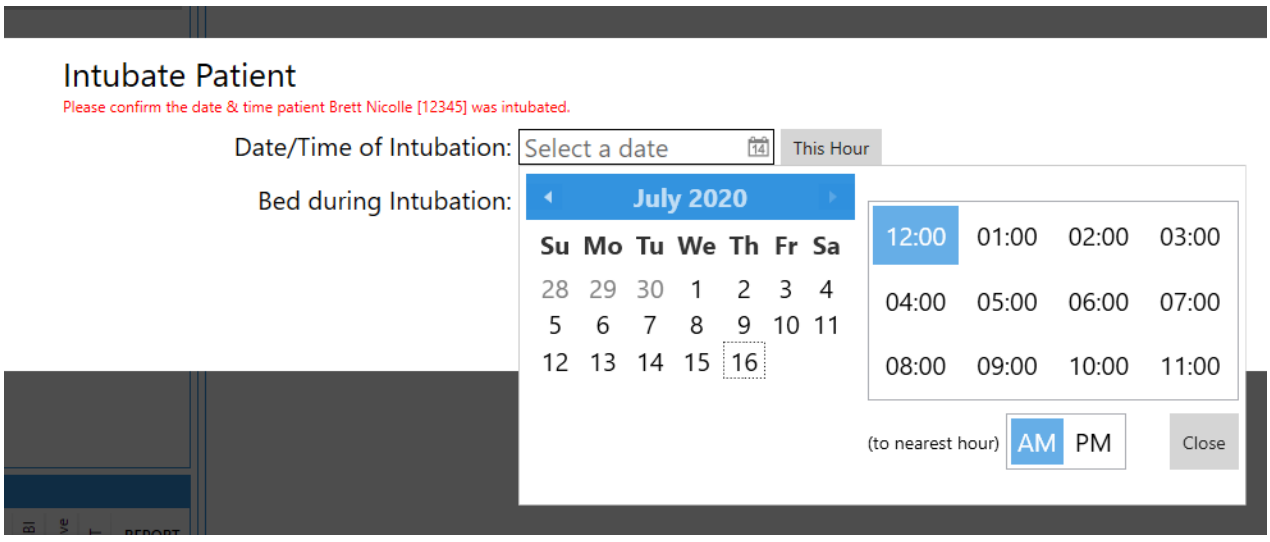
The **Intubation Information** table displays the patient's current Intubation and Extubation history, along with the number of days the patient was ventilated and the number of SBTs carried out using EA. The patient's **Airway Status** is also detailed if documented.

Ventilator Liberation Outcome		**Planned Extubation**
		Self-Extubated
		Tracheostomy
		Deceased



The **Intubation Information** is documented when you press the **Perform SBT** button for a selected patient for the first time.

1. Select the **Date / Time of the intubation** as required.
2. Press the **Close** button and you are presented with the **Admission Information** form.

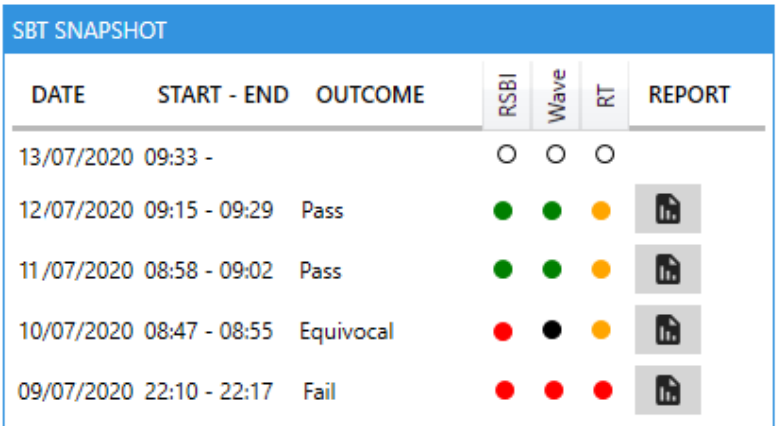


Note: If you have discharged a patient from EA and then re-admitted them, the **Intubation Info** table will only show the most recent intubation date and associated ventilator days and number of SBT's performed until that patient is discharged again.

SBT Snapshot

The **SBT Snapshot** provides an overview of a selected patient's SBT history with outcome, and the risk of extubation failure according to **RSBI, WAVE** score and **RT Impression**.

SBT Outcomes		**None Documented yet**
		Pass
		Equivocal
		Fail



Color Key Information for RSBI, WAVE and RT Impression	
	SBT Analysis not carried out yet
	Low risk of extubation failure
	Above average risk of extubation failure
	High risk of extubation failure
	Unable to calculate. Refer to the SBT Synoptic Report for more details.

You can select and review the generated **SBT Synoptic Report** by selecting the report icon.

If enabled by your IT Department, you will then have the option to **Print** the report.

Note: The **Print Report** feature will need to be set up and configured by your EA Administrator / IT Department. If disabled, the Print Report button will not be available for selection.

Note: If **manually printing** the SBT synoptic report as part of your workflow is preferred, it is recommended a **colour printer is used.**

Performing an SBT

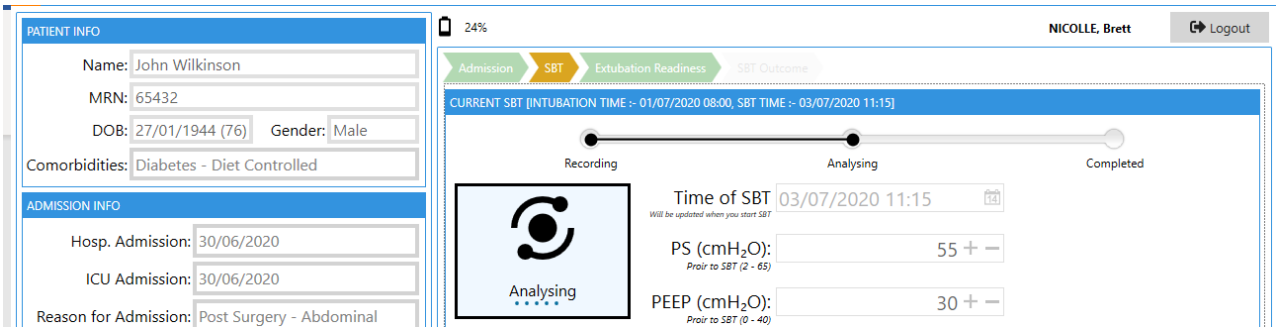
This section describes the various stages involved in documenting an SBT and the recording of the Patient Monitor Waveforms required to calculate the WAVE Score.

1. **Admission Info, Reason and Comorbidity Info**
2. **SBT and recording of Patient Monitor waveform data for WAVE score**
3. **Extubation Readiness Checklist**
4. **SBT Outcome and SBT Synoptic Report Generation**

Each section is represented as part of a Progress Bar that can be selected to allow you to complete the sections various information as required. The **SBT Outcome** requires the **SBT** section to have been completed and resulting analysis saved.

As each section is documented, the **Progress Bar** is changed from Gray to Orange and to Green.

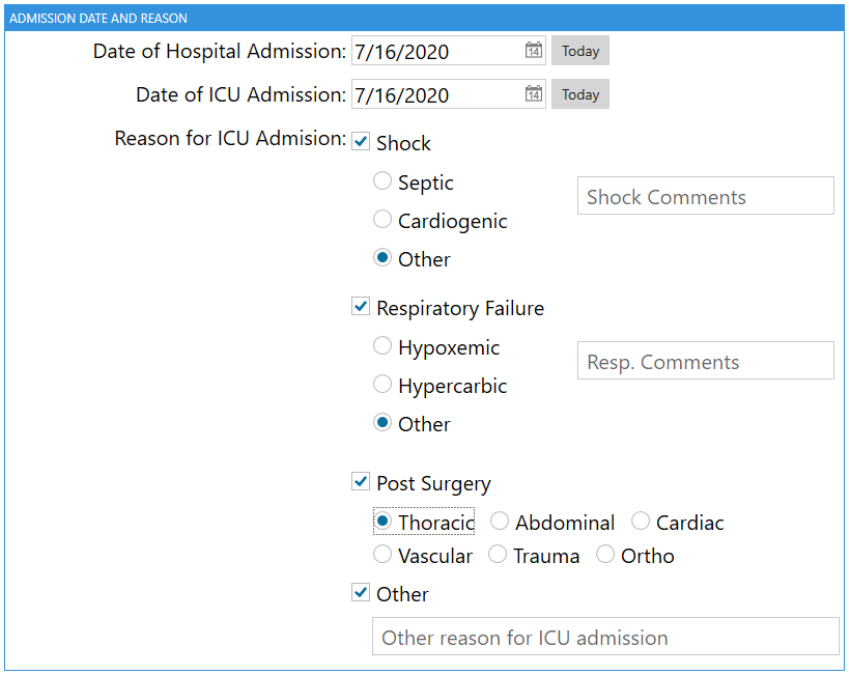
	Gray = Not Started
	Orange = In Progress
	Green = Completed

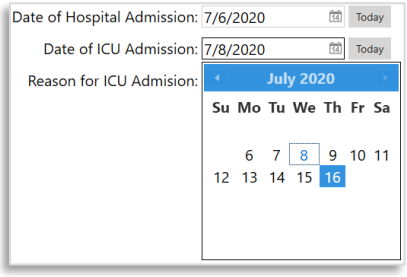


Note: Admission and **Extubation Readiness** sections can be completed in any order depending on your own workflow preferences.

Admission Information & Reason

Use this section to detail the patient's **Admission Reason**, as well as the associated dates for the **Hospital** and **ICU Admission**. You can update this section at any stage, however you must ensure the most current information is selected, as it is this data that is used when generating a SBT Synoptic Report.





Click on the **Calendar Icon** to select the **Hospital** and **ICU Admission Dates**.

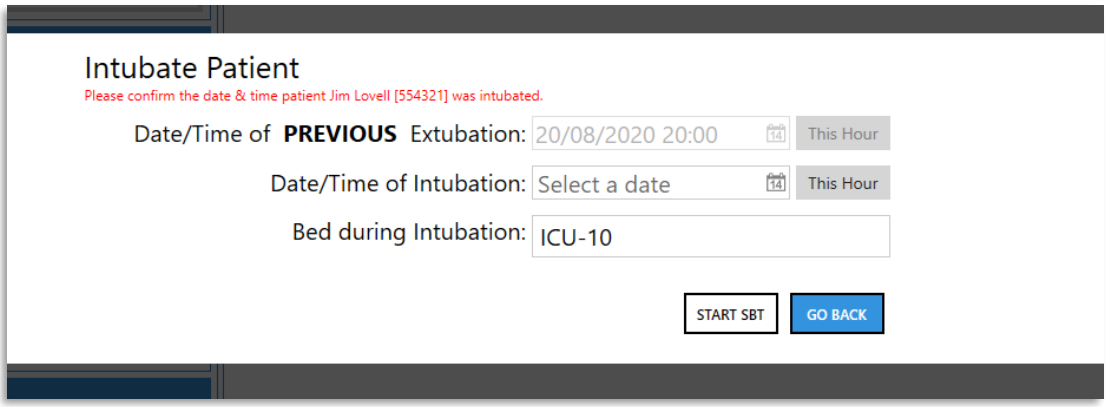
- Current date is highlighted in blue.
- **The selected Date** has blue border and text.

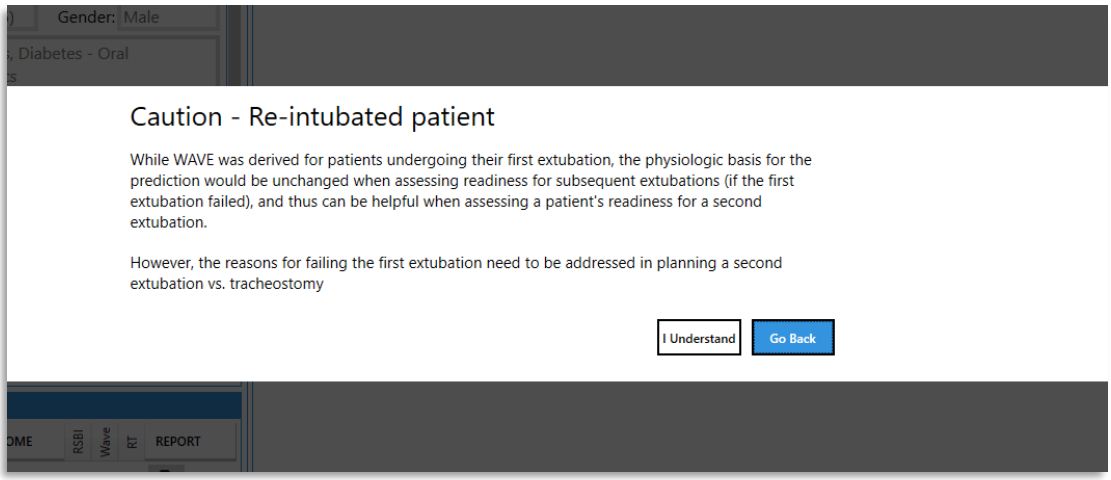
Select the **Today button** if admitting the patient in real time.

Once an **SBT Synoptic Report** has been generated for the first time, the **Admission information**, **Comorbidities information** and **Current Intubation Information** as entered are all locked to preserve the information for future SBTs, all associated reports, and for **Documenting an** and **Documenting a Reintubation**

To document a Reintubation, select the **extubated patient** you wish to update, then select the **Perform SBT** button via the **Patient Roster** and complete the form as required.

1. The patients **Previous Extubation date and time** will be displayed.
2. Document the **Date and Time for the new intubation.**
3. Document the **Bed location for the new intubation.**
4. Press the **Start SBT** button.
5. Review the **dialog message displayed** and **confirm I Understand to proceed** or **Go Back** to decline to proceed to document future SBT's for the Reintubated patient using EA.





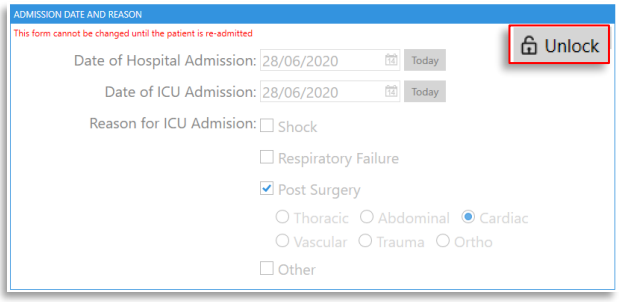
Note: The patient's location (Unit/Bed) can be updated whenever a new SBT is performed.

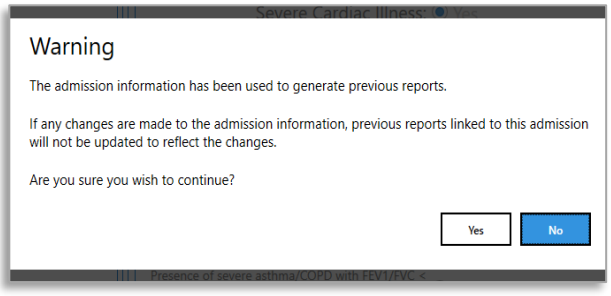
Caution

While WAVE was derived for patients undergoing their first extubation, the physiologic basis for the prediction would be unchanged when assessing readiness for subsequent extubations (if the first extubation failed), and thus may be helpful when assessing a patient's readiness for a second extubation.

However, the reasons for failing the first extubation need to be addressed in planning a second extubation vs. tracheostomy.

Discharging a Patient from the Patient Roster**.**





If an error is made when documenting the various **Admission** and **Comorbidity information** and a **SBT Synoptic Report** has subsequently been generated, thus locking the admission information, you

are able to unlock the section to update as required. If you do decide to **unlock** the **Admission** and **Comorbidities information**, a **warning message** is displayed requesting you to confirm yes to proceed. Select Yes, and then update the **Admission** and **Comorbidities information** as required and **Save** to proceed.

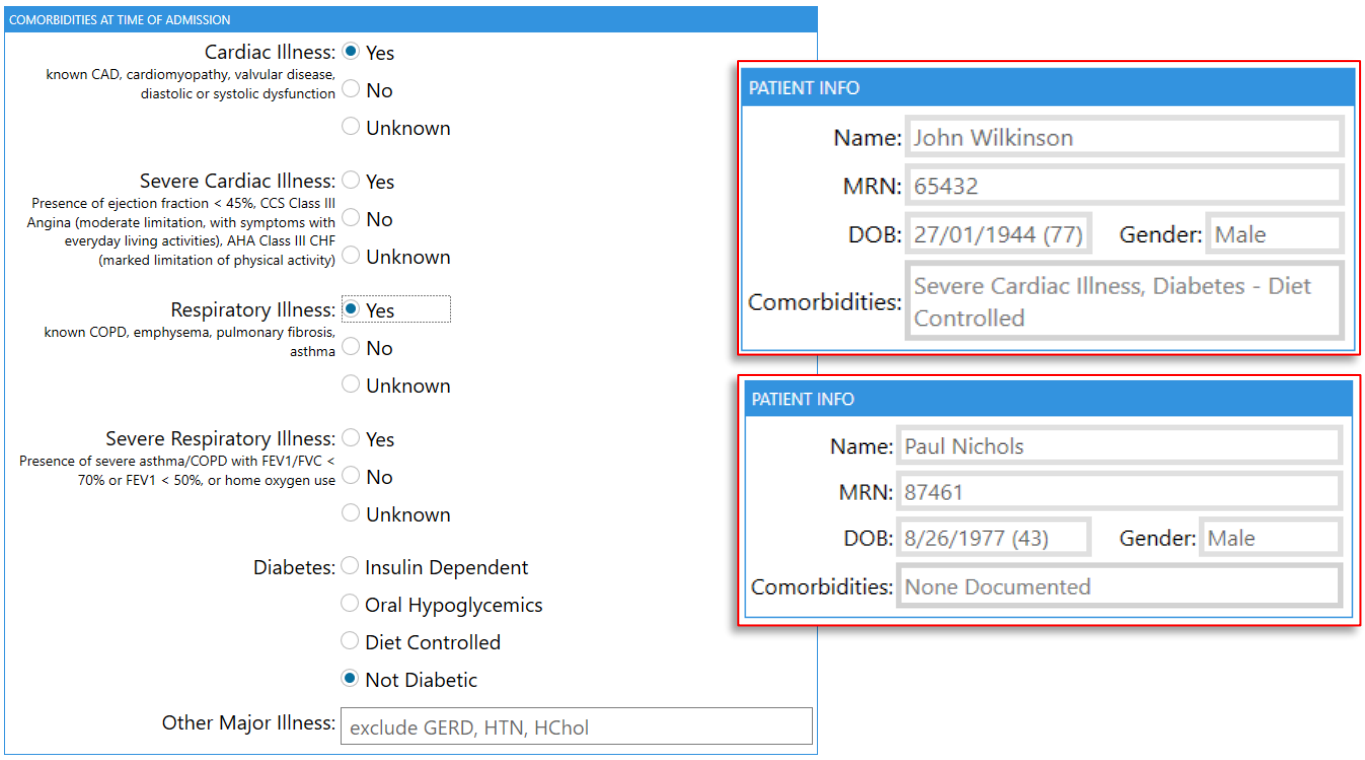
Note: Any updates made will only apply to future generated SBT Synoptic Reports and will not retrospectively update historic reports. Its vital to ensure you preview all reports for accuracy before commitng to save and email the report.

Comorbidities Information

Use this section to detail a patient's **Comorbidity information**.

The **options for Severe Cardiac Illness** and **Severe Respiratory Illness** are only displayed once you have selected **Yes** for a particular Illness. You are then required to document the status for **Severe Illness.**

You can update this section at any stage. However, you must ensure the most current information is selected, as it is this data that is used when generating a report. The current Comorbidity information is displayed via the Patient Info section of the dashboard.



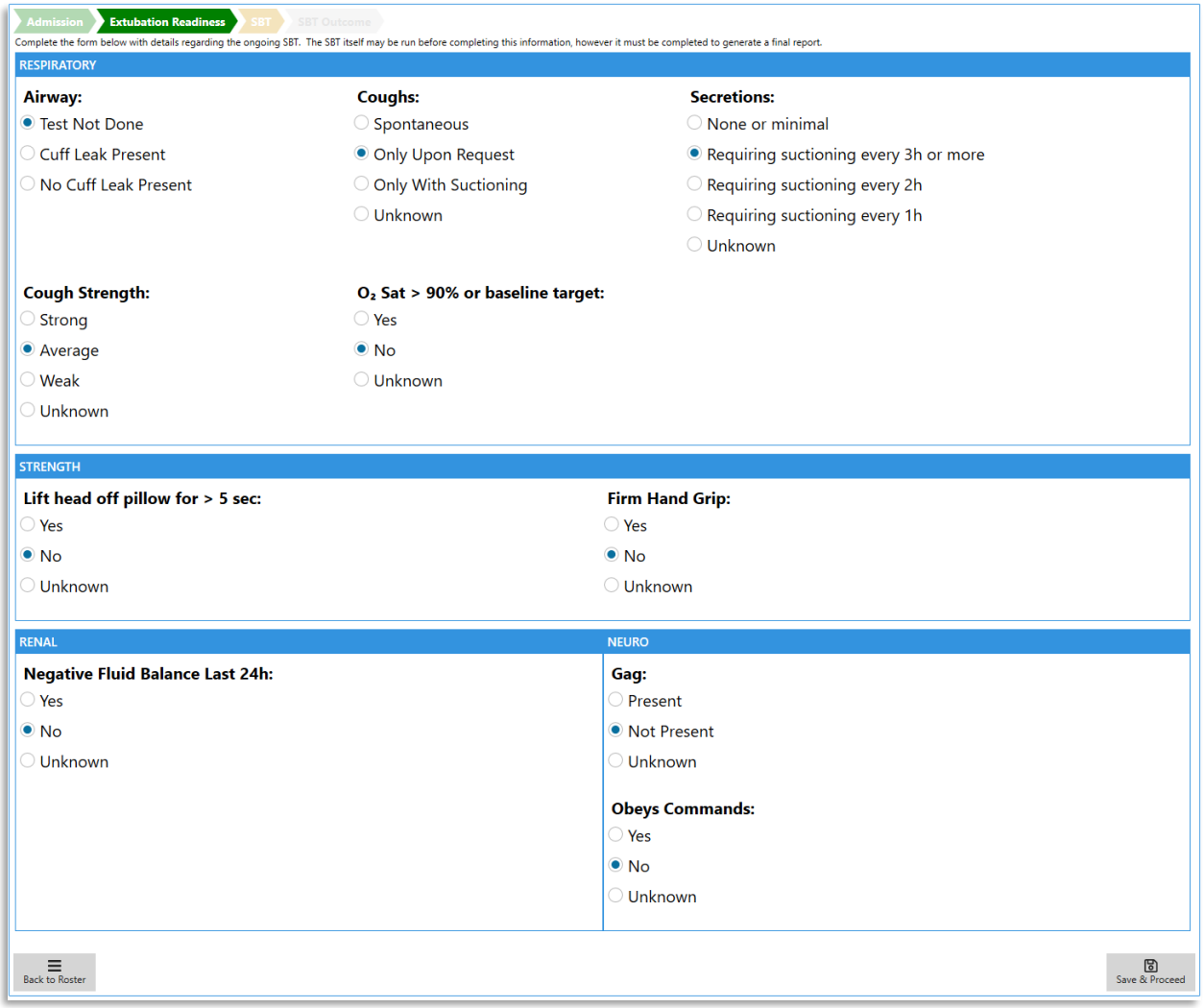
Once the **Admission Information, Reason** and **Comorbidities information** has been documented the **SBT Progress** bar is updated to confirm the section has been completed.

Note: Selecting **Unknown** for all options - Cardiac Illness, Severe Cardiac Illness and Respiratory Illness, Severe Respiratory Illness will place a comment in the generated report stating "**None Documented**" at the time of the report.

Extubation Readiness Checklist

You will be required to complete the **Extubation Readiness Checklist** before you can document the SBT Outcome information and generate the **SBT Synoptic Report.**

1. Complete the **Extubation Readiness Checklist** as required.
2. Select the **Save & Proceed** button.
3. The Progress Bar for **Extubation Readiness** will turn green.



Note: The Extubation Readiness Checklist is typically completed during the SBT Recording stage, however it can be completed in any order. Select Extubation Readiness from the Progress Bar at the top of the EA screen to complete.

Note: Selecting **Unknown** for any of the checks will place a comment in the generated report that the check was **"Not Reviewed"** at the time of the report.

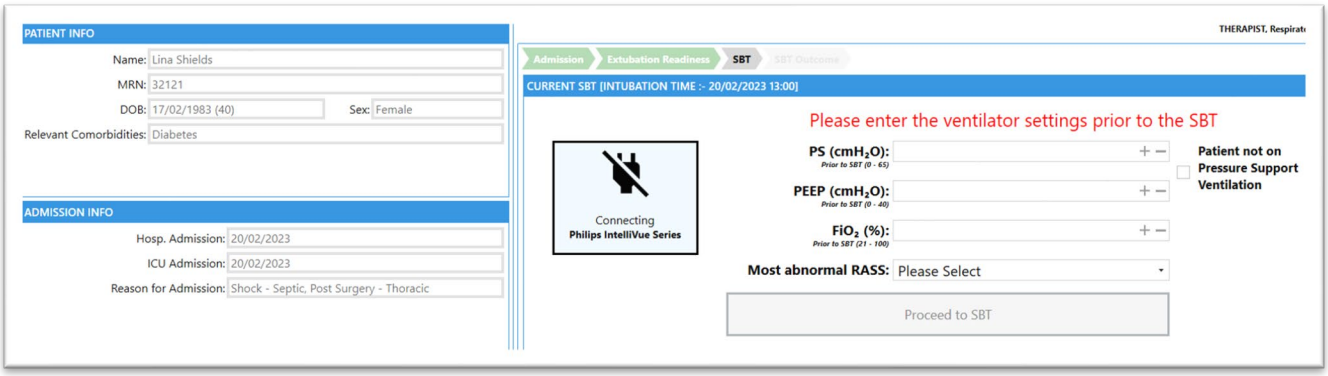
Documenting Ventilator Settings prior to SBT

Before you can begin to start an **SBT recording**, you are required to document the Ventilator settings **Prior to the SBT**.

If the **patient is not on Pressure Support Ventilation** or you do not use **PS or PEEP**, then select the checkbox to override these required field settings, and simply document the RASS.

Otherwise proceed to document the PS and PEEP values.

1. Document the Pressure Support **(PS) (cmH_2O)** settings prior to SBT.
2. Document the Positive end-expiratory pressure **(PEEP) (cmH_2O)** settings prior to SBT.
3. Document the Fraction of inspired Oxygen **(FiO_2) (%)** prior to SBT.
4. Document the Most abnormal **Richmond Agitation-Sedation Scale (RASS)** value.
5. Select the **Proceed to SBT** button.



Cautions	⚠ When connected to a Patient Monitor, the device running EA cannot be connected to mains power.	
	⚠ When not in use, the device running EA should be kept on charge to ensure it can be used on battery when connected to a Patient Monitor.	
	⚠ Please note if you attempt to connect mains power during an SBT recording, all recording data to that point will be lost.	
Battery Charging Icon & Percentage	100%	Device running EA is fully charged, ready to be disconnected from mains power and used as required.
Battery Low Warning Message	⚠ Battery Low	Consider sourcing a different device running EA that has a fully charged battery.
Battery Critical Warning Message	⚠ Battery Critical	Stop using device running EA and connect it to mains power to fully recharge battery.

Note: RASS is a 10-point scale, with four levels of anxiety or agitation (+1 to +4 [combative]), one level to denote a calm and alert state (0), and 5 levels of sedation (−1 to −5) culminating in unarousable (−5).

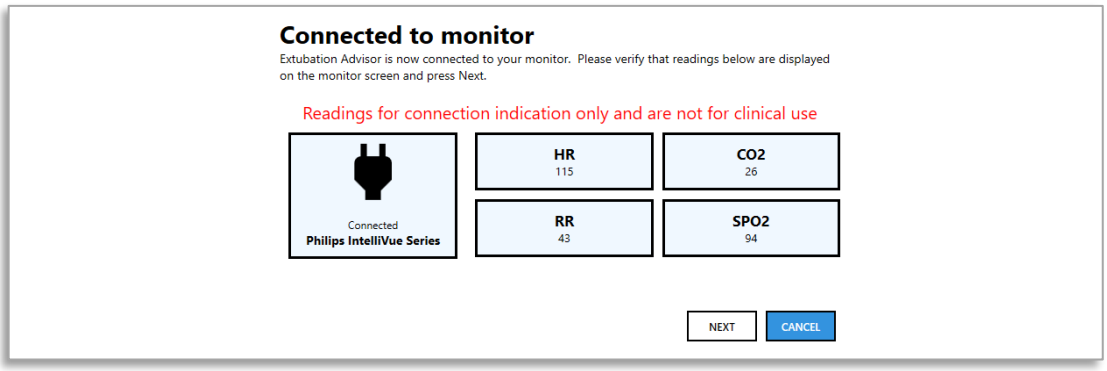
Connecting to a configured Patient Monitor

EA has been validated for use on two major families of patient monitors:

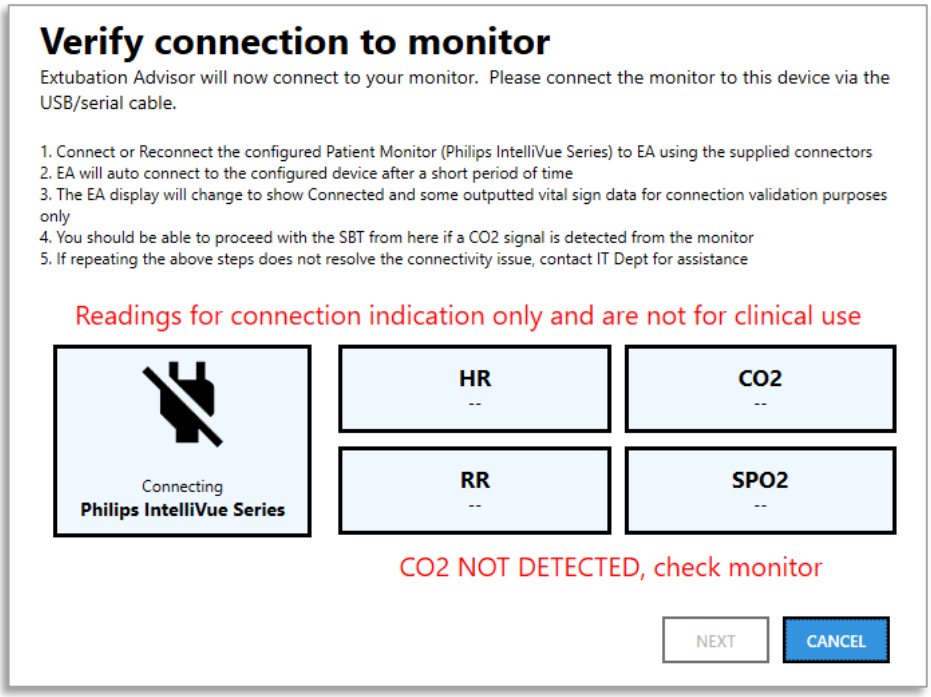
Manufacturer	Family	Example models	Supported Transports
Philips	IntelliVue Series	MP30, MP50, MP70	Serial (MIB/RS232), Isolated LAN (IP)
GE	Datex Carescape/Datex	B450, S/5	Serial (RS232)

Ensure a **Capnograph (CO2) module** is installed on the Patient Monitor and that the **CO2 sensor and tubing are connected to the capnograph module and the patient breathing circuit**, with a **CO2 signal** being displayed by the monitor in accordance with your normal clinical practice.

Depending on your system configuration, connect the Patient Monitor to EA using the appropriate cable as supplied by your Biomedical Engineering Department. EA will then attempt to verify the connection with the configured Patient Monitor. If a cable is already connected, check to confirm vital sign and CO2 readings are being received.



A message will be displayed if either the Patient Monitor is not connected, or no CO2 is being output by the module. Follow the instructions as outlined in the dialogue screen.



If you experience any issues connecting the Patient Monitor, confirm that the Patient Monitor in use is the same as the monitor reported in the Connection Box and disconnect and reconnect the cable from EA to the Patient Monitor.

Contact your Biomedical Dept or EA Administrator if reconnecting the supplied cable to EA does not work after a couple of attempts.

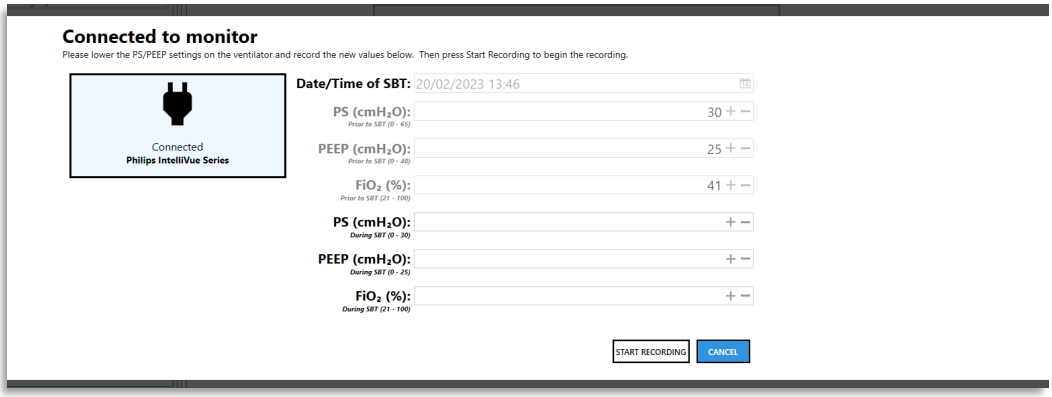
Note: See **EA – Patient Monitor Compatibility List** in the support section for more information if required.

Documenting the Ventilator Settings during the SBT

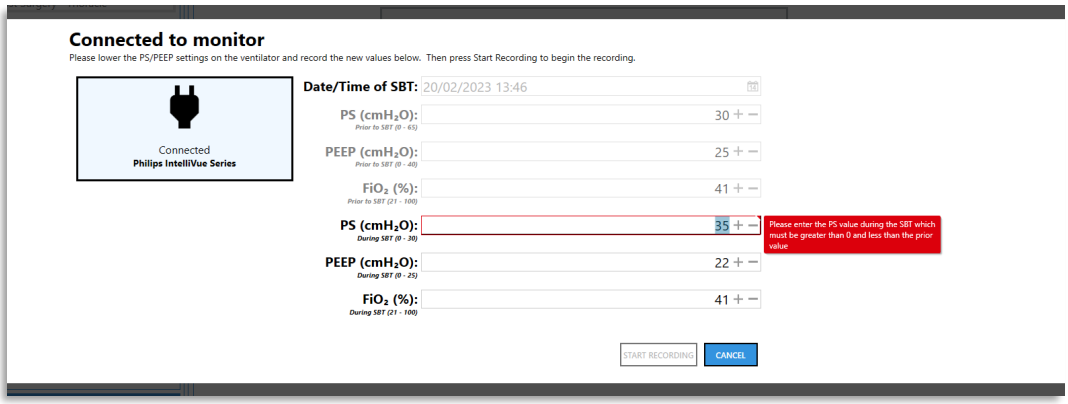
Once successfully connected to the configured Patient Monitor, and CO2 and other vital sign data is being received, you will be instructed to lower the PS/PEEP settings on the ventilator and document the new values:

- **PS (cmH_2O) – During SBT**
- **PEEP (cmH_2O) – During SBT**
- **Fraction of inspired oxygen (FiO_2) (%) – During SBT**

EA will not allow you to enter values higher than those documented Prior to the SBT for PS and PEEP.



Review any error messages as displayed and correct as required.



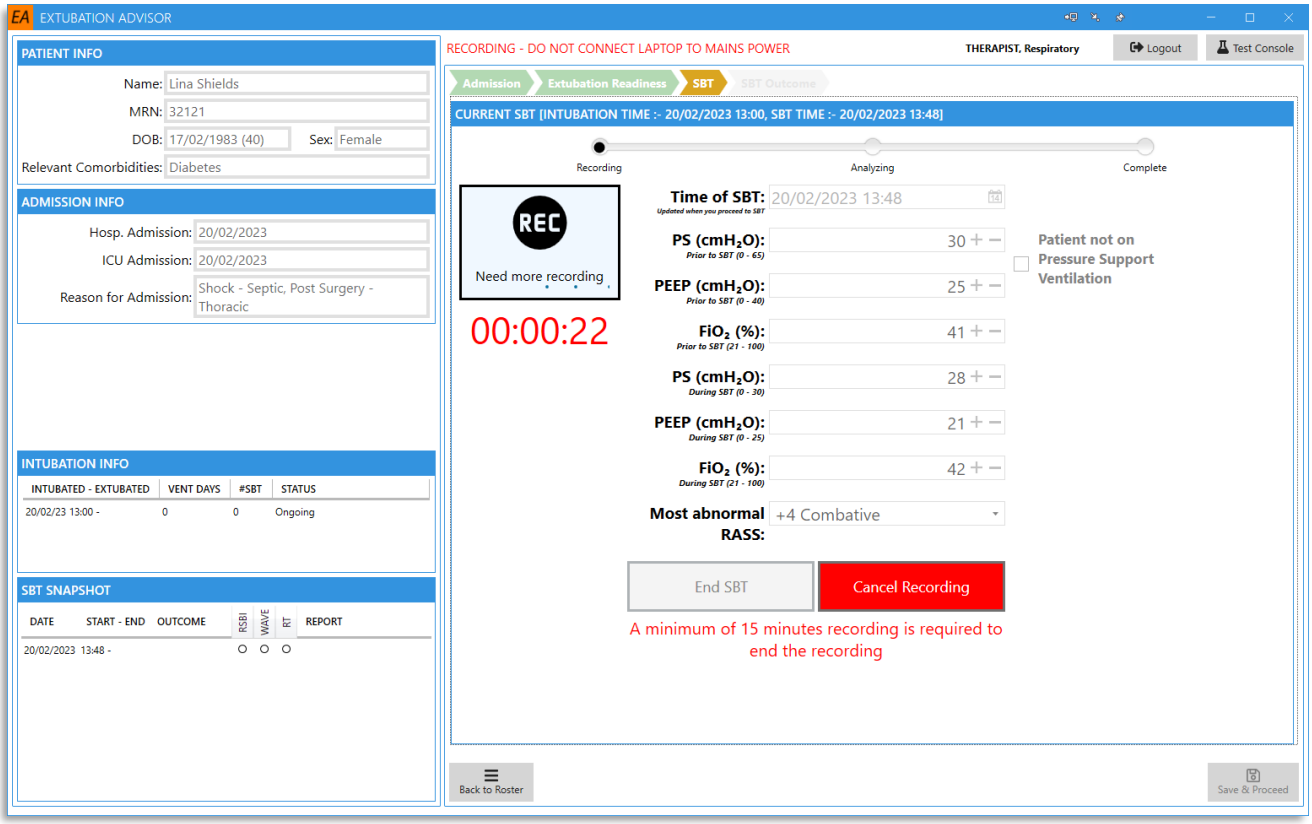
Press the **Start Recording** button.

Cautions	⚠ When connected to a Patient Monitor, the device running EA cannot be connected to mains power. If you attempt to connect mains power during an SBT recording, all recording data to that point will be lost. When not in use, the device running EA should be kept on charge to ensure it can be used on battery when connected to a Patient Monitor.

Cancelling an SBT Recording

If for any reason you need to cancel the recording of the waveforms as outputted by the Patient Monitor during the SBT, select the **Cancel Recording** button.

The **Cancel Recording** button is only available until the **minimum recording threshold (15 Minutes)** time is reached. After this, your only option is to **End the SBT** and document any issues experienced via the **SBT Outcome** section.



Cancelling a recording will take you back one stage. At this stage you can update the clinical information **Prior To SBT** and **During SBT** as required.

Restart the recording when ready.

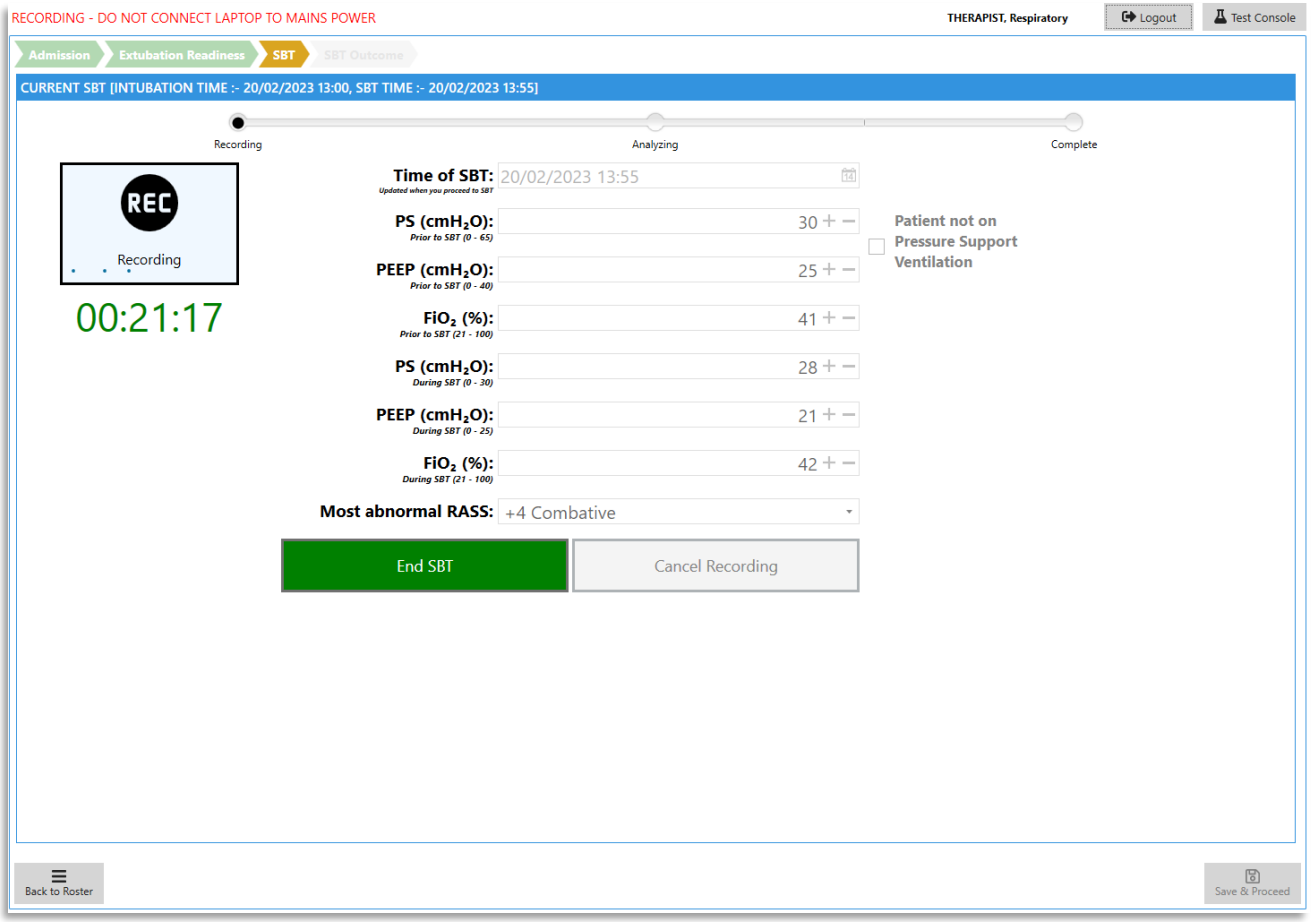
Note: A minimum of 15 minutes recording is required to calculate the WAVE Score, however the SBT can be as long as clinically necessary.

Ending an SBT Recording

You will only be allowed to End SBT recording once the system defined minimum recording time threshold has been reached.

Once the **minimum recording threshold** has been reached the End SBT button will turn green.

1. When you are ready to end the SBT recording for a Patient – press the End SBT button.
2. This will trigger EA to begin to analyze the recorded data and to calculate the **WAVE Results.**
3. The Progress Bar for **SBT** will turn Green.



Cautions

⚠ When connected to a Patient Monitor, the device running EA cannot be connected to mains power. If you attempt to connect mains power during an SBT recording, all recording data to that point will be lost. When not in use, the device running EA should be kept on charge to ensure it can be used on battery when connected to a Patient Monitor.

Disconnection of Patient Monitor during an SBT Recording

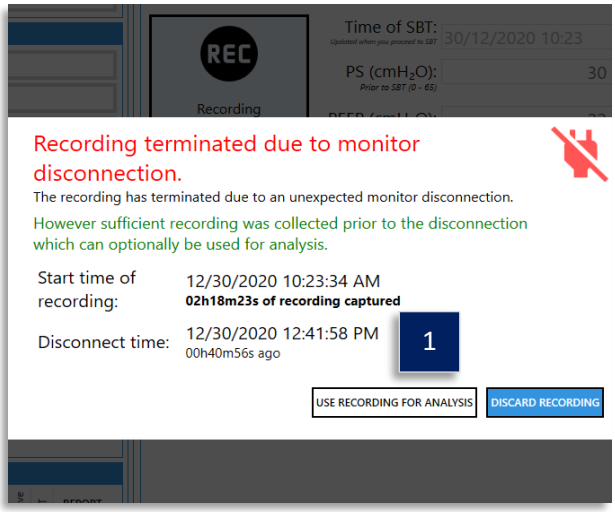
The cable connecting the Patient Monitor and the device running EA should **not be disconnected during an SBT Recording**.

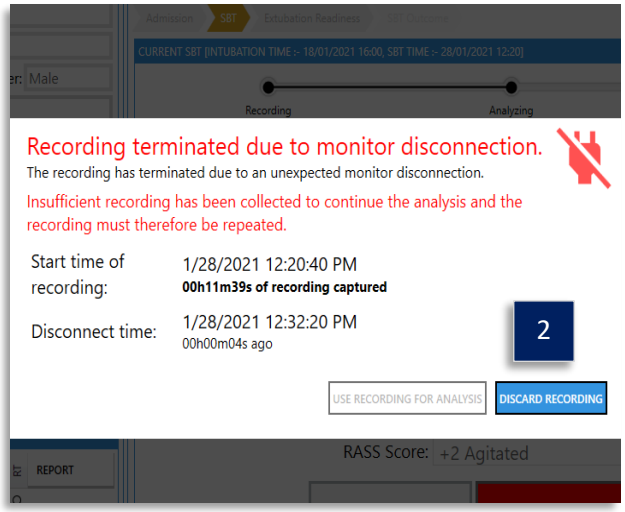
However, if for any reason the cable is disconnected during the SBT Recording, an error message and dialogue screen will be displayed – **"Recording terminated due to monitor disconnection".**

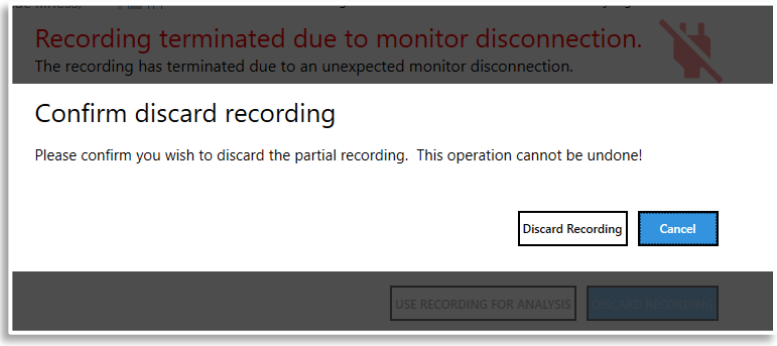
- An optional **audible alert** is sounded to notify you of the **monitor disconnection error**.

Depending on the length of recording prior to the disconnection occurring, you will be presented with **two outcomes**:

- **Outcome 1.** The duration of the SBT Recording is such that **sufficient recording was collected** prior to the disconnection, that you can **optionally use for the WAVE Analysis** to continue.
    - If you decide to discard the recording, a message is displayed requesting you to confirm your choice as the operation cannot be undone.
- **Outcome 2.** The duration of the SBT Recording is such that **insufficient recording was collected** prior to the disconnection to continue the WAVE Analysis, and the **recording has to be discarded** and the **SBT recording repeated**.







Note: RTs should rely on their own experience and discretion when deciding which option to choose, given the circumstances for the disconnection and duration of the SBT recording. EA provides the start / stop and duration of the recording to assist with this judgement.

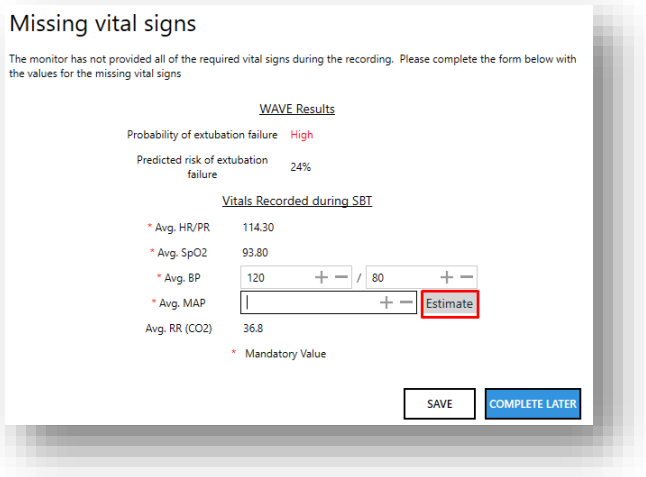
Note: The **audible alert** is a configurable option. It is recommended to be enabled, given RTs are extremely busy during an SBT and might not notice the monitor disconnection until much later.

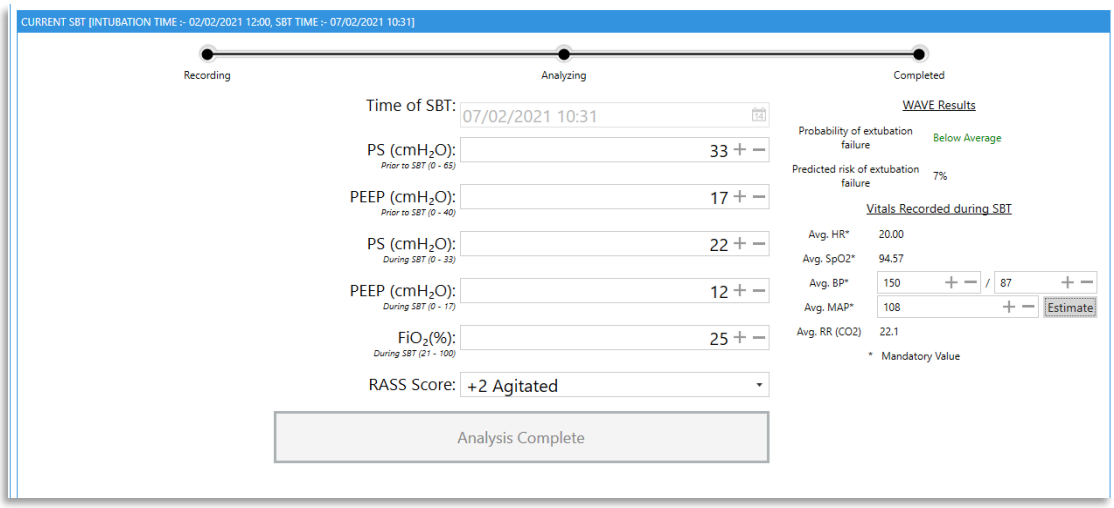
Reviewing the SBT Analysis Results

Once the **SBT recording has been ended**, EA will display the **WAVE Results** and a list of **Vitals Recorded** during the SBT, along with the **vent settings prior to and during the SBT**.

The Wave Results will detail the **probability of extubation failure** and the **predicted risk of extubation failure.** Depending on your system configuration, **you may be required to manually input vital sign data** that was not automatically recorded or output by the device connected to EA.

1. Input all required (* Mandatory Values) for **Vital Signs** not automatically acquired from the connected device.
   - If possible, **always input the Avg. MAP value from the monitor**, as it will be more accurate than an estimation.
   - **Avg. MAP** can be **estimated** if not output by the monitor by using the **Estimate** button.
   - Ensure Systolic / Diastolic values are inputted first, before using Estimate.
2. Press **SAVE** for the inputted missing vitals.
3. Review the analysis data and press **Save & Proceed** button





Depending on your workflow, you will either be directed to the **Extubation Readiness** Checklist or **SBT Outcome** sections. The **SBT Snapshot** will update to show the **WAVE** risk information.

Note: Only vital sign data received / inputted during the SBT Recording will be reported. If vital sign data was not automatically captured during the SBT recording, it will be displayed as a **(-) Gray Mark.**

Mandatory vital signs not captured, will need to be manually inputted to proceed. Which vital signs are mandatory is decided during the installation and configuration of the system.

Avg. MAP Estimation can be displayed / hidden as a configurable option.

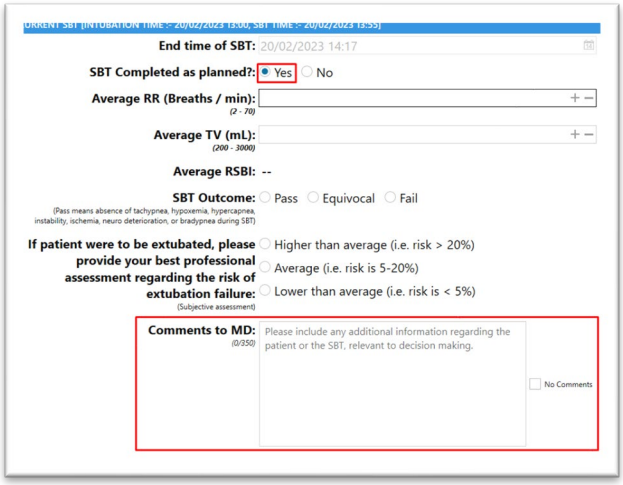
SBT Outcome Information

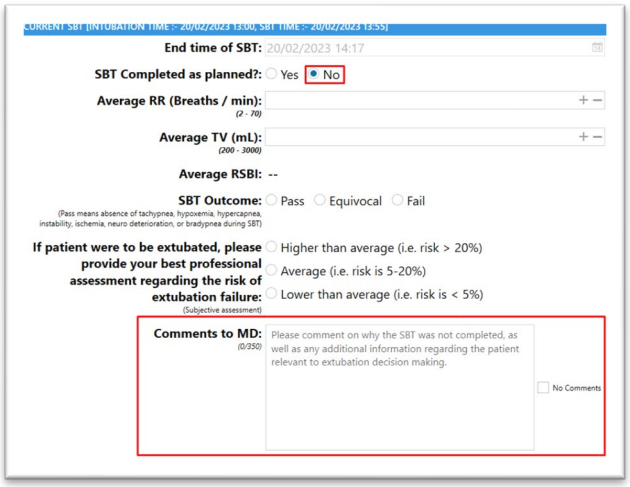
Once you have Ended the **SBT Recording** and reviewed the **SBT Analysis Results**, you are required to document the **SBT Outcome** Information.

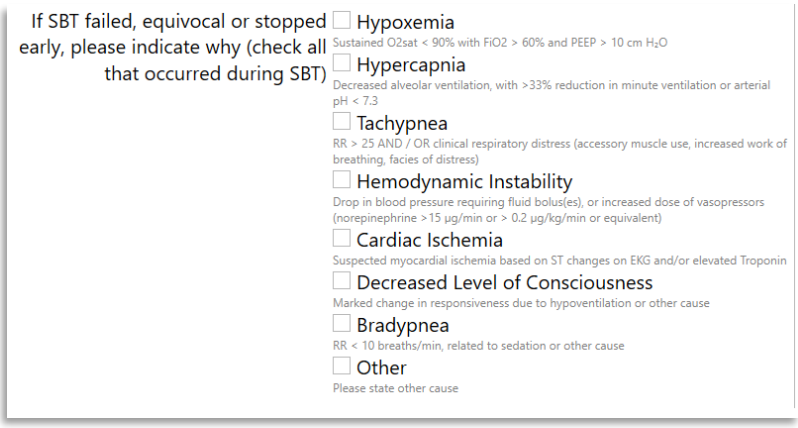
1. Complete the **SBT Outcome form** as required.

   If the SBT was **not completed as planned**, document the reasons and any relevant information via the **Comments to MD section (max length 350 characters).**

2. If the **SBT Failed** or was **Equivocal**, document the various reasons, or use **Other** to explain if the reason is not listed. Use the **MD Comments section** for any other notes you wish to document for consideration, otherwise select the **No Comments** checkbox.







Note: Both **Equivocal** and **Fail** require you to document the various reasons of concern or failure. Any additional comments can be documented in the **Comments to MD section** to be included in the report.

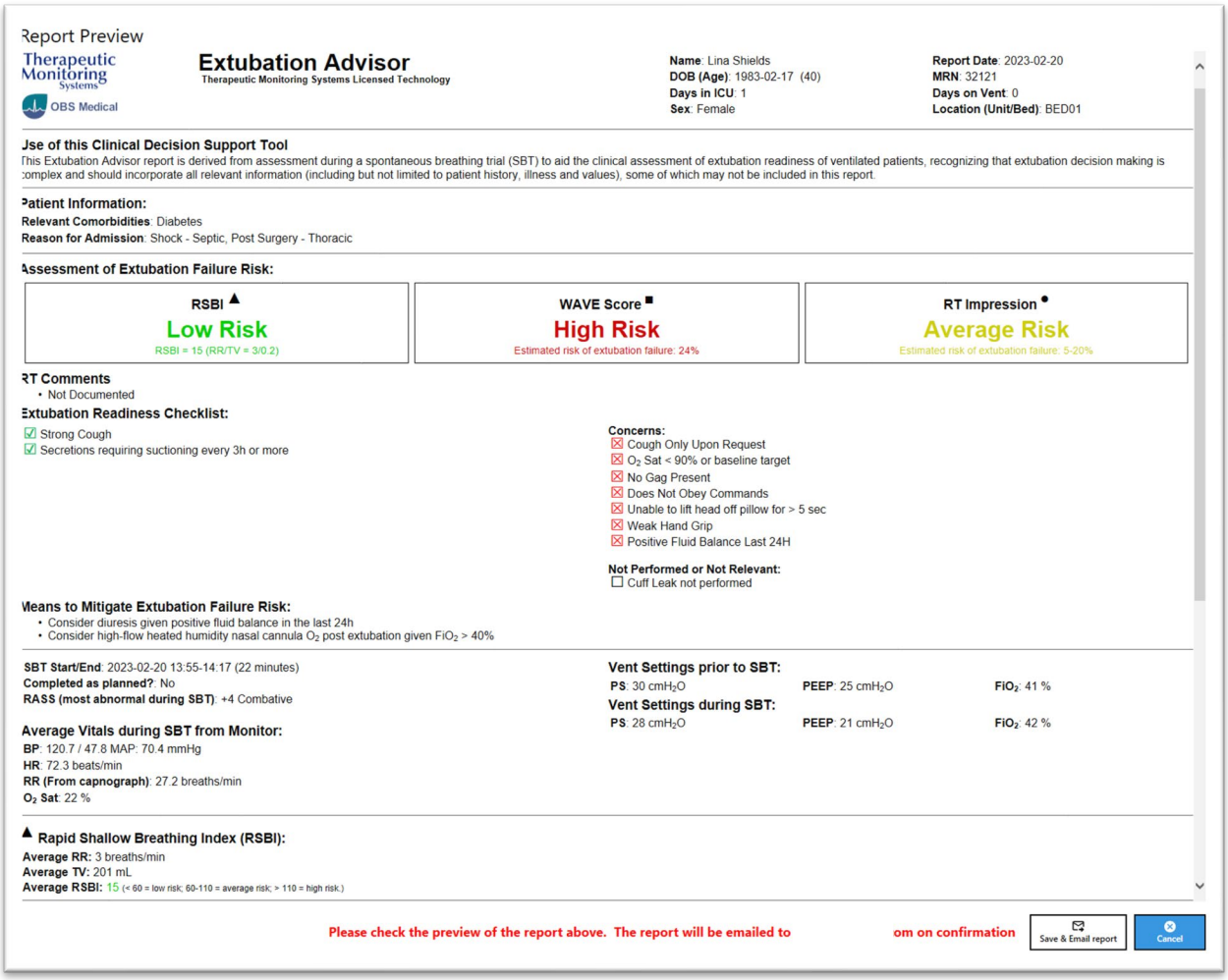
Note: The **RSBI** will be auto calculated using the **manually inputted Average RR** [Breaths / min] and Average TV [mL].

SBT Synoptic Reports

Generating the SBT Synoptic Report

Once you have completed the SBT Outcome Information, you will then have the option to Generate the SBT Synoptic Report.

1. Select the **Generate EA Report** button.
2. Review the **Report Preview,** and then **Save & Email Report** if no changes are required.
3. If for any reason you need to amend the report, select the **cancel button,** and navigate to the section in question for the data you need to update, update it, and save accordingly, and return to **SBT Outcome** Section and select **Generate EA Report** again.



Note: Depending on your local configuration settings, you will either have the option to **Save** the report or to **Email & Save** the report. The name of the User the report will be emailed to is displayed.

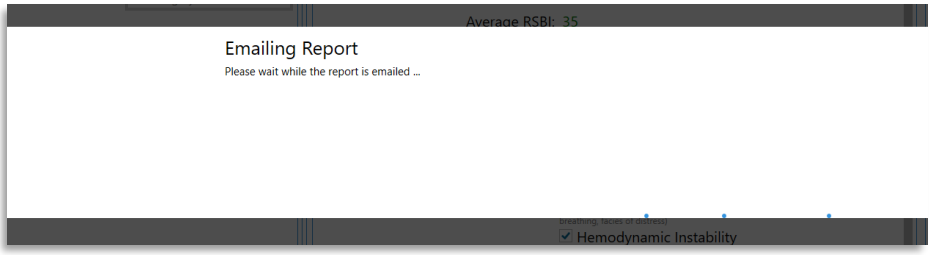
Note: The **Vent Settings prior to SBT** section will display a comment - **Patient not on Pressure Support Ventilation prior to SBT** if the corresponding checkbox for this section was selected.

Warnings	▲ EA is a tool to assist in the complex decisions made in assessing extubation readiness of ventilated patients. It does not replace the clinical judgment of a Clinician.

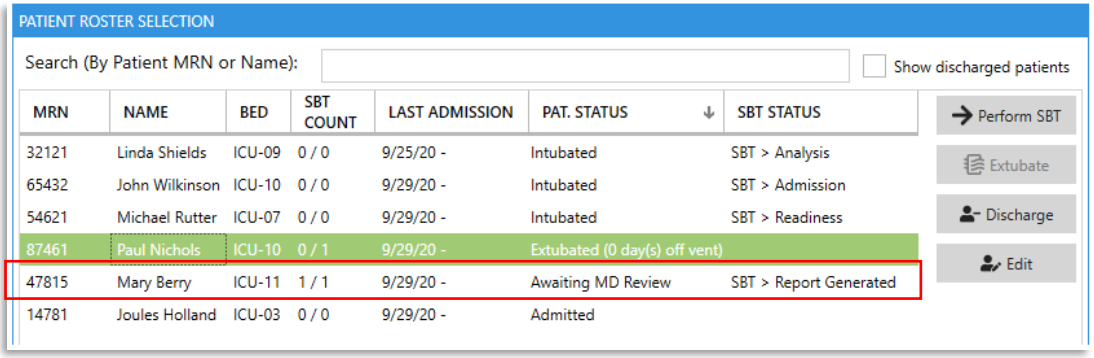
Emailing the SBT Synoptic Report

EA will automatically email the SBT Synoptic Report to the email account of the User as displayed via the **Report Preview,** as well as any additional email accounts configured to receive the SBT Synoptic Reports.

1. Having reviewed the **Report Preview**, select the **Save & Email report** button.
    - EA will now attempt to email the report as required.

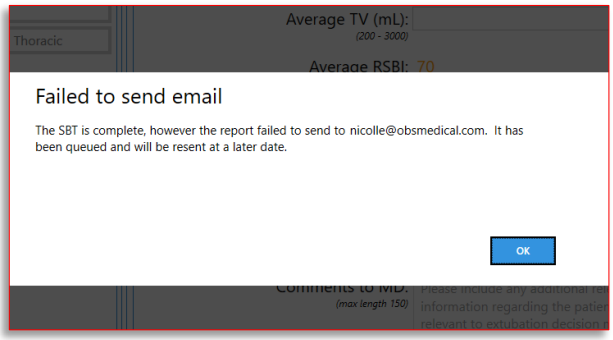


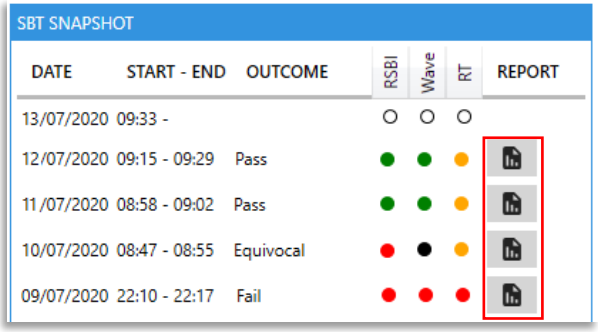
2. Once successfully emailed, you will be returned to the Patient Roster.
    - The **Patient Status column** will advise – **Awaiting MD Review**
    - The **SBT Status column** will advise – **SBT > Report Generated**



If for any reason the SBT Synoptic Report cannot be emailed at the time of you selecting **Save & Email report**, an error message will be displayed. EA will attempt to resend any unsent emails in the background.

- EA Generated **SBT Synoptic Reports** will be available for **review via the SBT Snapshot Section.**
- These can then be **Printed** for instances where the report has failed to be emailed as expected.





Means to Mitigate Extubation Failure Risk

The EA Generated Report might include a section called **Means to Mitigate Extubation Failure Risk**.

This section and its associated mitigations are only displayed if certain criteria as outlined in the below table are met from the patients documented **Comorbidities, Extubation Readiness Checklist** options and the **SBT Recordings Analysis** results.

	Criteria	Means to Mitigate Extubation Failure
1	Comorbidity is either: • Severe Cardiac Illness • Respiratory Illness • Severe Respiratory Illness	Consider non-invasive ventilation post extubation given the history of <Comorbidities Selected>.
2	Comorbidity is: • Severe Cardiac Illness and SBT Recording Analysis Results: • Average Sys BP > 140 or MAP > 85	Suggest afterload reduction given elevated blood pressure and history of impaired left ventricular function.
3	Extubation Checklist: • Weak Cough and SBT Recording Analysis Results: • FiO2 During SBT ≤ 40	Consider high flow heated humidity nasal cannula O2 post extubation given weak cough strength.
4	Extubation Checklist: • Weak Cough and SBT Recording Analysis Results: • FiO2 During SBT > 40	Consider high flow heated humidity nasal cannula O2 post extubation given FiO2 > 40% and weak cough strength.
5	Extubation Checklist: • No Cuff Leak	Consider steroid administration due to absence of cuff leak.
6	Extubation Checklist: • No – Negative Fluid Balance Last 24H	Consider diuresis given positive fluid balance in last 24h.
7	Patient is extubated and then, • Re-intubated	While WAVE was derived for patients undergoing their first extubation, the physiologic basis for the prediction would be unchanged when assessing readiness for subsequent extubations (if the first extubation failed), and thus may be helpful when assessing a patient's readiness for a second extubation. However, the reasons for failing the first extubation need to be addressed in planning a second extubation vs. tracheostomy.

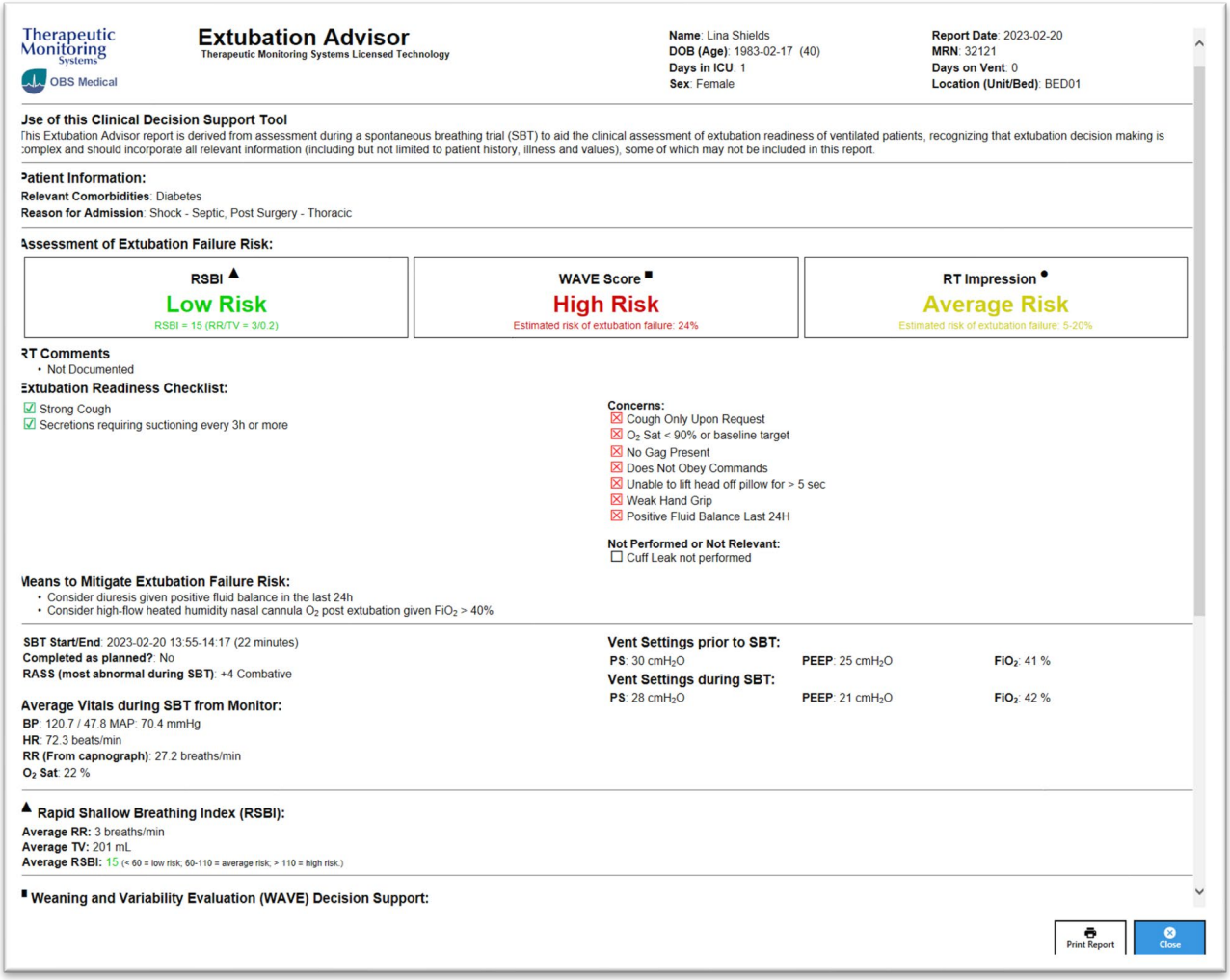
Note: If any items on the **Extubation Readiness Checklist as documented as Unknown** and you decide to continue to generate a report, these unknown items will be detailed under a section called **Not Reviewed.**

Warnings	
	▲ EA is a tool to assist in the complex decisions made in assessing extubation readiness of ventilated patients. It does not replace the clinical judgment of a Clinician.

Printing EA Generated SBT Synoptic Reports

EA can be configured to print the generated reports. Once Print is enabled, you will have an option to **Print** the EA Generated SBT Synoptic Report when reviewing the report by selecting the relevant report via the **SBT Snapshot** table.

1. Select the report from the **SBT Snapshot**
2. Select **Print Report** button.



Note: The Print Report feature will need to be setup by your EA Administrator or IT Department during installation and configuration of the system. If disabled, the Print Report button will be hidden.

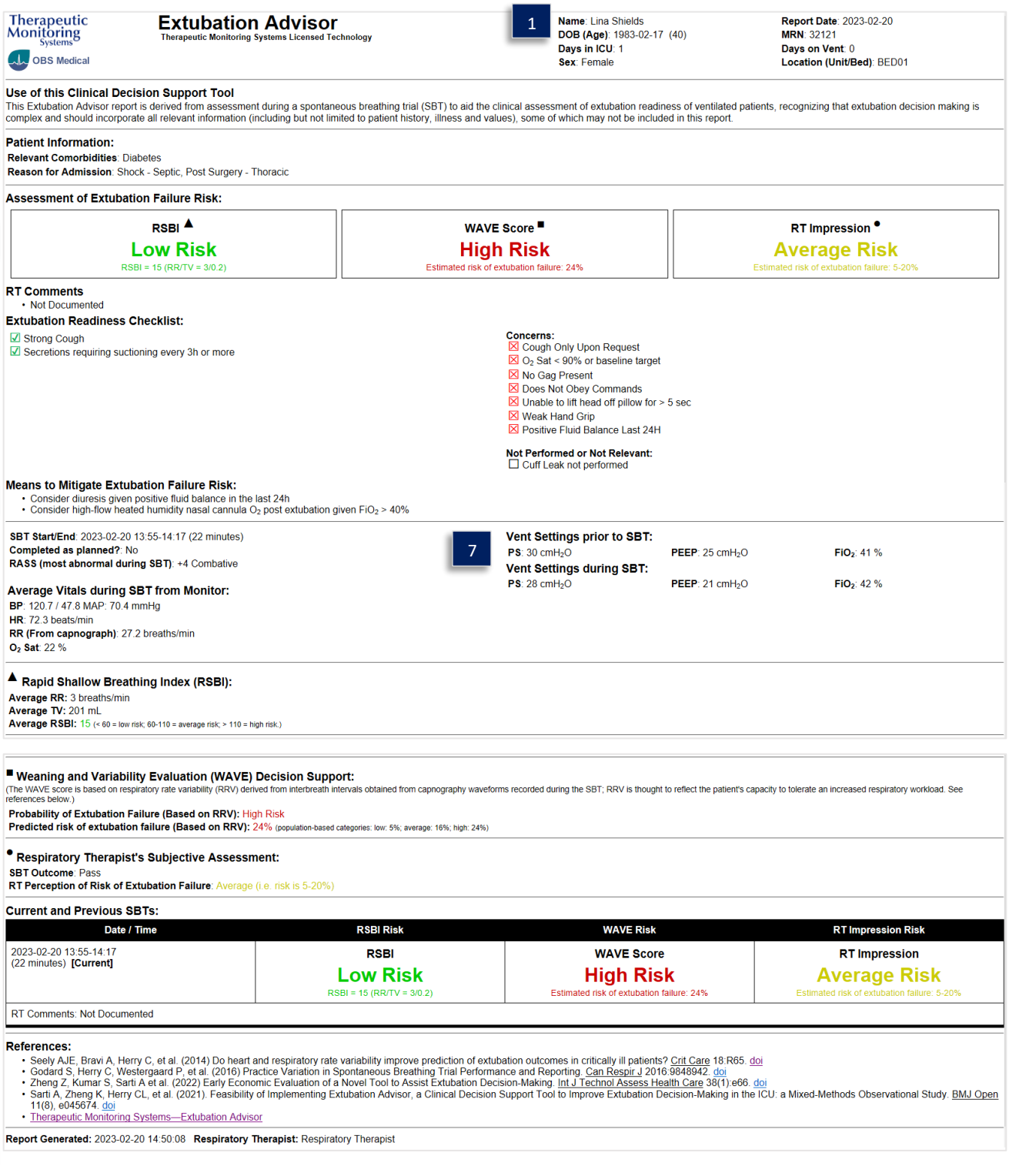
Note: You can review an EA Generated Reports for a selected Patient using the SBT Snapshot Dashboard and clicking on the associated SBT Report.

Note: If **manually printing** the SBT synoptic report as part of your workflow is preferred, it is recommended a **color printer is used.**

Overview of the EA Generated SBT Synoptic Report

EA utilizes best current practices, respiratory rate variability, and the knowledge/expertise of bedside Respiratory Therapists to generate a conclusive report of extubation readiness as well as risk-mitigation strategies to optimize extubation outcomes, and to assist Physicians in the complex decisions made in assessing extubation readiness of ventilated patients.

It does not replace the clinical judgment of a Clinician. The EA Synoptic Report comprises the following sections and components.



Therapeutic Monitoring Systems
OBS Medical

Extubation Advisor
Therapeutic Monitoring Systems Licensed Technology

1
Name: Lina Shields
DOB (Age): 1983-02-17 (40)
Days in ICU: 1
Sex: Female
Report Date: 2023-02-20
MRN: 32121
Days on Vent: 0
Location (Unit/Bed): BED01

Use of this Clinical Decision Support Tool
This Extubation Advisor report is derived from assessment during a spontaneous breathing trial (SBT) to aid the clinical assessment of extubation readiness of ventilated patients, recognizing that extubation decision making is complex and should incorporate all relevant information (including but not limited to patient history, illness and values), some of which may not be included in this report.

2
Patient Information:
Relevant Comorbidities: Diabetes
Reason for Admission: Shock - Septic, Post Surgery - Thoracic

Assessment of Extubation Failure Risk:

3

RSBI ▲	WAVE Score ■	RT Impression ●
Low Risk	High Risk	Average Risk
RSBI = 15 (RR/TV = 3/0.2)	Estimated risk of extubation failure: 24%	Estimated risk of extubation failure: 5-20%

RT Comments
- Not Documented

4
Extubation Readiness Checklist:
☑ Strong Cough
☑ Secretions requiring suctioning every 3h or more

Concerns:
☒ Cough Only Upon Request
☒ O_2 Sat < 90% or baseline target
☒ No Gag Present
☒ Does Not Obey Commands
☒ Unable to lift head off pillow for > 5 sec
☒ Weak Hand Grip
☒ Positive Fluid Balance Last 24H

Not Performed or Not Relevant:
☐ Cuff Leak not performed

5
Means to Mitigate Extubation Failure Risk:
- Consider diuresis given positive fluid balance in the last 24h
- Consider high-flow heated humidity nasal cannula O_2 post extubation given FiO_2 > 40%

SBT Start/End: 2023-02-20 13:55-14:17 (22 minutes)
Completed as planned?: No
RASS (most abnormal during SBT): +4 Combative

7
Vent Settings prior to SBT:
PS: 30 cmH_2O **PEEP**: 25 cmH_2O **FiO_2**: 41 %
Vent Settings during SBT:
PS: 28 cmH_2O **PEEP**: 21 cmH_2O **FiO_2**: 42 %

6
Average Vitals during SBT from Monitor:
BP: 120.7 / 47.8 MAP: 70.4 mmHg
HR: 72.3 beats/min
RR (From capnograph): 27.2 breaths/min
O_2 Sat: 22 %

8
▲ Rapid Shallow Breathing Index (RSBI):
Average RR: 3 breaths/min
Average TV: 201 mL
Average RSBI: 15 (< 60 = low risk; 60-110 = average risk; > 110 = high risk.)

9
■ Weaning and Variability Evaluation (WAVE) Decision Support:
(The WAVE score is based on respiratory rate variability (RRV) derived from interbreath intervals obtained from capnography waveforms recorded during the SBT; RRV is thought to reflect the patient's capacity to tolerate an increased respiratory workload. See references below.)
Probability of Extubation Failure (Based on RRV): High Risk
Predicted risk of extubation failure (Based on RRV): 24% (population-based categories: low: 5%; average: 16%; high: 24%)

10
● Respiratory Therapist's Subjective Assessment:
SBT Outcome: Pass
RT Perception of Risk of Extubation Failure: Average (i.e. risk is 5-20%)

Current and Previous SBTs:

11

Date / Time	RSBI Risk	WAVE Risk	RT Impression Risk
2023-02-20 13:55-14:17 (22 minutes) **[Current]**	RSBI Low Risk (RSBI = 15 (RR/TV = 3/0.2))	WAVE Score High Risk (Estimated risk of extubation failure: 24%)	RT Impression Average Risk (Estimated risk of extubation failure: 5-20%)
RT Comments: Not Documented			

12
References:
- Seely AJE, Bravi A, Herry C, et al. (2014) Do heart and respiratory rate variability improve prediction of extubation outcomes in critically ill patients? Crit Care 18:R65. doi
- Godard S, Herry C, Westergaard P, et al. (2016) Practice Variation in Spontaneous Breathing Trial Performance and Reporting. Can Respir J 2016:9848942. doi
- Zheng Z, Kumar S, Sarti A et al. (2022) Early Economic Evaluation of a Novel Tool to Assist Extubation Decision-Making. Int J Technol Assess Health Care 38(1):e66. doi
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- Therapeutic Monitoring Systems—Extubation Advisor

13
Report Generated: 2023-02-20 14:50:08 **Respiratory Therapist:** Respiratory Therapist

No#	Section / Component	Description
1.	Patient Information	This section is extracted from the patient information found on the patient dashboard.
2.	Admission information	This section is extracted from the hospital admission found on the patient dashboard.
3.	Clinical Indices of extubation failure risk recorded during the SBT	A respiratory rate variability-derived predictive model of workload response by the patient (WAVE score), the rapid shallow breathing index (RSBI), and clinical impression for extubation by Respiratory Therapists.
4.	Extubation Readiness Checklist	This section details the standard readiness checklist completed by RTs on the patient's readiness for endotracheal tube removal.
5.	Means to Mitigate Extubation failure risk	This section and its associated mitigations are only displayed if certain criteria are met from the patients' documented comorbidities, extubation readiness checklist options and the SBT recordings analysis results that increase their risk for extubation failure. The suggestions provided are intended to mitigate extubation failure outcomes should the Team decide to proceed with extubation for an at-risk patient.
6.	SBT Information	This section details the Ventilator settings (PS/PEEP/FiO2) set before and during the SBT, as well as the SBT duration.
7.	Vitals	This section details the average vitals captured during the SBT.
8.	RSBI	RR and VT manually input by the RT as based on the recorded ventilator values during the SBT.
9.	WAVE Decision Support	The WAVE score value and probability of extubation failure.
10.	Respiratory Therapist Assessment	The subjective assessment by the RTs on the patient's readiness for extubation (as extracted from the SBT Outcome checklist.
11.	Historic SBT Table	The dates and times of previous SBT's for the same intubation session, along with the risk indices.
12.	Clinical references	Details on clinical papers relating to Extubation Advisor
13.	Generator details	Details on when the report was generated and by whom

Note: RR (from capnography) in the Vitals section and RR in the RSBI section are different. RR (from capnography) is from the waveforms and RR is manually entered via the RSBI section.

Warnings	▲ EA is a tool to assist in the complex decisions made in assessing extubation readiness of ventilated patients. It does not replace the clinical judgment of a Clinician.

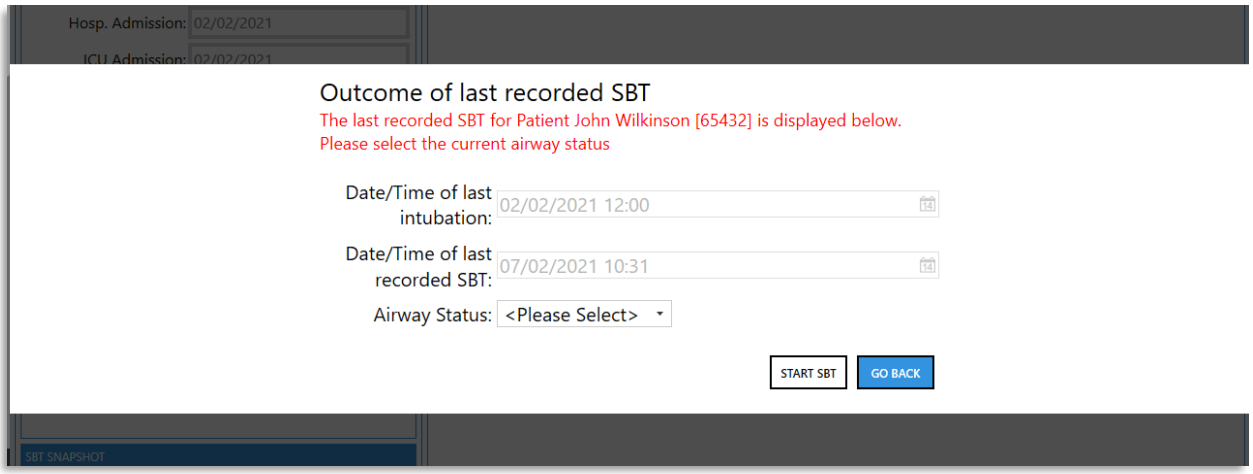
Subsequent SBTs, Extubation, Reintubation and Discharge

Documenting Subsequent SBTs

EA can be run multiple times, providing updated SBT performance, prediction of extubation failure reports and clinical assessment, to be used when considering extubation.

To document **subsequent SBTs for a patient**, for the same admission and intubation session:

1. Select the patient from the Patient Roster and select the **Perform SBT** button.
2. Document the **outcome of the last recorded SBT.**
    - The date / time of the last intubation will be displayed.
    - The date / time of the last recorded SBT will be displayed.



3. Document the patient's airway status prior to the new SBT:

Airway Status		**Still Intubated**
		Planned Extubation
		Self Extubated
		Tracheostomy

4. Select the **Start SBT** button to proceed to document the **subsequent SBT as required**.

Note: The previously documented **Admission Information** will be retained. However, you should always check the Admission Information and update it accordingly, to ensure any future generated SBT Synoptic Reports are correct.

Documenting an Extubation

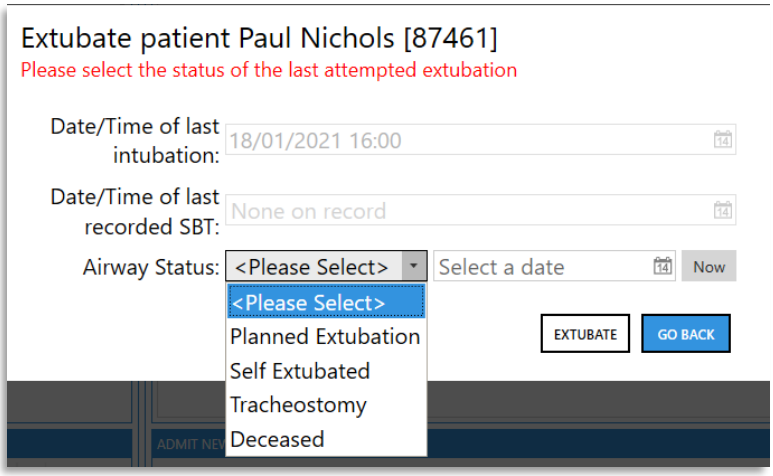
To document an **extubation**, choose the patient you wish to update, then select the **Extubate** button via the **Patient Roster**.

The **Extubate** button is only available to those patients who have intubation Information documented. The system will detail both the **intubation date / time** as well as **date / time** for the last **recorded SBT.**

1. Select the **patients current Airways Status** from the available options:

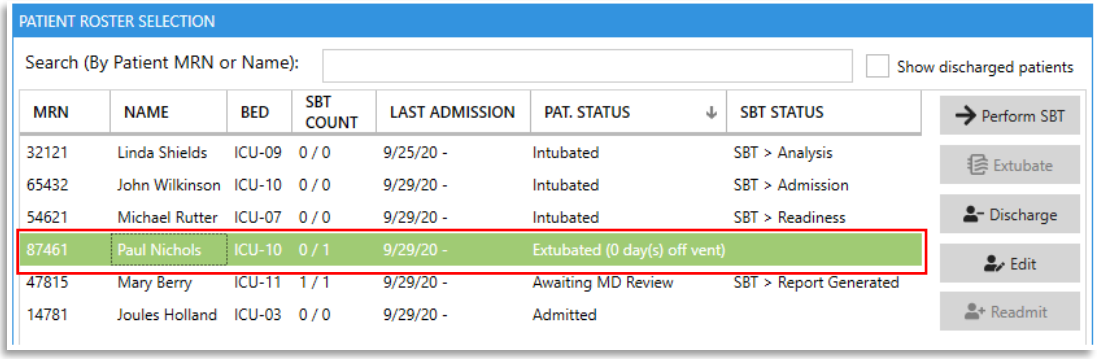
Airway Status		Planned Extubation
		Self Extubation
		Tracheostomy
		Deceased

2. Document the **associated date and hour** when the extubation occurred selecting the approritae Airway Status.



3. Select the **Extubate** button. You will then be returned to the Patient Roster.

4. The Patient Roster will then display the **updated extubation status** under the **Pat. Status column.**

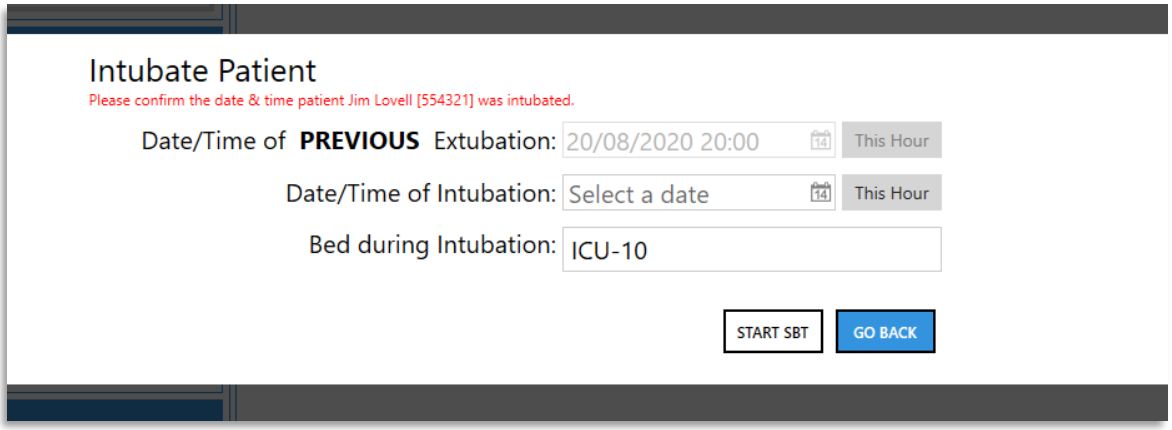


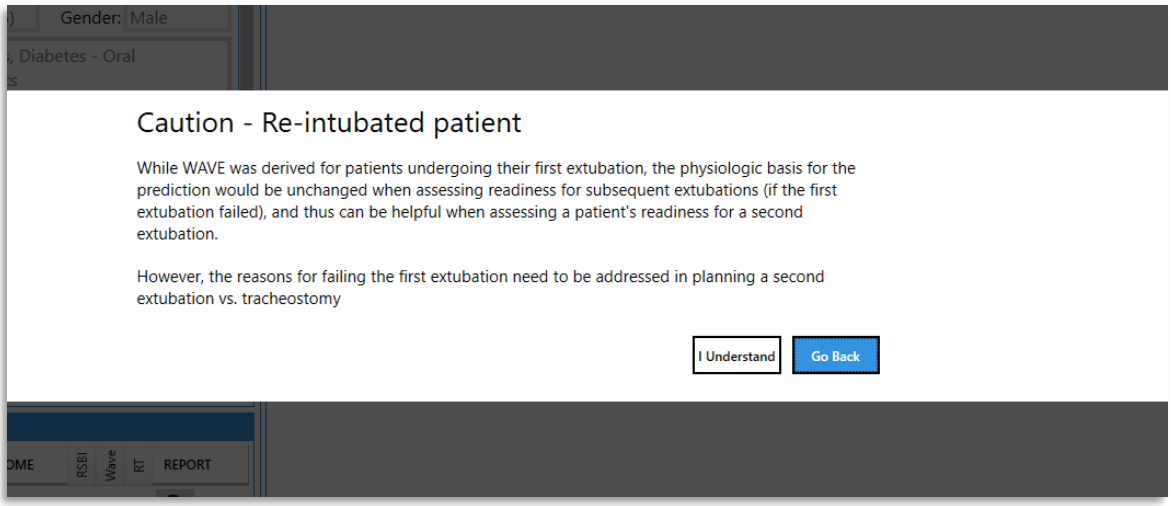
Note: The **Extubate button** is only available to patients who have had **Intubation Information** documented.

Documenting a Reintubation

To document a **Reintubation**, select the **extubated patient** you wish to update, then select the **Perform SBT** button via the **Patient Roster** and complete the form as required.

6. The patients **Previous Extubation date and time** will be displayed.
7. Document the **Date and Time for the new intubation.**
8. Document the **Bed location for the new intubation.**
9. Press the **Start SBT** button.
10. Review the **dialog message displayed** and **confirm I Understand to proceed** or **Go Back** to decline to proceed to document future SBT's for the Reintubated patient using EA.





Note: The patient's location (Unit/Bed) can be updated whenever a new SBT is performed.

Caution

⚠ While WAVE was derived for patients undergoing their first extubation, the physiologic basis for the prediction would be unchanged when assessing readiness for subsequent extubations (if the first extubation failed), and thus may be helpful when assessing a patient's readiness for a second extubation.

However, the reasons for failing the first extubation need to be addressed in planning a second extubation vs. tracheostomy.

Discharging a Patient from the Patient Roster

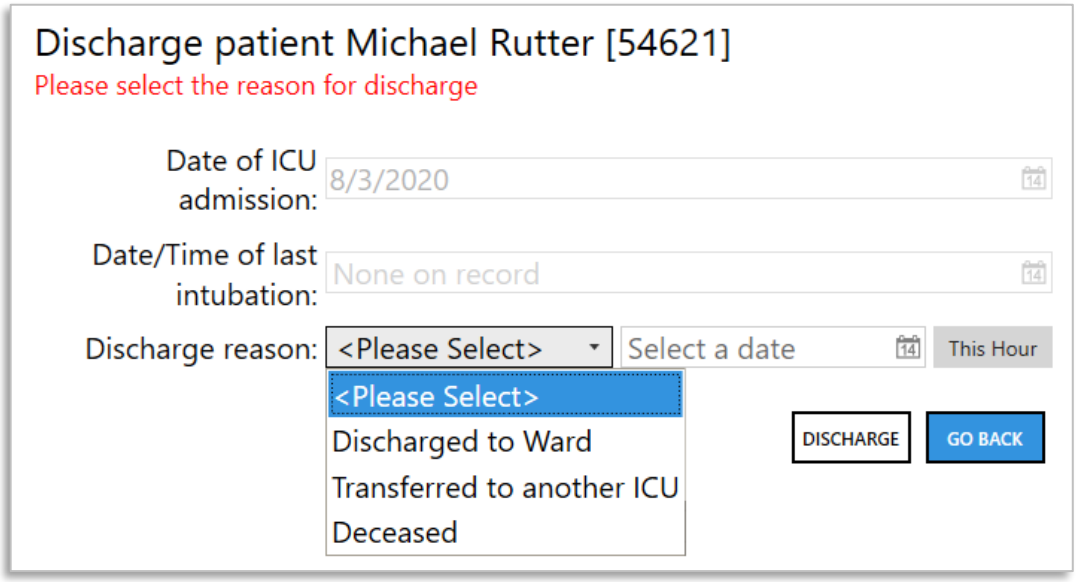
To discharge a patient from the Patient Roster, select the **Discharge** button via the **Patient Roster** and complete the form as required. You should only discharge a patient from EA after they have been discharged from the Unit.

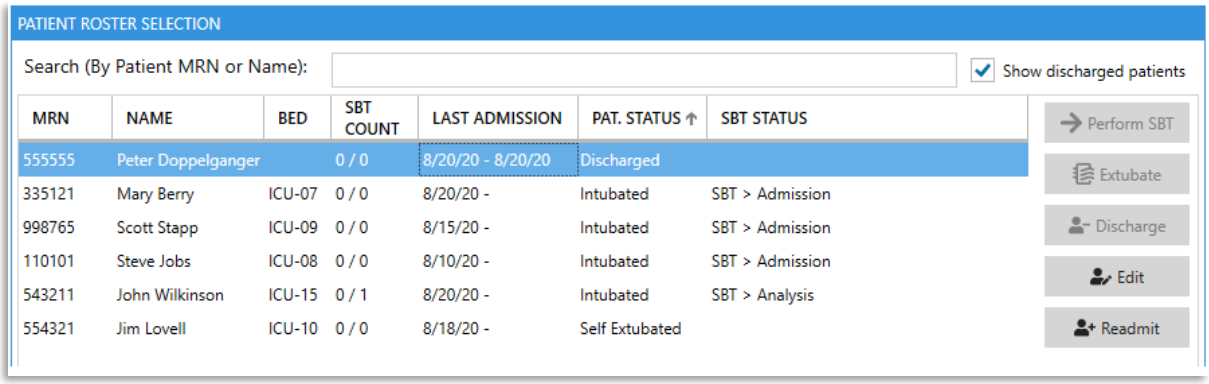
The **Discharge** button is only available to those patients who have had their **Extubation Information** documented or have not had any **SBT documented**.

1. Select the **Discharge reason** from the available options:

Discharge Reason		**Discharged to Ward**
		Transferred to another ICU
		Deceased

2. Document the associated discharge **date and hour** as required.
3. Select the **Discharge** button. You will then be returned to the **Patient Roster**.
4. To view discharged patients, select the **Show discharged patients' checkbox.**
5. The Patient Roster will then update to include discharged patients as highlighted by the **Pat. Status column.**



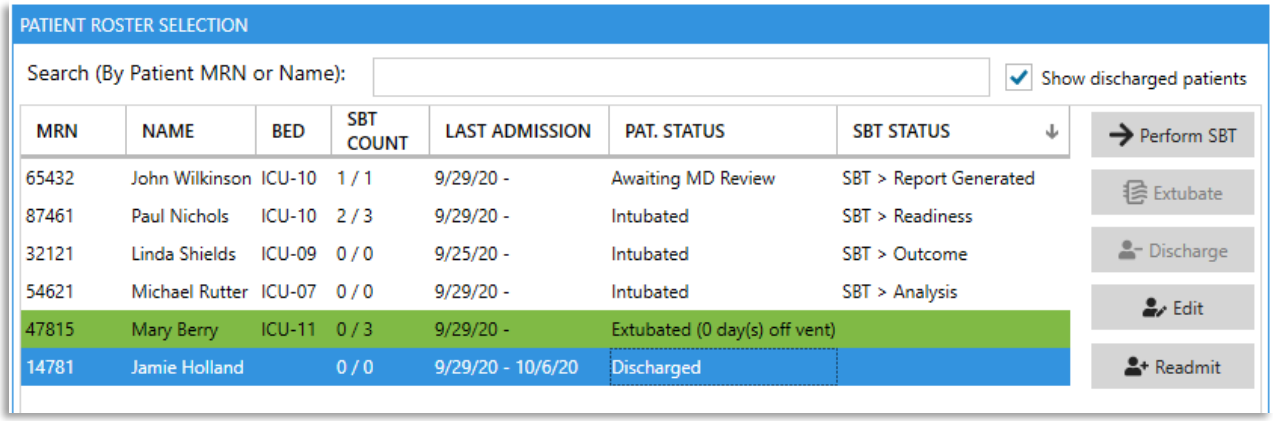


Note: The **Discharge** button is only available to those patients who have had their **Extubation Information** documented or have not had any **SBT documented**.

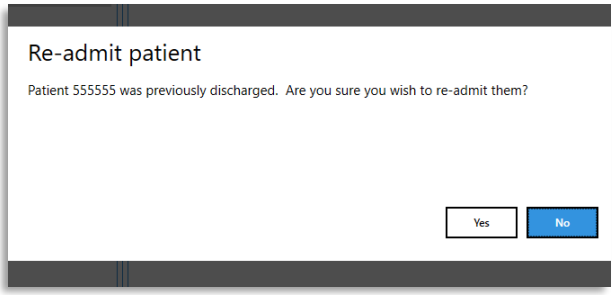
Readmitting a previously discharged Patient

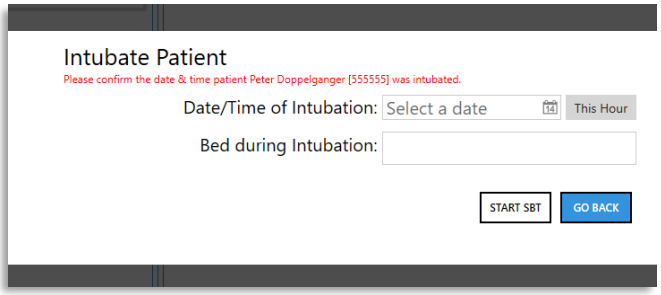
If for any reason you are required to **readmit a patient previously admitted and discharged using EA,** then you will need to action the following:

1. Enable the **Show discharged patients' checkbox** via the Patient Roster.



2. **Search for the discharged patient** using the Patient MRN or Name.
3. Select the patient you wish to readmit, and then **select the Readmit button.**
4. A dialogue message will be displayed asking you to confirm if you wish to **Re-admit the selected patient** [Their MRN will be displayed].
5. Select **Yes**.





6. Now **document the Date/Time of Intubation and Bed Location** for the current intubation for the re-admitted patient.
7. Select the **Start SBT** button.

The **readmitted patient** will now be displayed in the **Patient Roster** along with the new intubation date/time and BED location as documented.

Note: Only the patients **current admission information will be displayed**. You will need to document the patients **Admission Reason and Comorbidity information** as if they were a new patient.

Note: The previous Admission and Comorbidity information, as well as any historic SBT's and Reports for the readmitted patient are no longer available to access and review within the application itself, until the patient is discharged again. At this point, all documented SBT's and associated reports for all admissions are displayed and available to review within the application.

Troubleshooting and Incident Reporting

If any problems or unexpected operation errors are detected during the setup, use or maintenance of the Extubation Advisor product, please contact your OBS Medical representative. Alternatively, you can refer to the OBS Medical Ltd contact information on the back page of this manual. For any technical issues experienced, please contact your System Administrator.

Note: A printed copy of this user guide is also available on request. Please contact your local representative as required.

Problem	Cause & Solution
"Invalid license" is displayed on the login screen. RT or Data Manager users cannot login.	The system's trial or purchased license has expired. Please instruct your IT/purchasing department to contact OBS Medical to discuss renewal options.
"Thank you for evaluating Extubation Advisor" is displayed on the login screen.	The system is currently functioning using a trial license which will usually mean the 30-day trial license pre-installed with the software. You can continue to use Extubation Advisor normally during your evaluation period.
"Your license is due to expire in X days" is displayed in the login screen.	The systems license will shortly expire. Please instruct your IT/purchasing department to contact OBS Medical to discuss renewal options. and prevent being locked out of the system.
An error is displayed when trying to import or activate my license file.	Please instruct your IT/purchasing department to contact OBS Medical as the license key may have been issued with incorrect information for the machine.
Extubation Advisor will not connect to the monitor	Monitor incorrectly configured, incorrectly connected, or not supported. Please instruct your IT department to check: • The application is configured to connect to the correct type of bedside monitor • The monitor is supported by Extubation Advisor. Refer to the monitor compatibility list for more information (Part number: 011-1032-MM) • The cable is connected to the monitor in the correct port. Philips typically use RJ45 port connectors for both LAN and Serial connections. • The cable is correct for the monitor in use and is not damaged. Refer to the monitor user guide for more information. • Refer to installation and configuration guide (Part number:011-1015-LMAN)

Problem	Cause & Solution
Extubation Advisor connects to the monitor, but a CO2 signal is not detected.	Monitor incorrectly configured, incorrectly connected, or not supported. Please check: • The CO2 module is installed correctly on the monitor in accordance with the manufacturer's instructions. • The CO2 sensor is correctly installed in the patient's breathing circuit in accordance with the manufacturer's instructions. • The monitor itself is outputting a valid CO2 signal on its display.
Centralized Database Connection error	EA will display a critical error if the connection to a configured database is dropped due to poor network connectivity. At this point EA will not allow you to proceed until the connection is re-established. Network related critical errors should be reported to your System Administrator even if they resolve by themselves when the connection is re-established.
Centralized Database – Concurrency Error	EA will display an error when a user attempts to update the system while another user is also updating the same patient. The second user will be returned to the Patient Roster and required to repeat their actions if the first user's updates did not resolve the original need for the update

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