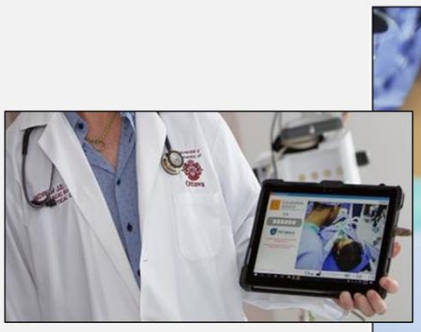


LEADS Trial
Extubation Advisor

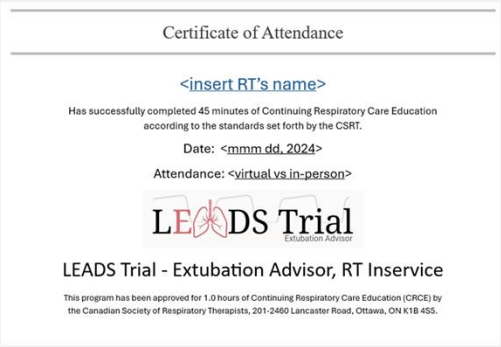
RT training tool for the LEADS Trial and navigation of Extubation Advisor

RRT LEADS Training:
Approved for 1.0 CSRT CPD credit

Please provide your name and e-mail to the chat section of this meeting (or e-mail elee@toh.ca) to receive a certification of attendance for this training session.

The LEADS Trial also requires a list of RT Trainees at each site.

Thank you.



Certificate of Attendance

<insert RT's name>

Has successfully completed 45 minutes of Continuing Respiratory Care Education according to the standards set forth by the CSRT.

Date: <mmm dd, 2024>

Attendance: <virtual vs in-person>

LEADS Trial - Extubation Advisor, RT Inservice

This program has been approved for 1.0 hours of Continuing Respiratory Care Education (CRCE) by the Canadian Society of Respiratory Therapists, 201-2460 Lancaster Road, Ottawa, ON K1B 4S5.

LEADS Trial - RT Training Learning Objectives

1. Understand the study's purpose, study flow, and RT responsibilities
2. Understand other RT responsibilities for the LEADS Trial

   Including: completing study case report forms, reviewing the EA report with the physician and obtaining the physician's completed questionnaire
3. Understand the purpose of Extubation Advisor (EA) and how to use it;

   Including: connecting laptop/tablet (with EA) to the patient monitor, entering patient data, generating and understanding the components of the EA report, printing off the report (for multidisciplinary review)
4. Know where to obtain the EA PIN ID (unique login code for each RT)
5. How to access support during the study

Therapeutic Monitoring Systems

LEADS Trial Extubation Advisor

About Extubation Advisor

- Extubation Advisor (EA) is a clinical decision support tool that evaluates risk of extubation failure
- EA is installed on a laptop or tablet, which attaches directly to the patient's monitor during a spontaneous breathing trial (SBT) to capture real-time patient performance and clinical presentation
- Extubation Advisor is designed to provide:
  - *A comprehensive evaluation of extubation risk*
    - RSBI / WAVE SCORE / RT's IMPRESSION / PATIENT RISK FACTORS
  - *A standardized extubation readiness assessment*
  - *Individualized risk mitigation strategies*

Extubation Advisor (EA) is the first clinical decision support tool to provide prediction of extubation outcomes by real-time bedside analysis of patient performance during spontaneous breathing trials (SBT) currently unavailable with standard-of-care monitoring.

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 provide risk-mitigation strategies, to optimize extubation outcomes.

The LEADS Trial – A Pilot Study

*Liberation from mechanical ventilation using **EA** Decision **S**upport – **The LEADS Trial***

- Extubation assessment and decision making is a complex and high-stakes clinical decision, yet it is performed variably with inadequate prediction of how the patient will do.

- The LEADS Trial is a randomized control trial designed to evaluate feasibility, usefulness, and resource utilization between:
  a) standard of care evaluation, and
  b) implementation of the Extubation Advisor clinical support tool

Therapeutic Monitoring Systems

LEADS Trial
Extubation Advisor

The LEADS Trial – A Pilot Study

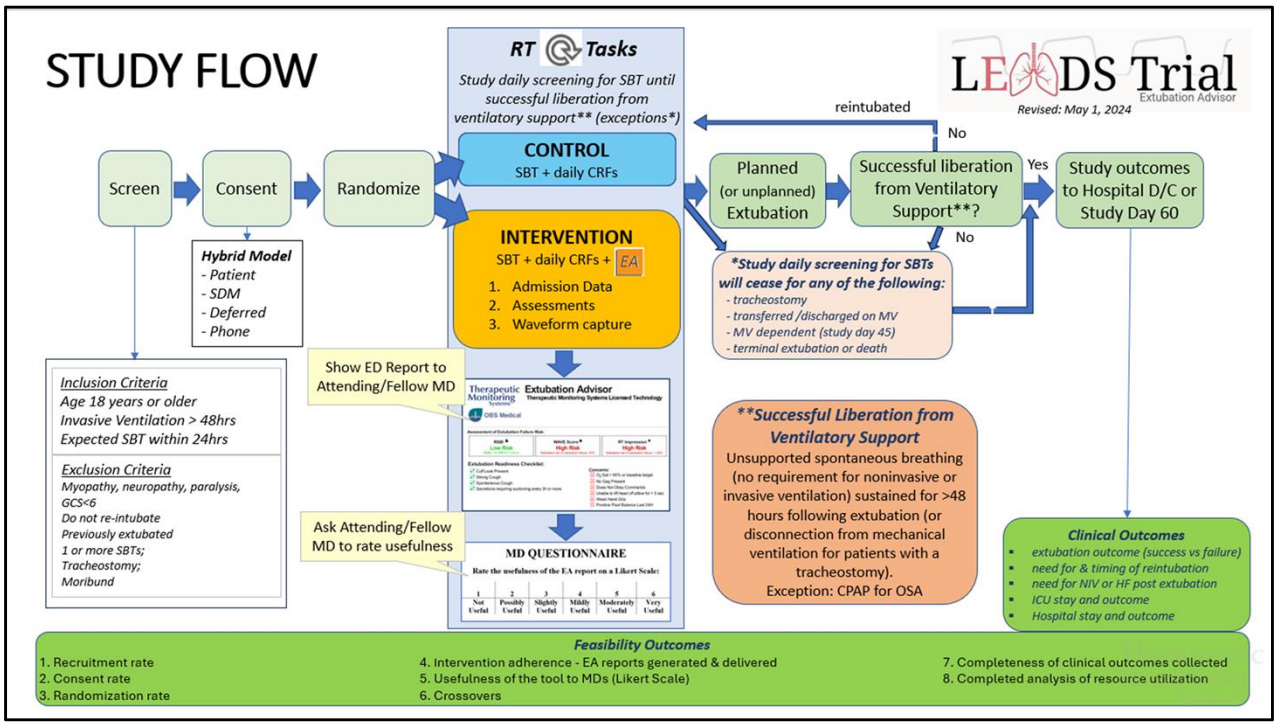
- **Patients:**

  Critically ill adults, invasively ventilated for ≥48 hours, ready to undergo an SBT with a view to extubation.

- Enrollment of 100 patients across 10+centres, randomized 1:1 (intervention : control)

- **Primary Objective:**

  Evaluate feasibility - study will be considered feasible if 1-2 patients are enrolled per centre per month (pilot phase)


STUDY FLOW
RT Tasks
Study daily screening for SBT until successful liberation from ventilatory support** (exceptions*)
LEADS Trial
Extubation Advisor
Revised: May 1, 2024
reintubated
No
Screen
Consent
Randomize
CONTROL
SBT + daily CRFs
INTERVENTION
SBT + daily CRFs + EA
1. Admission Data
2. Assessments
3. Waveform capture
Planned (or unplanned) Extubation
Successful liberation from Ventilatory Support**?
Yes
Study outcomes to Hospital D/C or Study Day 60
No
Hybrid Model
- Patient
- SDM
- Deferred
- Phone
*Study daily screening for SBTs will cease for any of the following:
- tracheostomy
- transferred /discharged on MV
- MV dependent (study day 45)
- terminal extubation or death
Inclusion Criteria
Age 18 years or older
Invasive Ventilation > 48hrs
Expected SBT within 24hrs
Exclusion Criteria
Myopathy, neuropathy, paralysis, GCS<6
Do not re-intubate
Previously extubated
1 or more SBTs;
Tracheostomy;
Moribund
Show ED Report to Attending/Fellow MD
Therapeutic Monitoring Extubation Advisor
Ask Attending/Fellow MD to rate usefulness
MD QUESTIONNAIRE
Rate the usefulness of the EA report on a Likert Scale:
Not Useful
Possibly Useful
Slightly Useful
Mildly Useful
Moderately Useful
Very Useful
**Successful Liberation from Ventilatory Support
Unsupported spontaneous breathing (no requirement for noninvasive or invasive ventilation) sustained for >48 hours following extubation (or disconnection from mechanical ventilation for patients with a tracheostomy).
Exception: CPAP for OSA
Clinical Outcomes
extubation outcome (success vs failure)
need for & timing of reintubation
need for NIV or HF post extubation
ICU stay and outcome
Hospital stay and outcome
Feasibility Outcomes
1. Recruitment rate
2. Consent rate
3. Randomization rate
4. Intervention adherence - EA reports generated & delivered
5. Usefulness of the tool to MDs (Likert Scale)
6. Crossovers
7. Completeness of clinical outcomes collected
8. Completed analysis of resource utilization

The LEADS Trial - Randomization

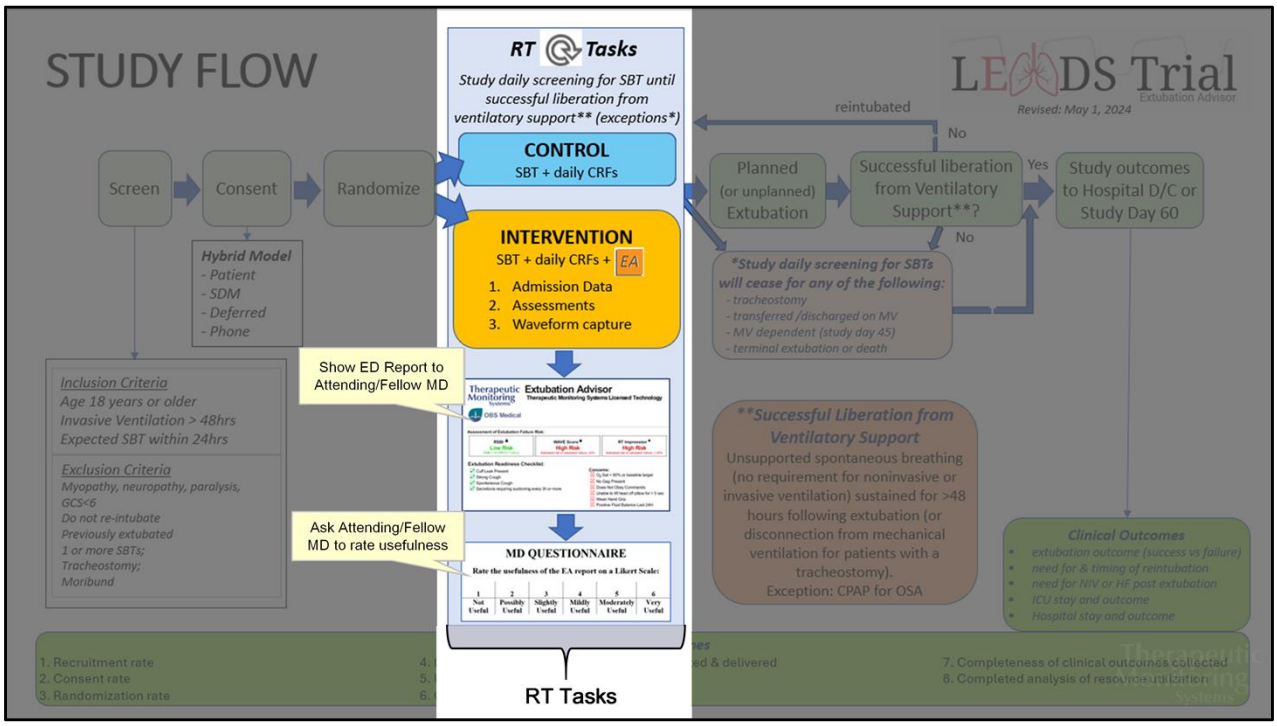
The Research Coordinator will randomize each study patient into one of two study groups:

Control Group:

+ Patients in the control arm will receive standard care for evaluating extubation readiness (without EA)

Intervention Group:

+ Patients in the intervention group will receive standard of care for evaluating extubation readiness with use of EA. A SBT summary will be generated by EA to help guide (*not direct*) extubation decision making.



RT involvement for the LEADS Trial

The LEADS Trial – RT Role

- RTs play an essential role in the LEADS trial to implement EA at the bedside and to provide user feedback on tool feasibility.

- RTs will be involved in the following trial components:
  - Control group: perform standard of care SBT (without EA)
  - Interventional group: Bedside setup, patient input into the EA roster, completion of EA forms/checklists, run SBT through EA, review the EA report with the MD *prior* to extubation decision-making (*MD to complete Usefulness Questionnaire*)
  - **Both groups**: complete *Form 6* – Daily Data Form, +/- Form 8 – Protocol Violations

  +/- Form 11 – Extubation Advisor Related Adverse Events, +/- Form 9 Adverse Event/Serious Adverse Event Form

Therapeutic Monitoring Systems

The LEADS Trial – RT Workflow: Intervention Group

RT attaches Extubation Advisor to the patient monitor (bedside or portable) with continuous capnography

RT enters basic information into EA interface including SBT parameters and extubation checklist

SBT initiated in usual manner, as per institutional practice

SBT completed

EA report generated (one EA report / SBT completed)

Multidisciplinary team reviews EA report, makes extubation decision

MD to complete Usefulness Questionnaire, RT to complete Form 6

Repeat steps above until patient is successfully extubated

*RTs will follow the study procedures (outlined above) until **Successful Extubation*** (or until transfer/discharge from ICU on mechanical ventilation, tracheostomy, or death)*

The LEADS Trial – RT Workflow: Control group

RT initiates SBT in usual manner, as per institutional practice

SBT completed

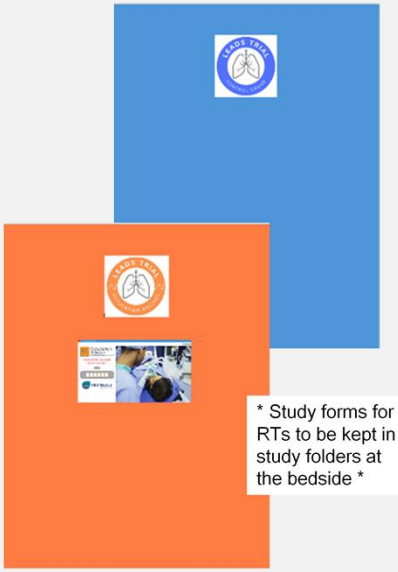
Multidisciplinary team makes extubation decision, RT to complete Form 6

Repeat steps above until patient is successfully extubated

*RTs will follow the study procedures (outlined above) until **Successful Extubation*** (or until transfer/discharge from ICU on mechanical ventilation, tracheostomy, or death)*

Therapeutic Monitoring Systems

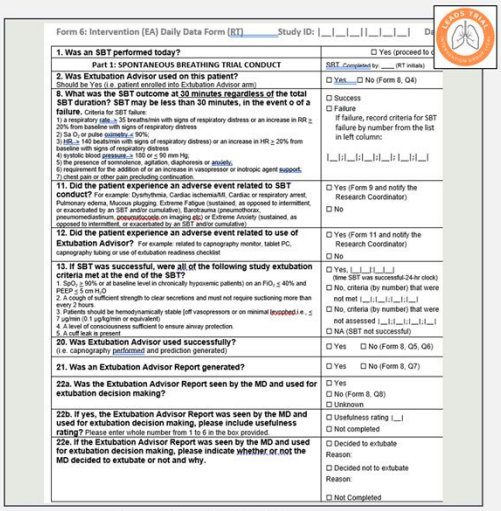
The LEADS Trial – Case Report Forms (For RTs)



* Study forms for RTs to be kept in study folders at the bedside *

Therapeutic Monitoring Systems

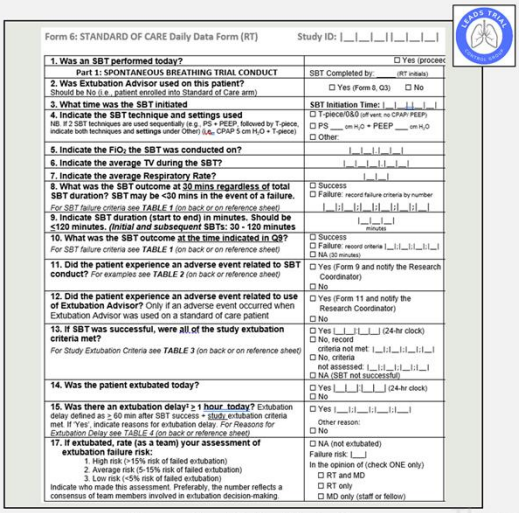
The LEADS Trial – Case Report Forms (For RTs)



Form 6: Intervention (EA) Daily Data Form (RT) Study ID: |__|__|__| |__|__|__|__|

1. Was an SBT performed today?	☐ Yes (proceed to c
Part 1: SPONTANEOUS BREATHING TRIAL CONDUCT	SBT Completed by: ____ (RT initials)
2. Was Extubation Advisor used on this patient? Should be Yes (i.e. patient enrolled into Extubation Advisor arm)	☐ Yes ☐ No (Form 8, Q4)
8. What was the SBT outcome at 30 minutes regardless of the total SBT duration? SBT may be less than 30 minutes, in the event o of a failure. Criteria for SBT failure: 1) a respiratory rate ≥ 35 breaths/min with signs of respiratory distress or an increase in RR ≥ 20% from baseline with signs of respiratory distress 2) Sa O_2 or pulse oximetry < 90%; 3) HR ≥ 140 beats/min with signs of respiratory distress) or an increase in HR ≥ 20% from baseline with signs of respiratory distress 4) systolic blood pressure > 180 or ≤ 90 mm Hg; 5) the presence of somnolence, agitation, diaphoresis or anxiety; 6) requirement for the addition of or an increase in vasopressor or inotropic agent support; 7) chest pain or other pain precluding continuation.	☐ Success ☐ Failure If failure, record criteria for SBT failure by number from the list in left column: |__|:|__|:|__|:|__|:|__|:|__|
11. Did the patient experience an adverse event related to SBT conduct? For example: Dysrhythmia, Cardiac ischemia/MI, Cardiac or respiratory arrest, Pulmonary edema, Mucous plugging, Extreme Fatigue (sustained, as opposed to intermittent, or exacerbated by an SBT and/or cumulative), Barotrauma (pneumothorax, pneumomediastinum, pneumatocoele on imaging etc) or Extreme Anxiety (sustained, as opposed to intermittent, or exacerbated by an SBT and/or cumulative).	☐ Yes (Form 9 and notify the Research Coordinator) ☐ No
12. Did the patient experience an adverse event related to use of Extubation Advisor? For example: related to capnography monitor, tablet PC, capnography tubing or use of extubation readiness checklist	☐ Yes (Form 11 and notify the Research Coordinator) ☐ No
13. If SBT was successful, were all of the following study extubation criteria met at the end of the SBT? 1. $SpO_2 \geq 90\%$ or at baseline level in chronically hypoxemic patients) on an $FiO_2 \leq 40\%$ and PEEP ≤ 5 cm H_2O 2. A cough of sufficient strength to clear secretions and must not require suctioning more than every 2 hours. 3. Patients should be hemodynamically stable (off vasopressors or on minimal levophed i.e., ≤ 7 µg/min (0.1 µg/kg/min or equivalent) 4. A level of consciousness sufficient to ensure airway protection. 5. A cuff leak is present	☐ Yes, |__|__|:|__|__| (time SBT was successful-24-hr clock) ☐ No, criteria (by number) that were not met |__|:|__|:|__|:|__|:|__| ☐ No, criteria (by number) that were not assessed |__|:|__|:|__|:|__| ☐ NA (SBT not successful)
20. Was Extubation Advisor used successfully? (i.e. capnography performed and prediction generated)	☐ Yes ☐ No (Form 8, Q5, Q6)
21. Was an Extubation Advisor Report generated?	☐ Yes ☐ No (Form 8, Q7)
22a. Was the Extubation Advisor Report seen by the MD and used for extubation decision making?	☐ Yes ☐ No (Form 8, Q8) ☐ Unknown
22b. If yes, the Extubation Advisor Report was seen by the MD and used for extubation decision making, please include usefulness rating? Please enter whole number from 1 to 6 in the box provided.	☐ Usefulness rating |__| ☐ Not completed
22e. If the Extubation Advisor Report was seen by the MD and used for extubation decision making, please indicate whether or not the MD decided to extubate or not and why.	☐ Decided to extubate Reason: ☐ Decided not to extubate Reason: ☐ Not Completed

Form 6 – Daily Data Form
(Intervention Group)



Form 6: STANDARD OF CARE Daily Data Form (RT) Study ID: |__|__|__| |__|__|__|__|

1. Was an SBT performed today?	☐ Yes (proceed
Part 1: SPONTANEOUS BREATHING TRIAL CONDUCT	SBT Completed by: ____ (RT initials)
2. Was Extubation Advisor used on this patient? Should be No (i.e., patient enrolled into Standard of Care arm)	☐ Yes (Form 8, Q3) ☐ No
3. What time was the SBT initiated	SBT Initiation Time: |__|__|:|__|__|
4. Indicate the SBT technique and settings used NB. If 2 SBT techniques are used sequentially (e.g., PS + PEEP, followed by T-piece, indicate both techniques and settings under Other) (i.e., CPAP 5 cm H_2O + T-piece)	☐ T-piece/0&0 (off vent; no CPAP/ PEEP) ☐ PS ____ cm H_2O + PEEP ____ cm H_2O ☐ Other:
5. Indicate the FiO_2 the SBT was conducted on?	|__|__|.|__|__|
6. Indicate the average TV during the SBT?	|__|__|.|__|__|
7. Indicate the average Respiratory Rate?	|__|__|
8. What was the SBT outcome at 30 mins regardless of total SBT duration? SBT may be <30 mins in the event of a failure. *For SBT failure criteria see TABLE 1 (on back or on reference sheet)*	☐ Success ☐ Failure: record failure criteria by number |__|:|__|:|__|:|__|:|__|:|__|
9. Indicate SBT duration (start to end) in minutes. Should be ≤120 minutes. (Initial and subsequent SBTs: 30 - 120 minutes	|__|__|__| minutes
10. What was the SBT outcome at the time indicated in Q9? *For SBT failure criteria see TABLE 1 (on back or on reference sheet)*	☐ Success ☐ Failure: record criteria |__|:|__|:|__|:|__| ☐ NA (30 minutes)
11. Did the patient experience an adverse event related to SBT conduct? *For examples see TABLE 2 (on back or reference sheet)*	☐ Yes (Form 9 and notify the Research Coordinator) ☐ No
12. Did the patient experience an adverse event related to use of Extubation Advisor? Only if an adverse event occurred when Extubation Advisor was used on a standard of care patient	☐ Yes (Form 11 and notify the Research Coordinator) ☐ No
13. If SBT was successful, were all of the study extubation criteria met? *For Study Extubation Criteria see TABLE 3 (on back or on reference sheet)*	☐ Yes |__|__|:|__|__| (24-hr clock) ☐ No, record criteria not met: |__|:|__|:|__|:|__| ☐ No, criteria not assessed: |__|:|__|:|__|:|__| ☐ NA (SBT not successful)
14. Was the patient extubated today?	☐ Yes |__|__|:|__|__| (24-hr clock) ☐ No
15. Was there an extubation delay[1] ≥ 1 hour today? Extubation delay defined as ≥ 60 min after SBT success + study extubation criteria met. If 'Yes', indicate reasons for extubation delay. *For Reasons for Extubation Delay see TABLE 4 (on back or reference sheet)*	☐ Yes |__|__|:|__|__|:|__|__| Other reason: ☐ No
17. If extubated, rate (as a team) your assessment of extubation failure risk: 1. High risk (>15% risk of failed extubation) 2. Average risk (5-15% risk of failed extubation) 3. Low risk (<5% risk of failed extubation) Indicate who made this assessment. Preferably, the number reflects a consensus of team members involved in extubation decision-making.	☐ NA (not extubated) Failure risk: |__|__| In the opinion of (check ONE only) ☐ RT and MD ☐ RT only ☐ MD only (staff or fellow)

Form 6 – Daily Data Form
(Control Group – Standard of Care)

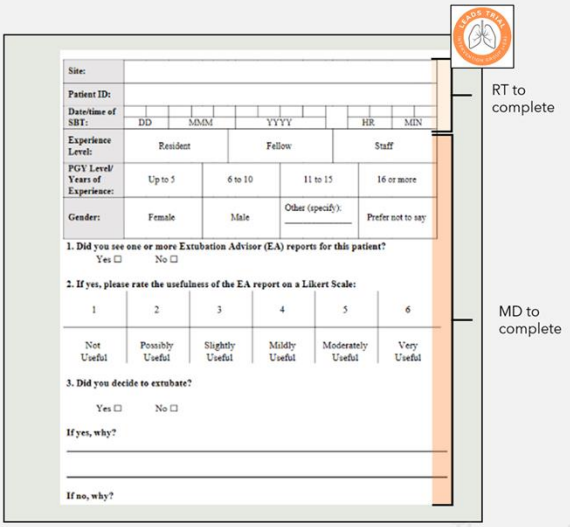
Therapeutic Monitoring Systems

After SBT completion, RT to complete the SBT outcome column in ***Form 6*** – *Daily Data Form,* for both study arms. Form 6 to be completed once daily while the patient undergoes SBTs.

The LEADS Trial – MD Usefulness Questionnaire

Intervention group:

- After each SBT performed with EA, review the generated report with the MD (Attending or Fellow) prior to extubation decision making
- Reviewing MD to complete Usefulness Questionnaire →



Site:				
Patient ID:				
Date/time of SBT:	DD MMM YYYY		HR MIN	
Experience Level:	Resident	Fellow	Staff	
PGY Level/ Years of Experience:	Up to 5	6 to 10	11 to 15	16 or more
Gender:	Female	Male	Other (specify):	Prefer not to say

1. Did you see one or more Extubation Advisor (EA) reports for this patient?
Yes ☐ No ☐

2. If yes, please rate the usefulness of the EA report on a Likert Scale:

1	2	3	4	5	6
Not Useful	Possibly Useful	Slightly Useful	Mildly Useful	Moderately Useful	Very Useful

3. Did you decide to extubate?
Yes ☐ No ☐

If yes, why?

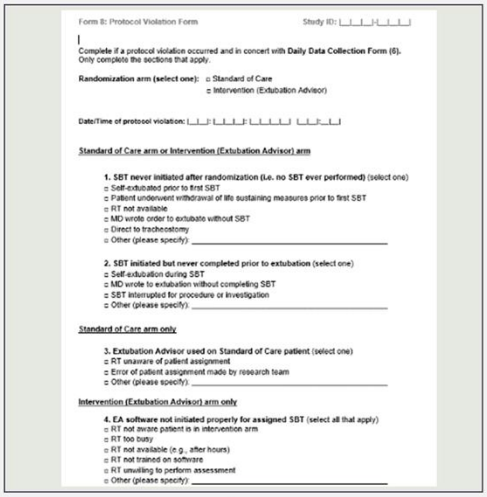
If no, why?

RT to complete

MD to complete

MD Usefulness Questionnaire

The LEADS Trial – Case Report Forms (For RTs)



Form 8: Protocol Violation Form Study ID: |_|_|_|-|_|_|_|

Complete if a protocol violation occurred and in concert with **Daily Data Collection Form (6).**
Only complete the sections that apply.

Randomization arm (select one): ¤ Standard of Care
¤ Intervention (Extubation Advisor)

Date/Time of protocol violation: |_|_|-|_|_|_|-|_|_|_|_| |_|_|:|_|_|

Standard of Care arm or Intervention (Extubation Advisor) arm

1. SBT never initiated after randomization (i.e. no SBT ever performed) (select one)
¤ Self-extubated prior to first SBT
¤ Patient underwent withdrawal of life sustaining measures prior to first SBT
¤ RT not available
¤ MD wrote order to extubate without SBT
¤ Direct to tracheostomy
¤ Other (please specify): _____

2. SBT initiated but never completed prior to extubation (select one)
¤ Self-extubation during SBT
¤ MD wrote to extubation without completing SBT
¤ SBT interrupted for procedure or investigation
¤ Other (please specify): _____

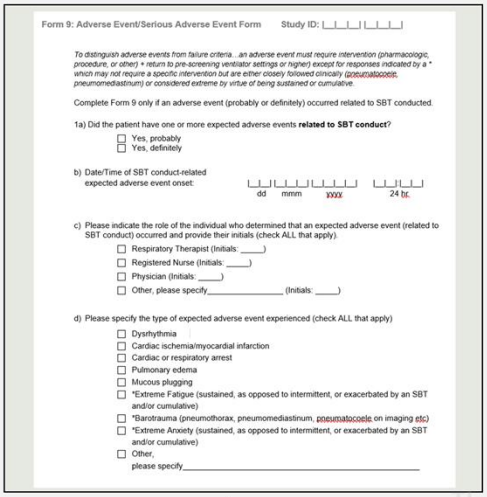
Standard of Care arm only

3. Extubation Advisor used on Standard of Care patient (select one)
¤ RT unaware of patient assignment
¤ Error of patient assignment made by research team
¤ Other (please specify): _____

Intervention (Extubation Advisor) arm only

4. EA software not initiated properly for assigned SBT (select all that apply)
¤ RT not aware patient is in intervention arm
¤ RT too busy
¤ RT not available (e.g., after hours)
¤ RT not trained on software
¤ RT unwilling to perform assessment
¤ Other (please specify): _____

Form 8 – Protocol Violation Form



Form 9: Adverse Event/Serious Adverse Event Form Study ID: |_|_|_|-|_|_|_|

*To distinguish adverse events from failure criteria…an adverse event must require intervention (pharmacologic, procedure, or other) + return to pre-screening ventilator settings or higher) except for responses indicated by a * which may not require a specific intervention but are either closely followed clinically (pneumatocoele, pneumomediastinum) or considered extreme by virtue of being sustained or cumulative.*

Complete Form 9 only if an adverse event (probably or definitely) occurred related to SBT conducted.

1a) Did the patient have one or more expected adverse events **related to SBT conduct**?
☐ Yes, probably
☐ Yes, definitely

b) Date/Time of SBT conduct-related expected adverse event onset: |_|_|-|_|_|_|-|_|_|_|_| |_|_|:|_|_|
dd mmm yyyy 24 hr

c) Please indicate the role of the individual who determined that an expected adverse event (related to SBT conduct) occurred and provide their initials (check ALL that apply).
☐ Respiratory Therapist (Initials: _____)
☐ Registered Nurse (Initials: _____)
☐ Physician (Initials: _____)
☐ Other, please specify_____ (Initials: _____)

d) Please specify the type of expected adverse event experienced (check ALL that apply)
☐ Dysrhythmia
☐ Cardiac ischemia/myocardial infarction
☐ Cardiac or respiratory arrest
☐ Pulmonary edema
☐ Mucous plugging
☐ *Extreme Fatigue (sustained, as opposed to intermittent, or exacerbated by an SBT and/or cumulative)
☐ *Barotrauma (pneumothorax, pneumomediastinum, pneumatocoele on imaging etc)
☐ *Extreme Anxiety (sustained, as opposed to intermittent, or exacerbated by an SBT and/or cumulative)
☐ Other,
please specify_____

Form 9 – AE / SAE

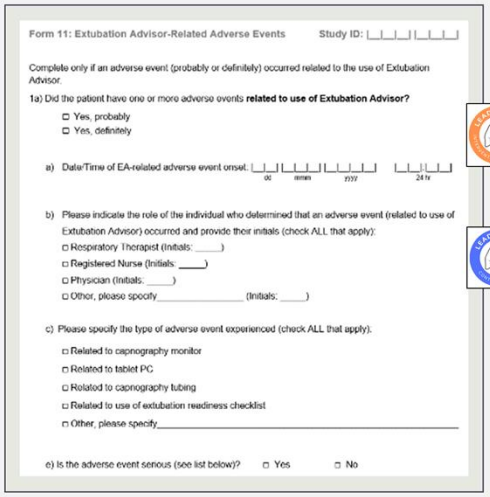
Therapeutic Monitoring Systems

In the event of a *protocol violation*, RT to complete **Form 8 -** *Protocol Violation Form*.

In the event of an *adverse event, or serious adverse event,* RT to complete **Form 9.**

Note: RT to notify Research Coordinator if Form 8 or 9 requires completion.

The LEADS Trial – Case Report Forms (For RTs)



Form 11: Extubation Advisor-Related Adverse Events Study ID: |_|_|_|-|_|_|_|

Complete only if an adverse event (probably or definitely) occurred related to the use of Extubation Advisor.

1a) Did the patient have one or more adverse events **related to use of Extubation Advisor?**

- ☐ Yes, probably
- ☐ Yes, definitely

a) Date/Time of EA-related adverse event onset: |_|_| |_|_| |_|_|_|_| |_|_| |_|_|
hr mmm yyyy 24 hr

b) Please indicate the role of the individual who determined that an adverse event (related to use of Extubation Advisor) occurred and provide their initials (check ALL that apply):

- ☐ Respiratory Therapist (Initials: _____)
- ☐ Registered Nurse (Initials: _____)
- ☐ Physician (Initials: _____)
- ☐ Other, please specify_____ (Initials: _____)

c) Please specify the type of adverse event experienced (check ALL that apply):

- ☐ Related to capnography monitor
- ☐ Related to tablet PC
- ☐ Related to capnography tubing
- ☐ Related to use of extubation readiness checklist
- ☐ Other, please specify_____

e) Is the adverse event serious (see list below)? ☐ Yes ☐ No

Form 11 – Extubation Advisor-Related Adverse Event Form

Intervention Arm:

+ Form 11 to be filed by RTs in the event of an adverse device event (related to EA use) occurs

Control Arm:

+ Form 11 to be filed by RTs in the event a control patient is inadvertently placed on EA and an adverse device event (related to EA use) occurs

Therapeutic Monitoring Systems

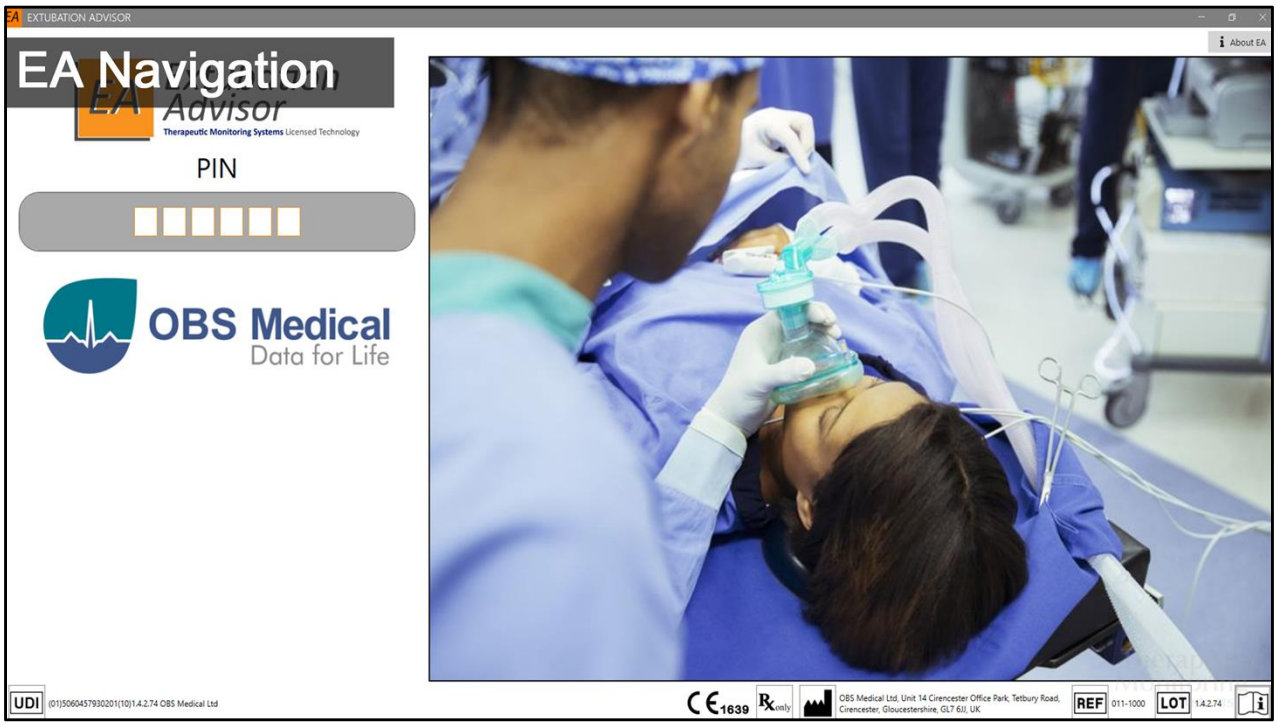
An EA-related **adverse event** *may* be:

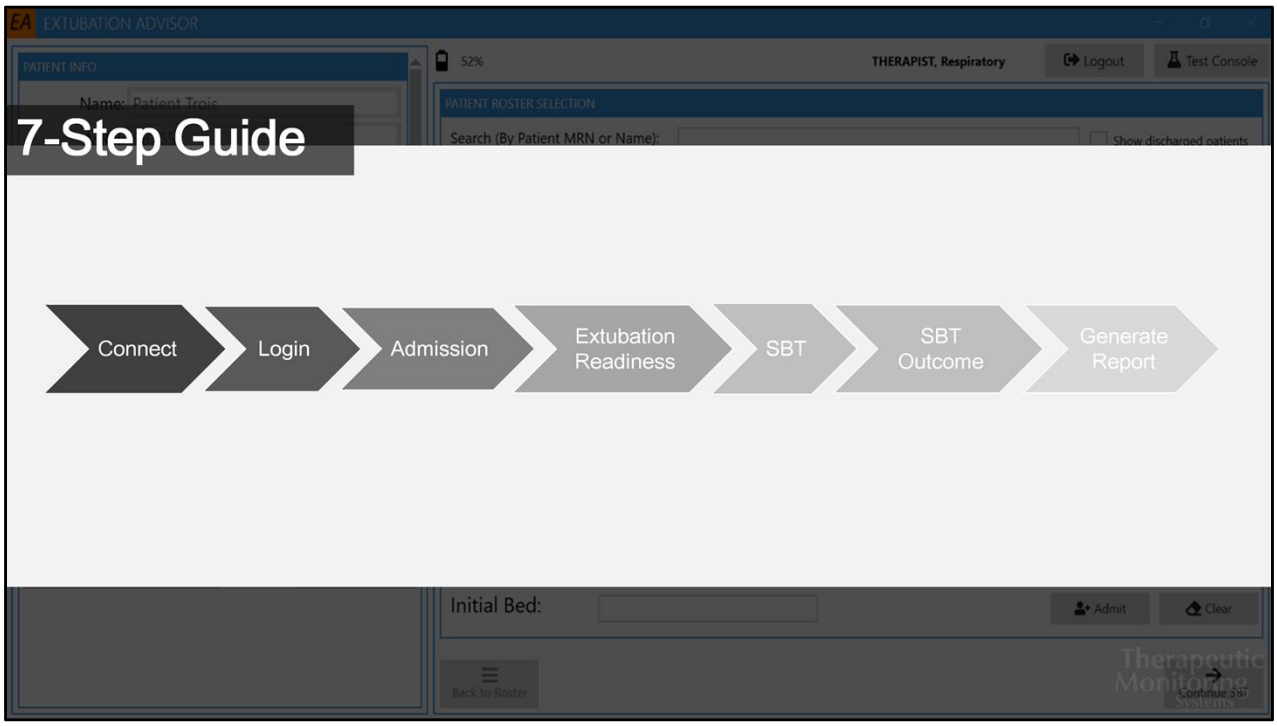
- Related to capnography monitor
- Related to capnography tubing
- Related to tablet / laptop use
- Related to use of extubation readiness checklist
- Other

A **serious adverse device event** *may* include:

- Death
- Life-threatening event
- Prolonged ICU stay/hospitalization
- Persistent or significant disability/ incapacity
- Need for medical or surgical intervention

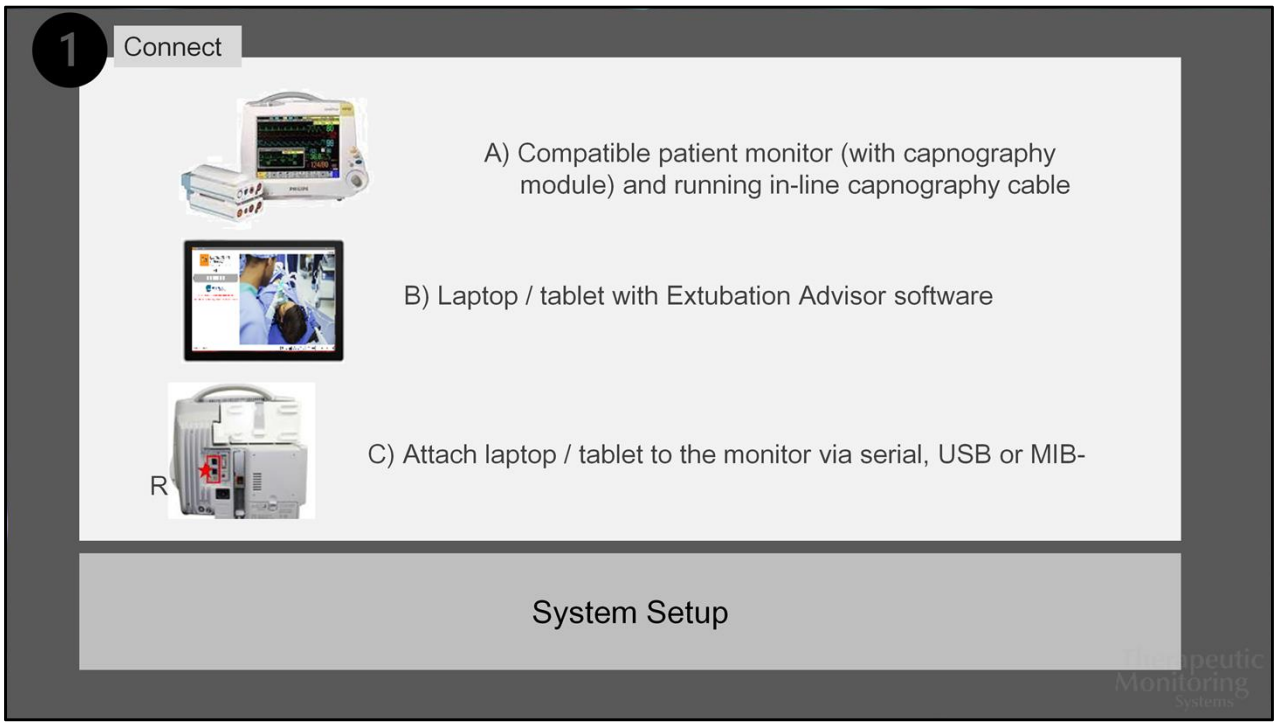
Note: RT to inform Research Coordinator in the event **Form 11** needs to be filled out.


EXTUBATION ADVISOR
About EA
EA Navigation
EA Advisor
Therapeutic Monitoring Systems Licensed Technology
PIN
OBS Medical
Data for Life
UDI
(01)5060457930201(10)1.4.2.74 OBS Medical Ltd
CE 1639
Rx only
OBS Medical Ltd, Unit 14 Cirencester Office Park, Tetbury Road, Cirencester, Gloucestershire, GL7 6JJ, UK
REF 011-1000
LOT 1.4.2.74



Extubation Advisor uses a 7-step guide to capture and record patient data during spontaneous breathing trials for precise point-of-care evaluation of extubation readiness.

Step-by-step navigation is built within the software for simplicity.

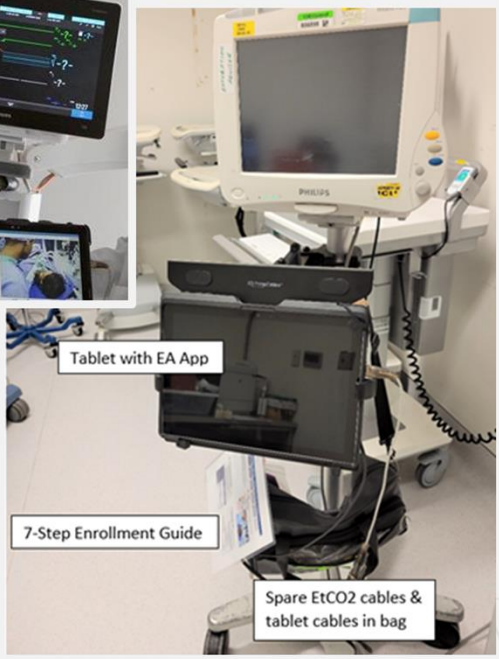


STEP 1: CONNECT
(ref: EA Monitor Connections document for greater detail)

Connect the capnography module to the patient monitor and place capnography cable in-line (if not currently running; required for duration of SBT). Connect the laptop / tablet containing the EA software to the monitor via serial , USB or MIB-RS232 port.

EA Bedside Set-up

- ✓ EA software on a study tablet or laptop (standalone or attached to a rolling stand)
- ✓ Phillips / GE / Medtronic compatible patient monitor (bedside or portable)
- ✓ Inline $EtCO_2$ cable
- ✓ Additional $EtCO_2$ cables, cable to connect laptop/tablet to patient monitor
- ✓ EA 7-Step Guide, LEADS Study Checklist



Refer to: EA Monitor Connections document for detailed bedside set-up

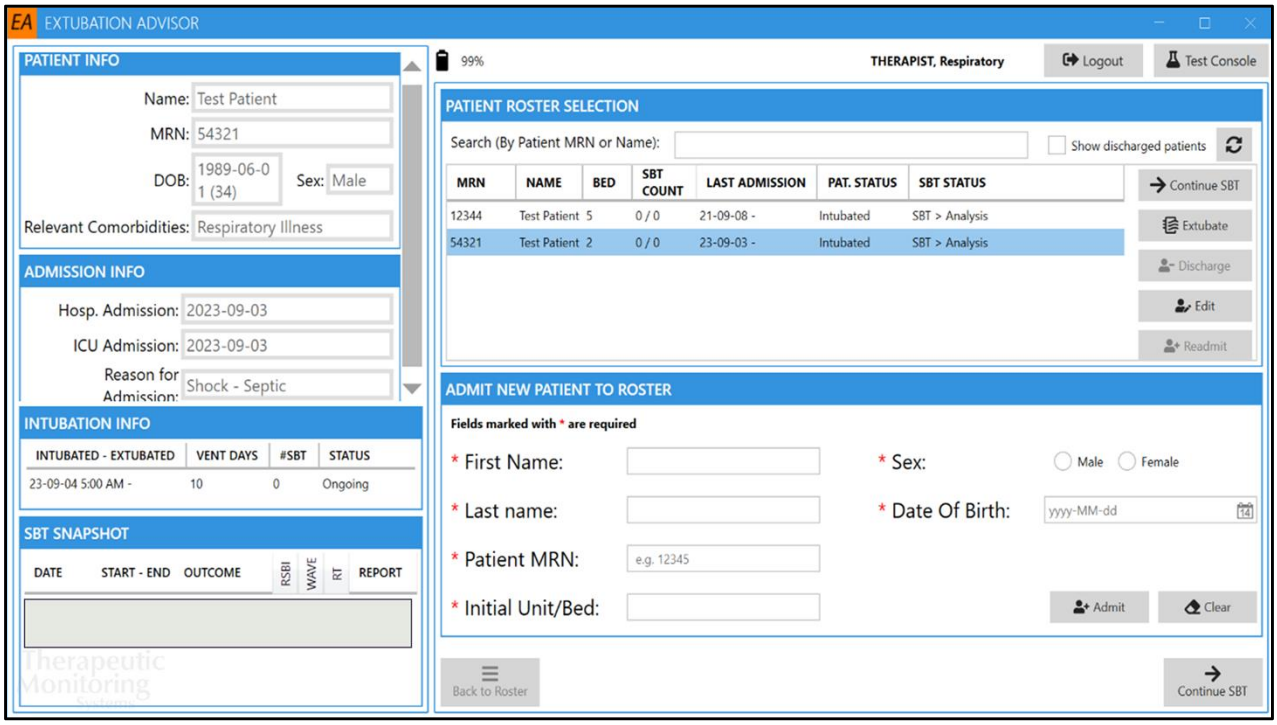
STEP 2: LOGIN

If installation of EA is centralized, ensure laptop/tablet is connected to the secure hospital network. Wifi is not required on local installations while running EA unless the laptop/tablet is connected to a shared network printer.

Locate the orange “EA” icon on the desktop.

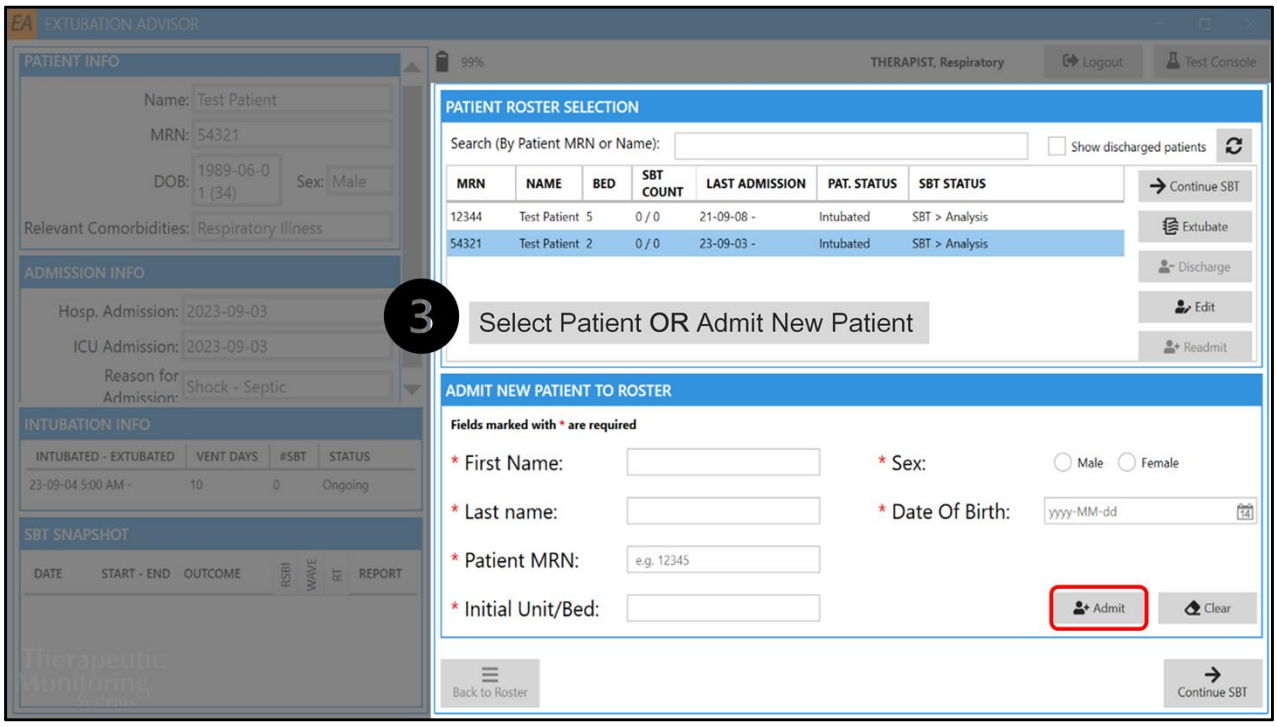
On the initial startup page, Respiratory Therapists will be asked to input a unique 6-digit PIN code to login. Individual PINs can be found in the RT Resource Binder, on the EA index cards, or with the Clinical Research Coordinator.

The user manual can also be accessed on this page through the information icon located on the bottom right corner. (arrow)



Once the PIN is entered, users will be directed to the homepage.

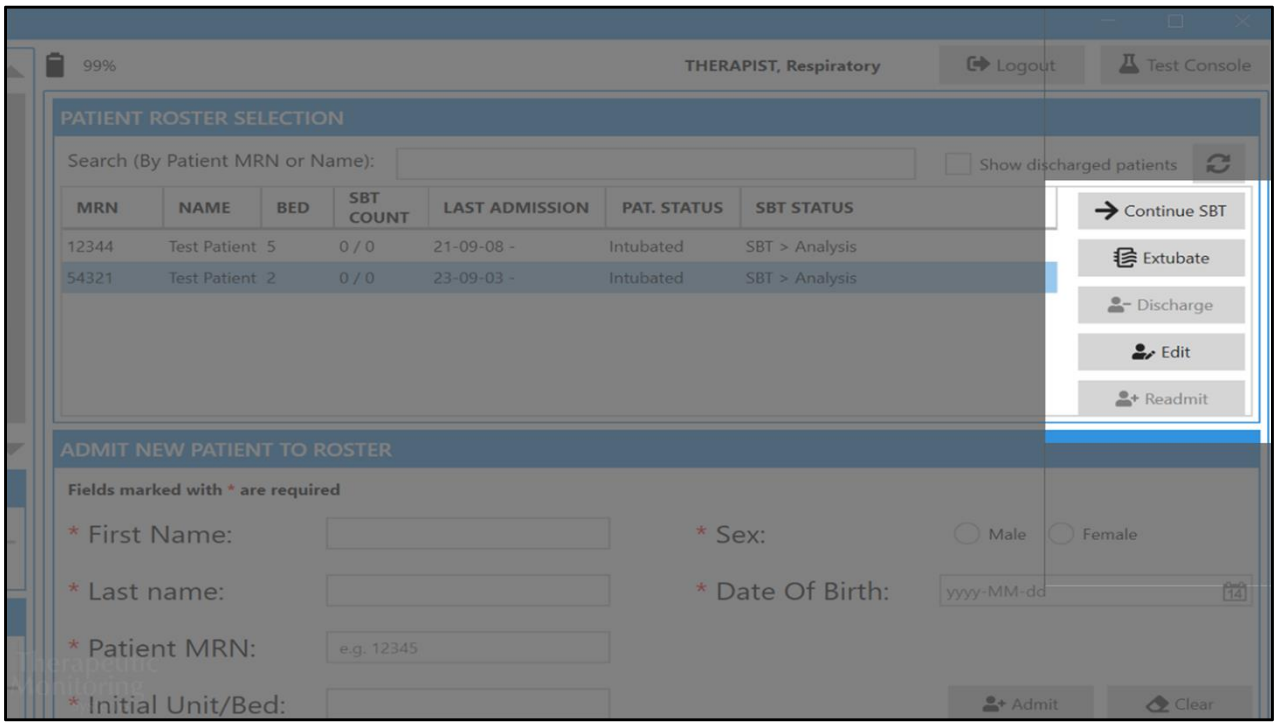
At the top right panel, you will see an active list of patients currently enrolled in the **Patient Roster Selection**, as well as how many SBTs have been performed for each patient. When you select a patient, the left-side dashboard will populate with the patient's medical history, admission information, intubation status and the SBTs performed (**SBT Snapshot**).



STEP 3: SELECT PATIENT OR ADMIT NEW PATIENT

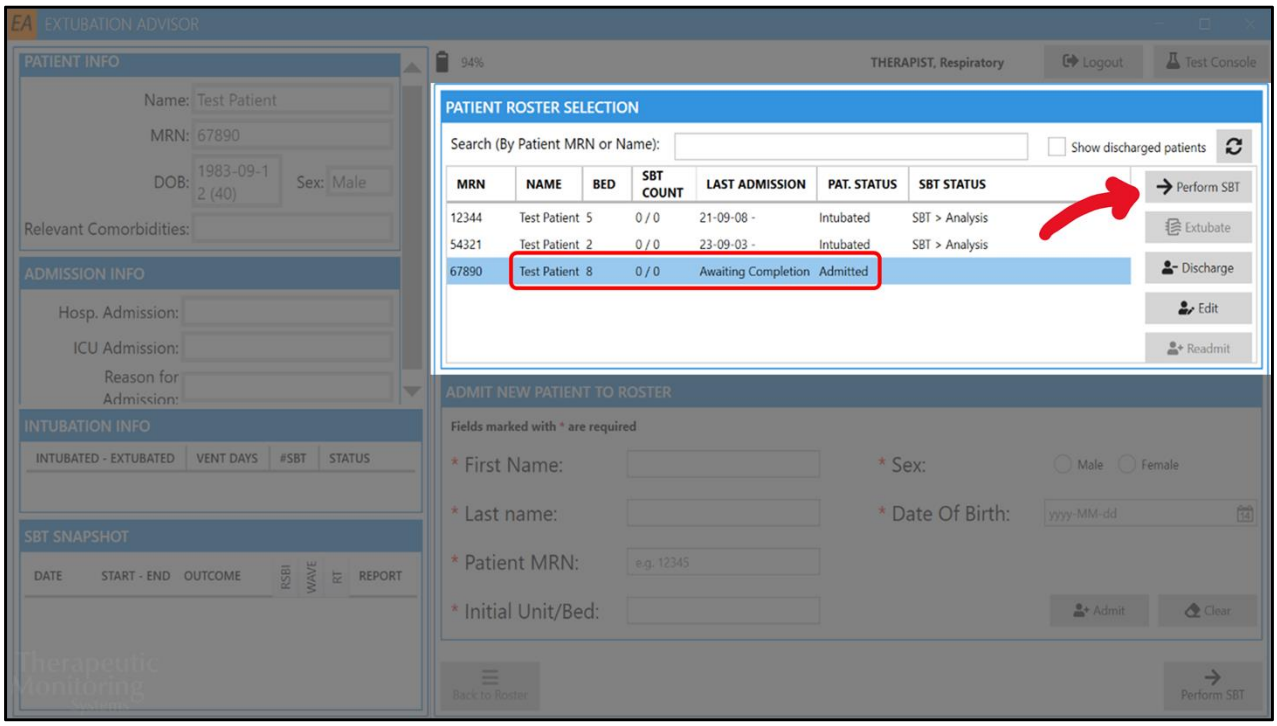
If a patient is already enrolled in the roster, select the patient's name under the **Patient Roster Selection** and **Continue SBT.**

To admit a new patient to the roster list, use the **Admit New Patient to Roster** form located at the bottom of the homepage to register the patient, then click on the **Admit** button. The patient's name will then populate to the roster. Select **Perform SBT** (in place of "Continue SBT") on the right-side panel to continue.

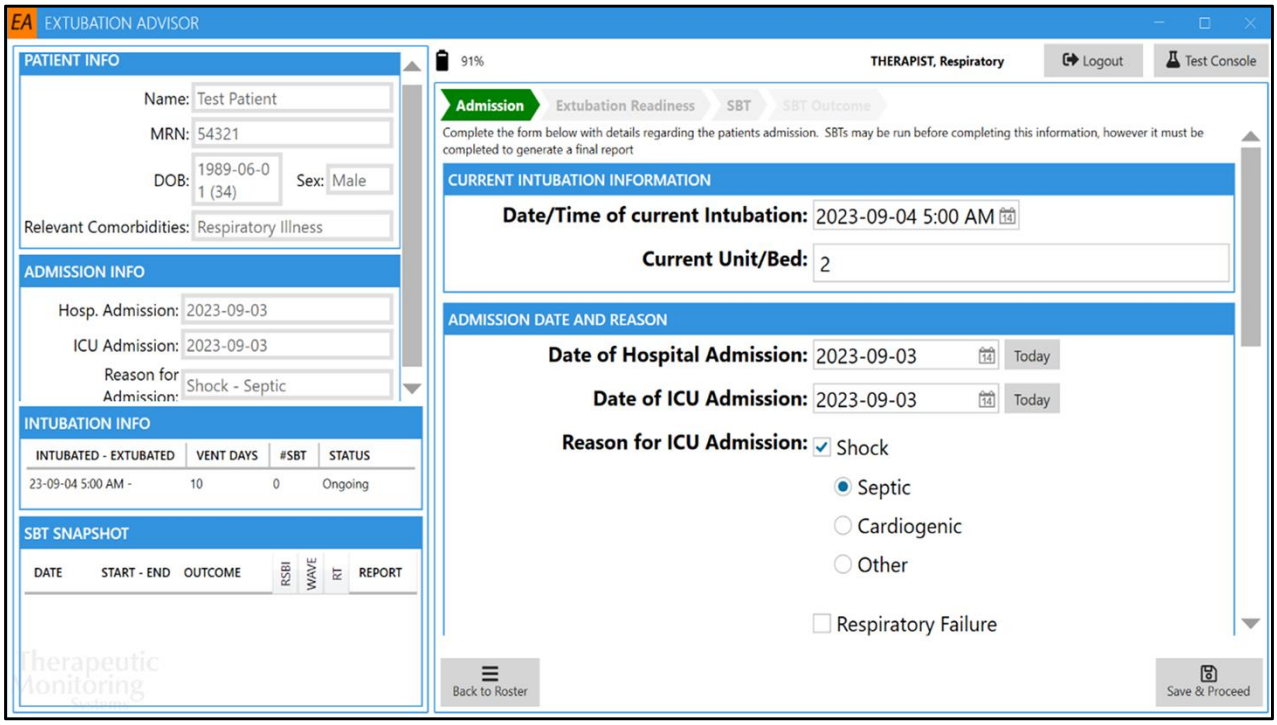


On the right-side of the homepage, **5** options exist:

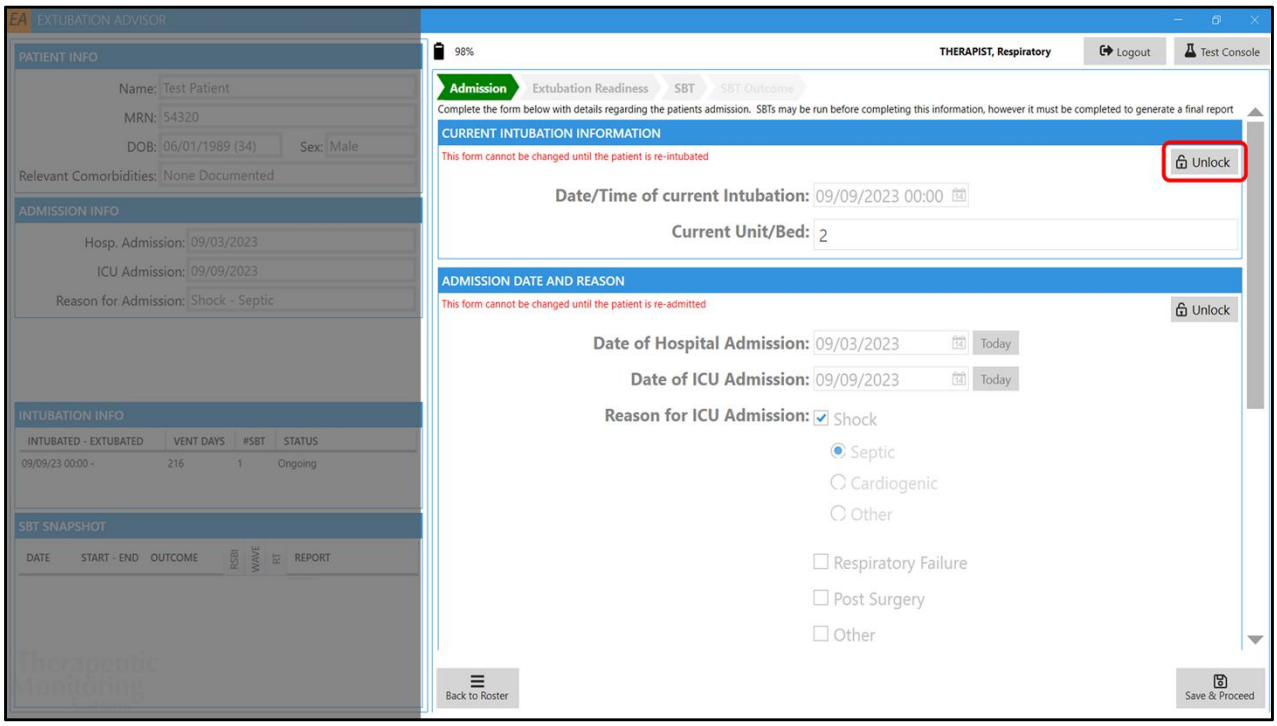
- **Perform SBT** (new patient or new SBT) or **Continue SBT** (existing patient, SBT in progress) – select this option to proceed with a SBT or continue where you left off in the SBT
- **Extubate** – select this option in the event that: 1) the patient is ready for a planned extubation, 2) the patient self-extubated, 3) the patient underwent a tracheostomy or 4) the patient is deceased to update the patient status in the roster.
- **Discharge** – select this option when the patient is discharged from ICU to remove the patient from the active roster. The patient will be moved to the **discharged patients** list.
- **Edit –** select this option to update patient-specific information (name, MRN, DOB, sex)
- **Readmit** – select this option in the event a patient is readmitted to ICU and is to continue on the study. Of note this would be extremely rare. The patient would have had to be extubated and off any ventilatory support, discharged from ICU, readmitted and intubated within 48 hours to continue on the study



Note: If this is the patient was just admitted into EA via the “Admit new patient to roster form”, select **Perform SBT** (in place of “Continue SBT”) to complete a brief **Admission Form** to capture the patient’s intubation duration and clinical information on relevant comorbidities. These forms will only show up once on initial enrollment. Once complete, the information will populate on the left-side dashboard and users will be able to continue with the SBT.

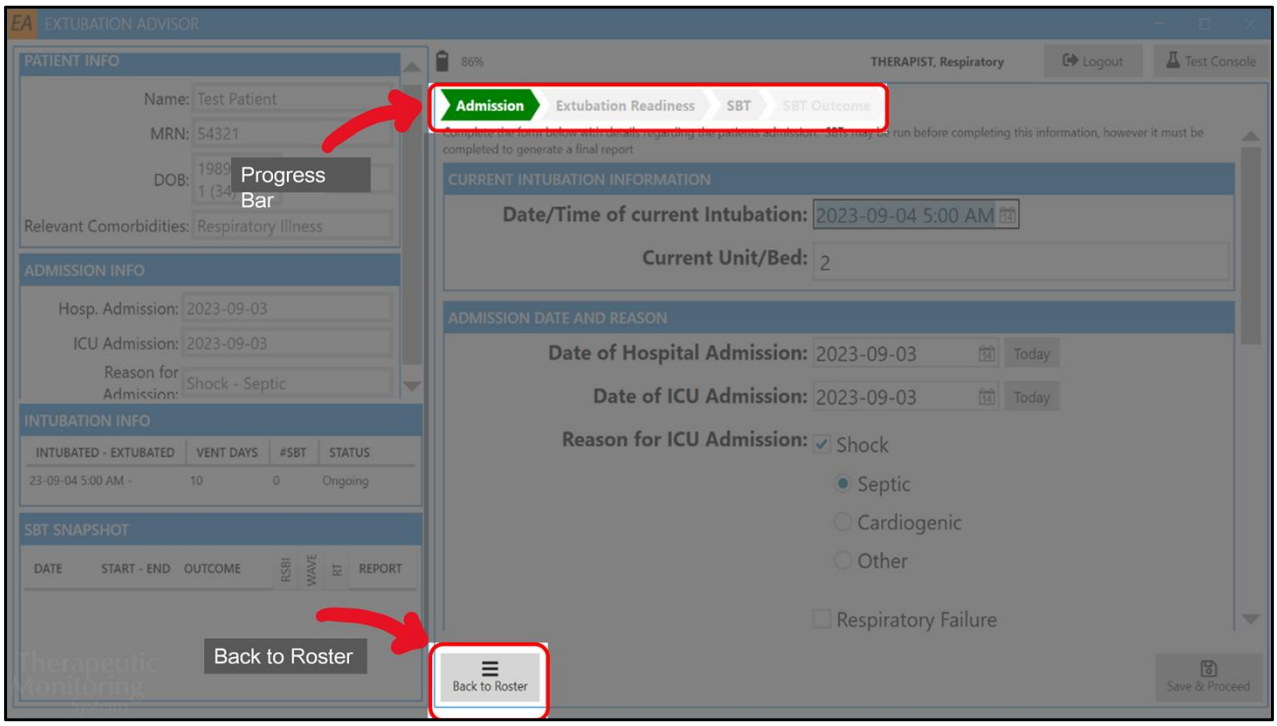


Admission Form: a 1-time entry for each enrolled patient in the *Intervention group*. This form can be completed before, during, or post initial SBT, but must be complete in order to generate a SBT summary report.



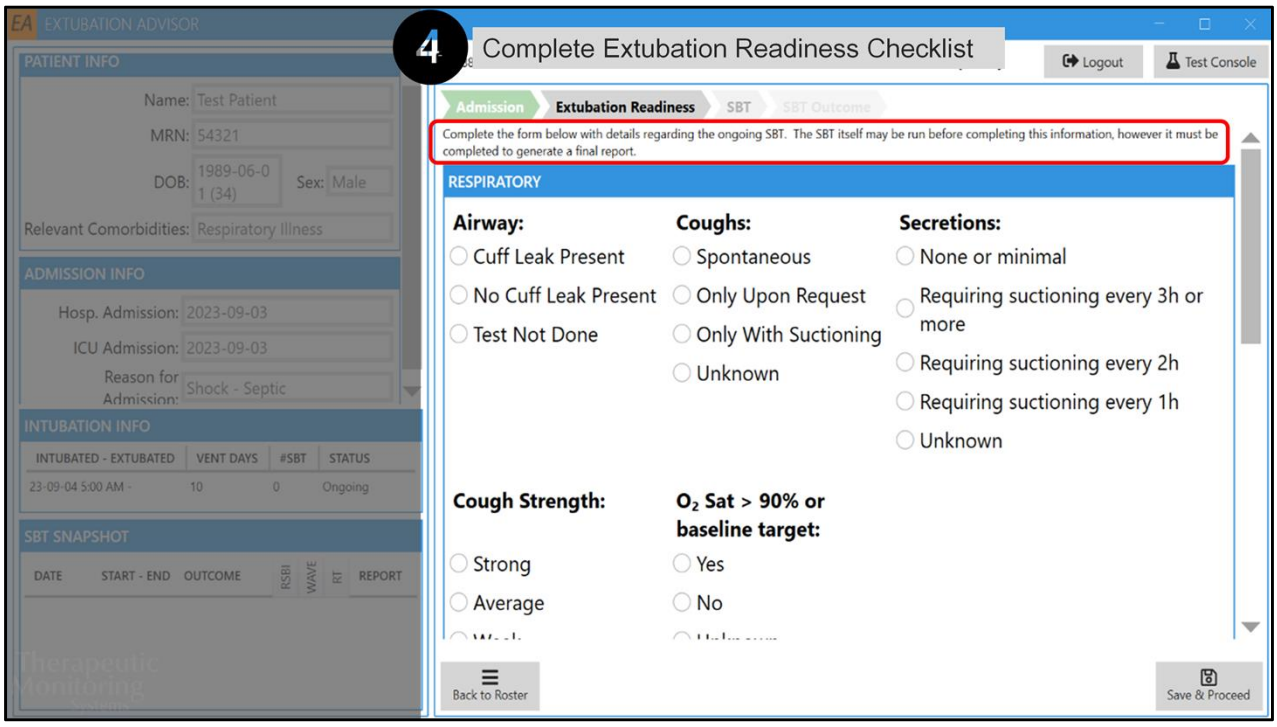
Note: Information entered in this admission form can be changed. Simply return to the Admission tab and select “unlock”

Note: The information from the Admission form populates into the EA generated reports. If any changes are made to this form, previous reports linked to this intubation will not be updated to reflect changes made (only in reports following the changes).



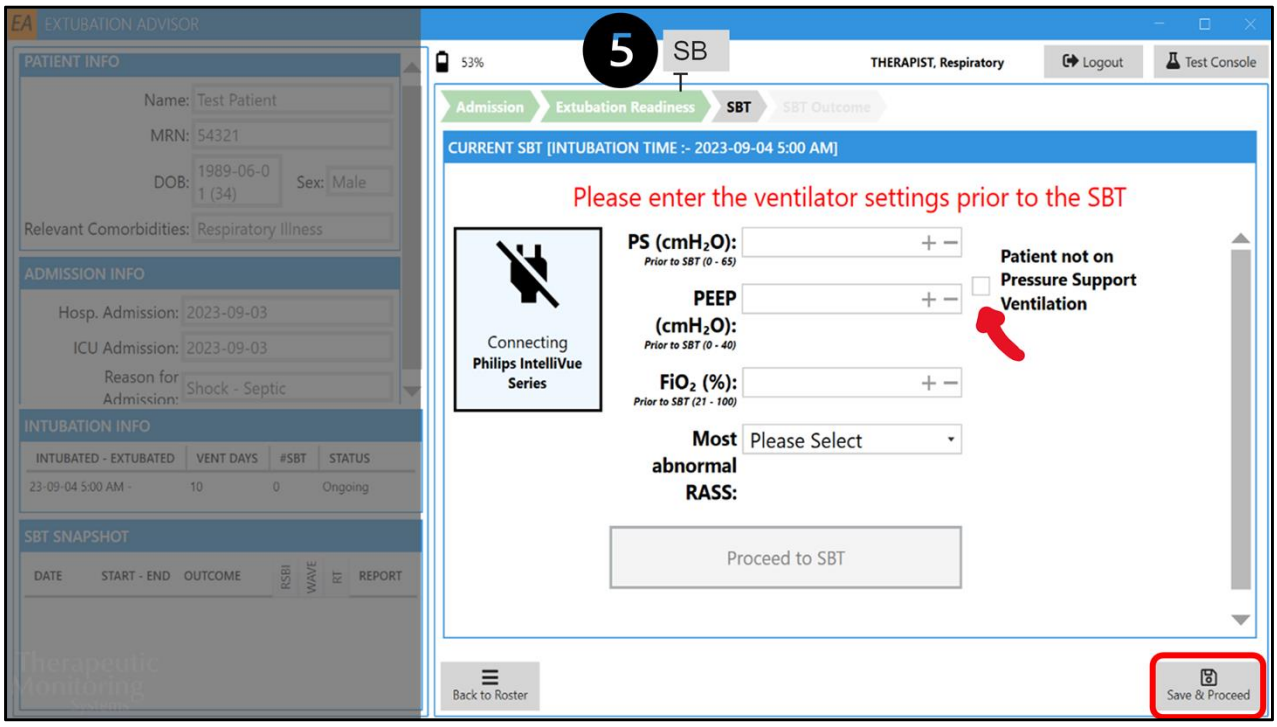
Use the **Progress Bar** to navigate through each section of the recorded trial.

If the patient is not ready for a SBT, an incorrect patient was selected, or you wish to return to the main patient list, click the **Back to Roster** button (*available on every page*).



STEP 4: COMPLETE EXTUBATION READINESS CHECKLIST

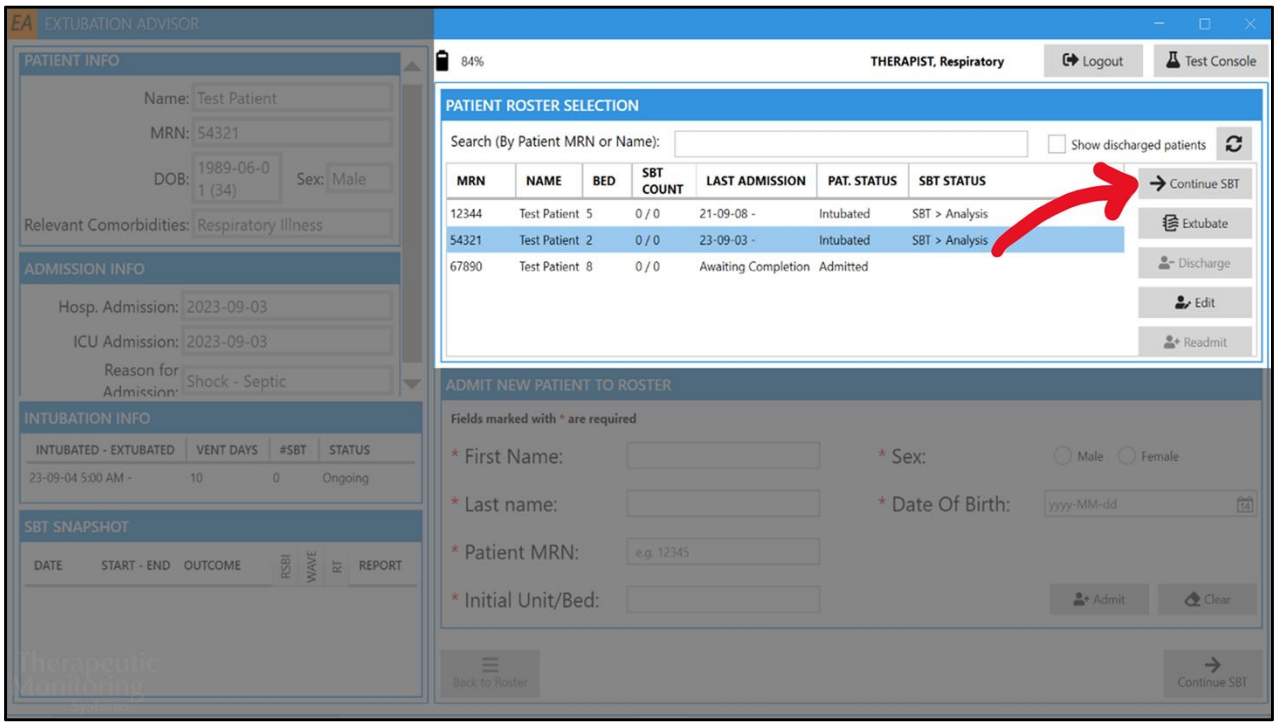
The **Extubation Readiness** checklist can be done before, during, or after running a SBT. This checklist must be completed to generate a final report.



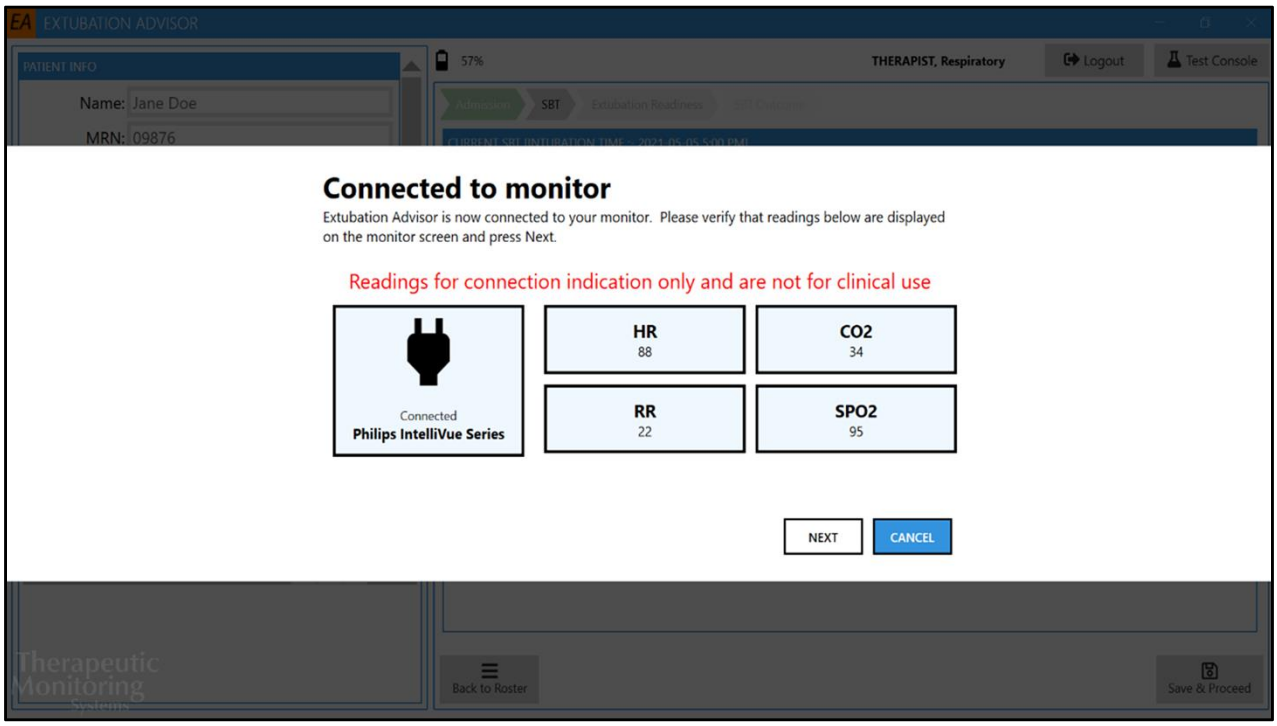
STEP 5: SBT

Once a patient is ready for a SBT and is fully connected to the EA/monitoring system, proceed with the SBT input.

Document the ventilator settings **prior to SBT** for PS (cmH2O), PEEP (cmH2O) and the patient's RASS. If the patient is not on pressure support ventilation prior to the SBT, choose **Patient not on Pressure Support Ventilation** option. Select **Save & Proceed** to continue.



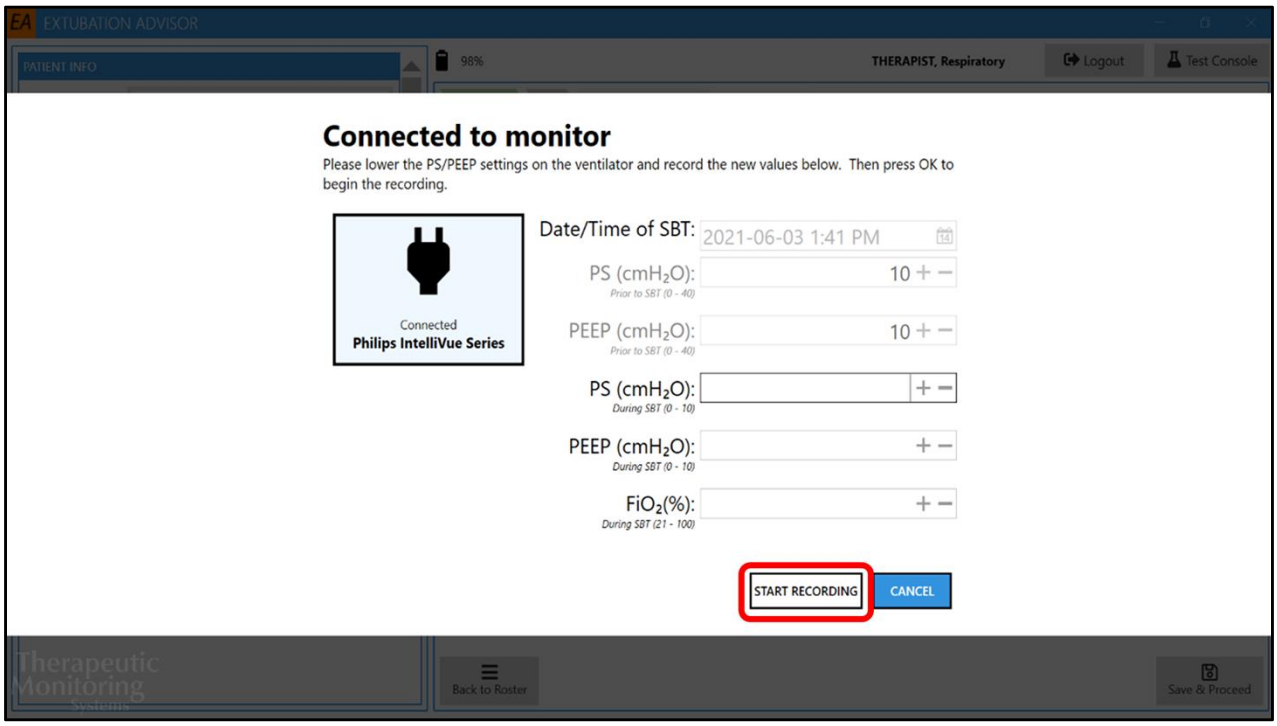
Note: If coming from the homepage, select the patient's name from the active roster selection and click **Continue / Perform SBT** from the options provided**.**



EA will identify which vital signs are being recorded before the SBT timer initiates.

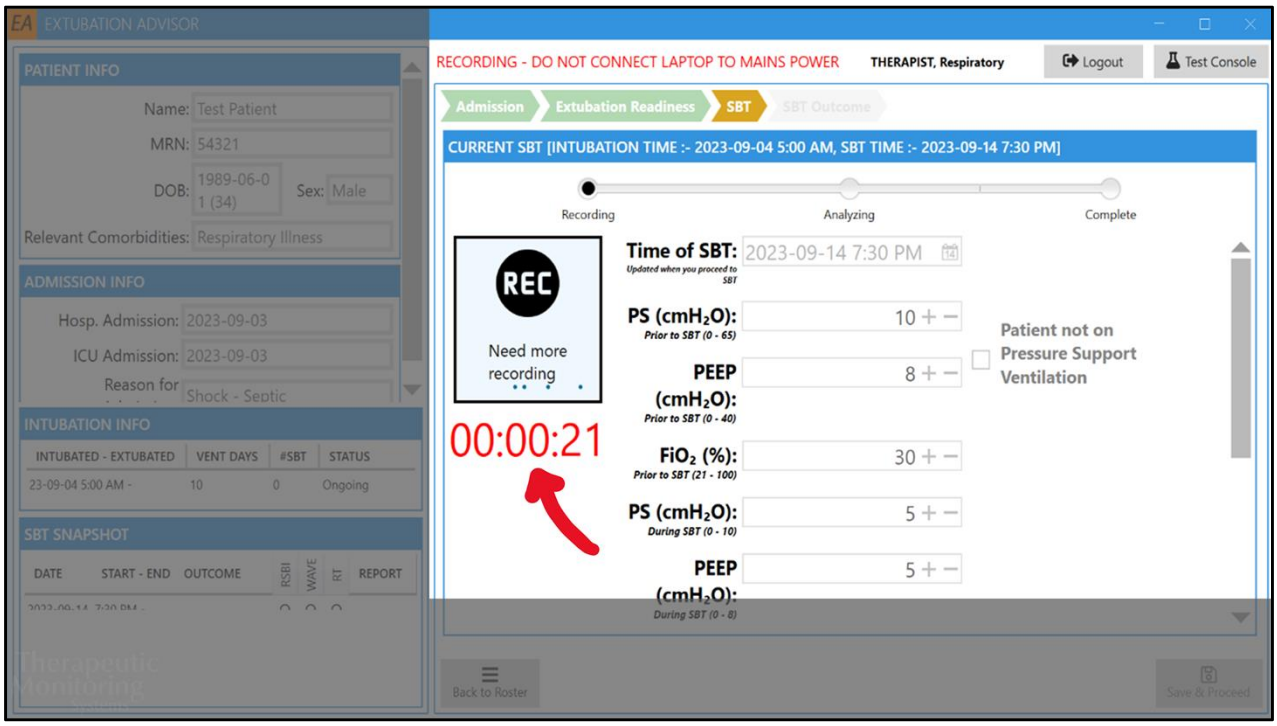
At this time, ensure the patient monitor is connected using the supplied cables and confirm EA is receiving the vital signs data.

If CO2 readings don't show, you will not be able to proceed to the next step. Select **Next** to proceed.

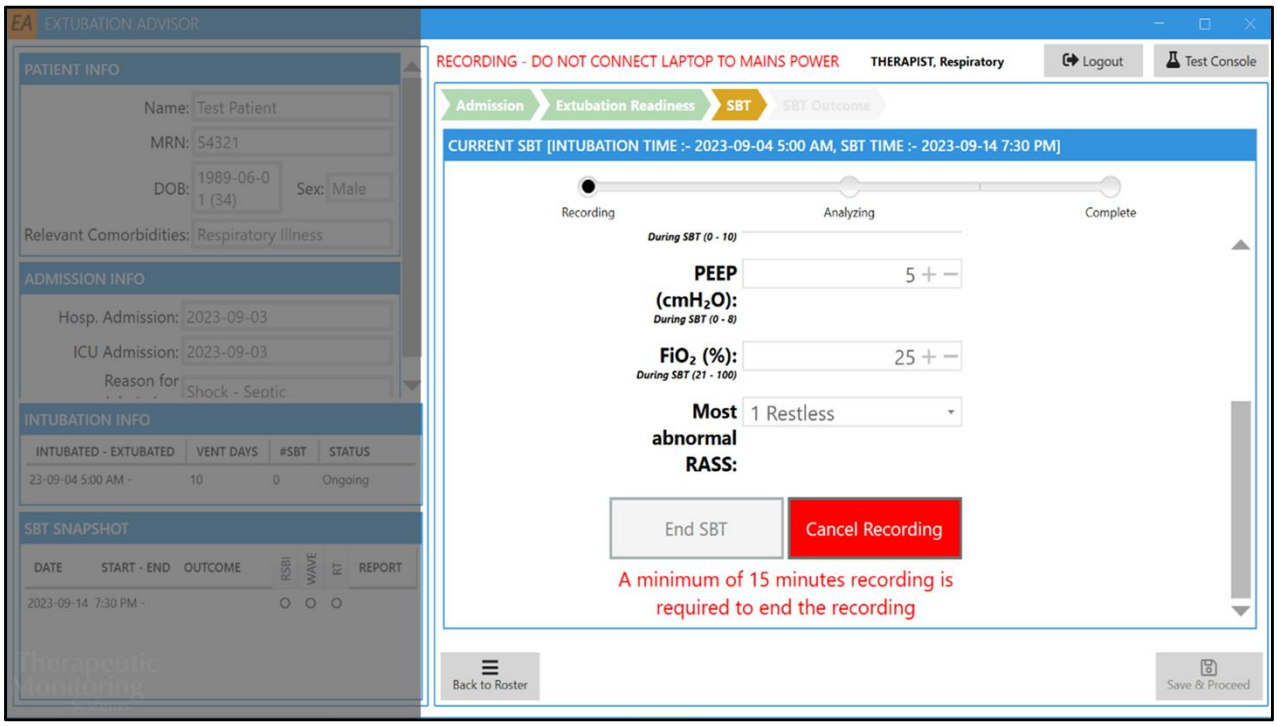


Lower the **PS / PEEP** settings on the ventilator and document the new values and **FiO2** for the SBT.

You may now **Start Recording.**

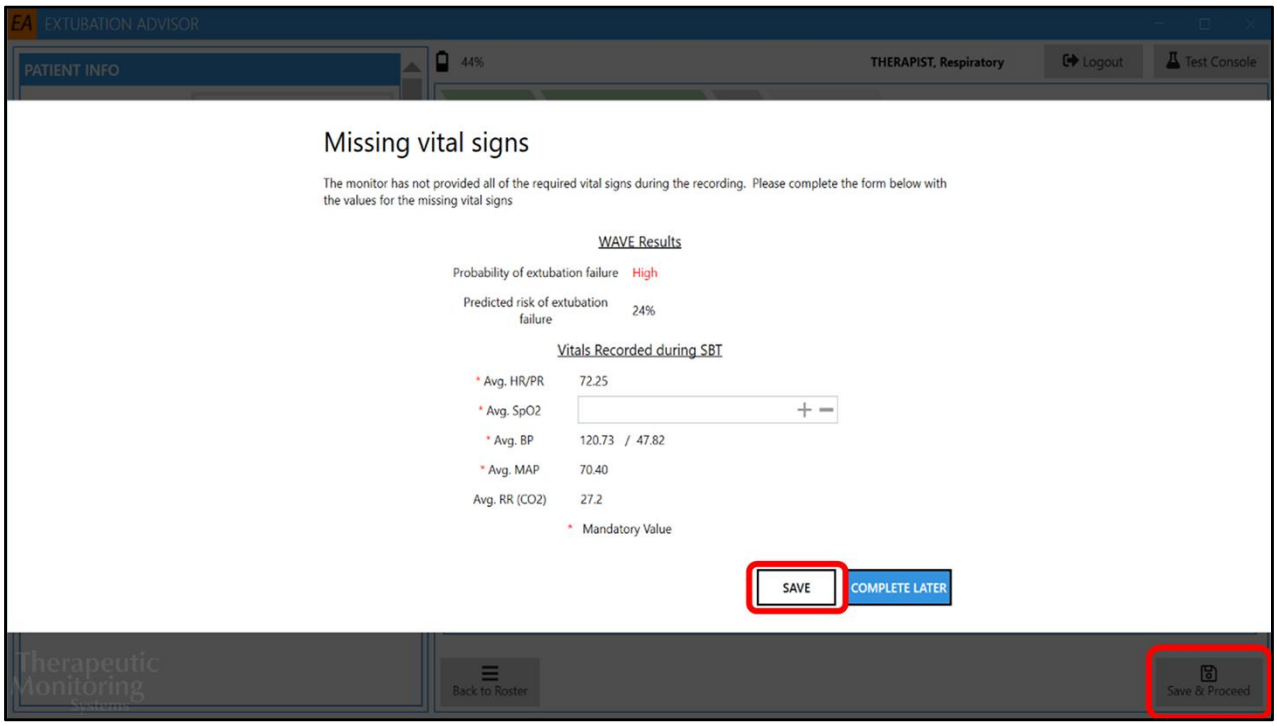


A timer will keep track of how long the SBT is running for. To generate a summary report through EA, a minimum recording time of **15mins** is required.



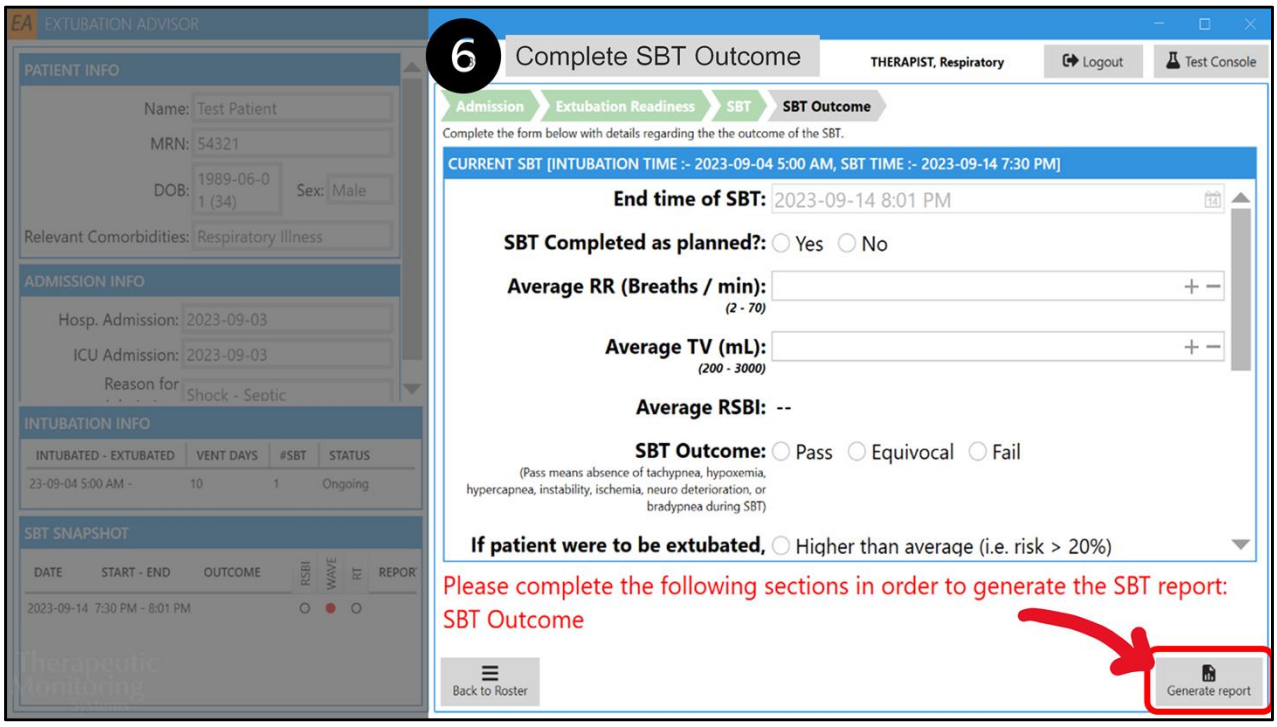
Before the 15 minutes, only the **Cancel Recording** option is available. If the patient is unable to complete 15mins, cancel the recording.

After the total desired SBT time has been met by the patient (duration determined by the RT and/or MD, and patient's tolerance), select **End SBT** (button to be available after 15min of recording).



Once the analysis is complete for the SBT recording, the *WAVE Score* and *Risk of Failure* will be displayed alongside the recorded vitals data.
Users will need to enter any missing vitals that were not captured during the SBT to generate a summary report.

Select ***Save and Proceed*** to access the SBT Outcome Form



STEP 6: COMPLETE SBT OUTCOME FORM

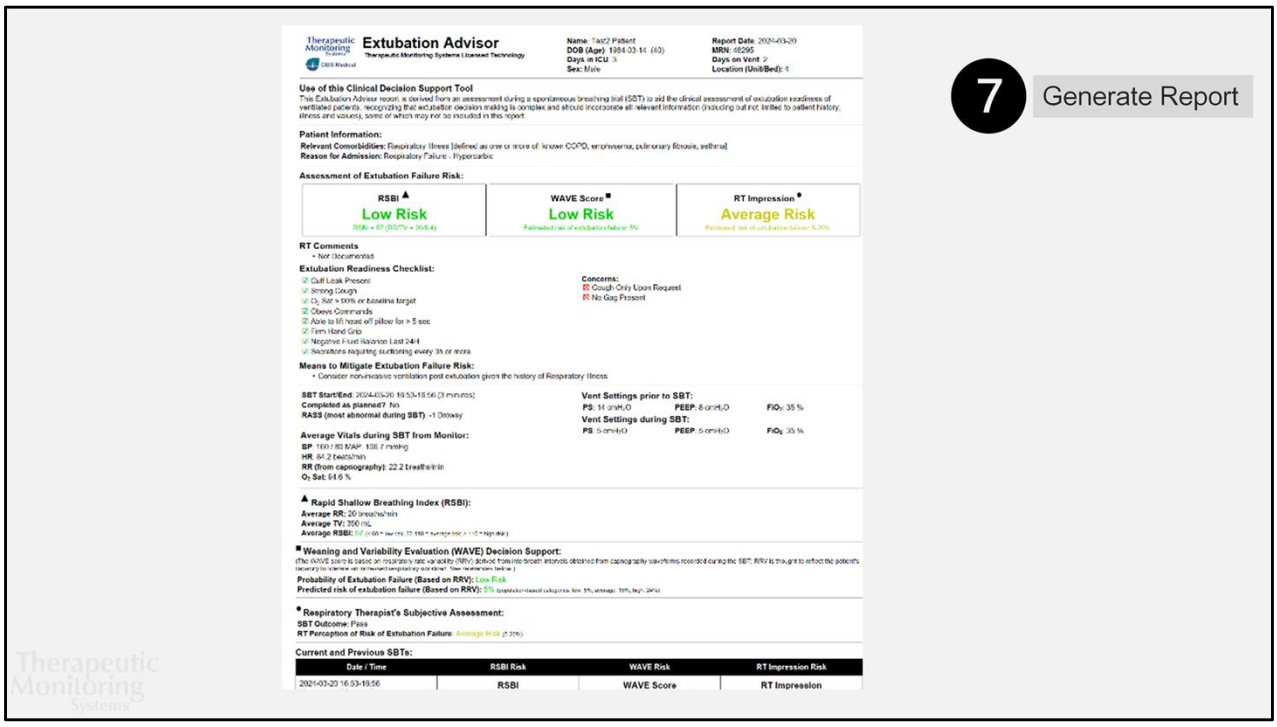
Input average RR & VT (mL) to calculate RSBI, and provide subjective opinion of the SBT performance

Once all fields are complete, select **Generate Report** to access the patient's SBT summary report.

Note: SBT Completed as planned? – Did the patient complete the SBT over the desired trial period, without an unexpected event (ie. patient self-extubates)?

Note: If the SBT Outcome is considered a *fail, equivocal* OR if the SBT was stopped early, the user will need to select reason(s) why via a drop-down menu provided.

Should the user have any additional comments for the MD pertaining to the SBT or extubation readiness, a comments section is provided at the bottom of this form and will populate into the generated summary report.

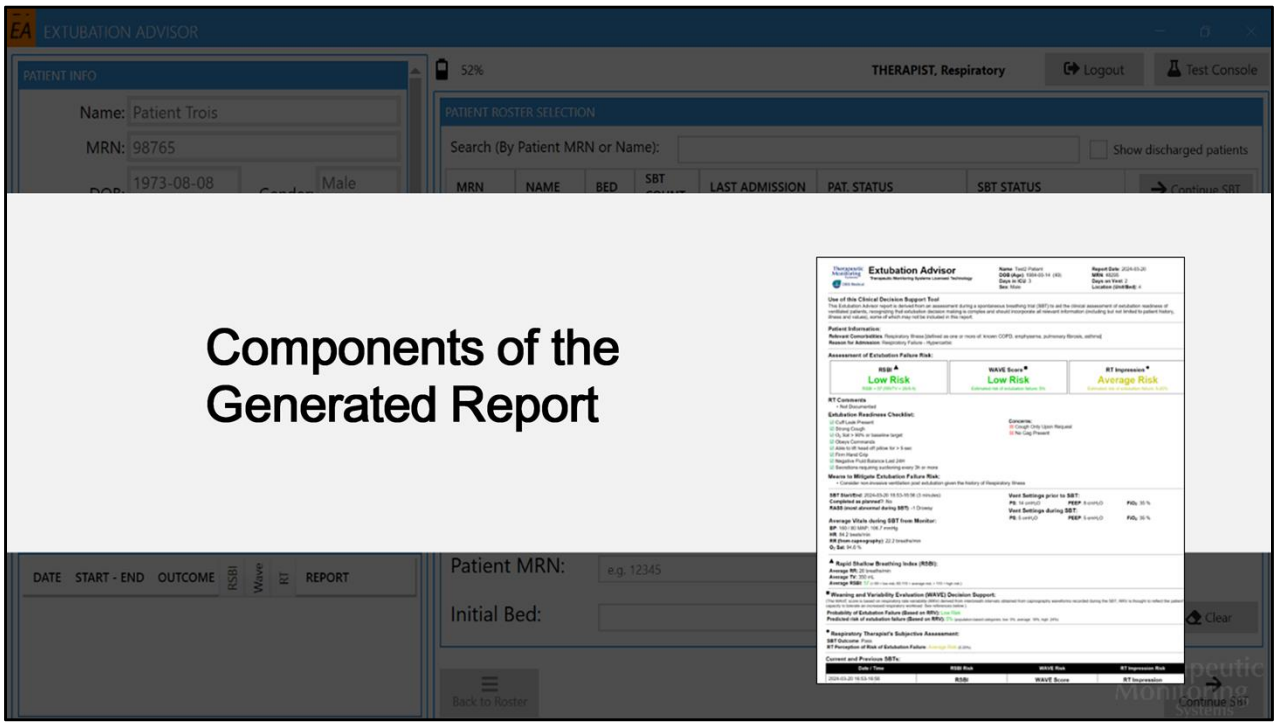


STEP 7: GENERATE REPORT

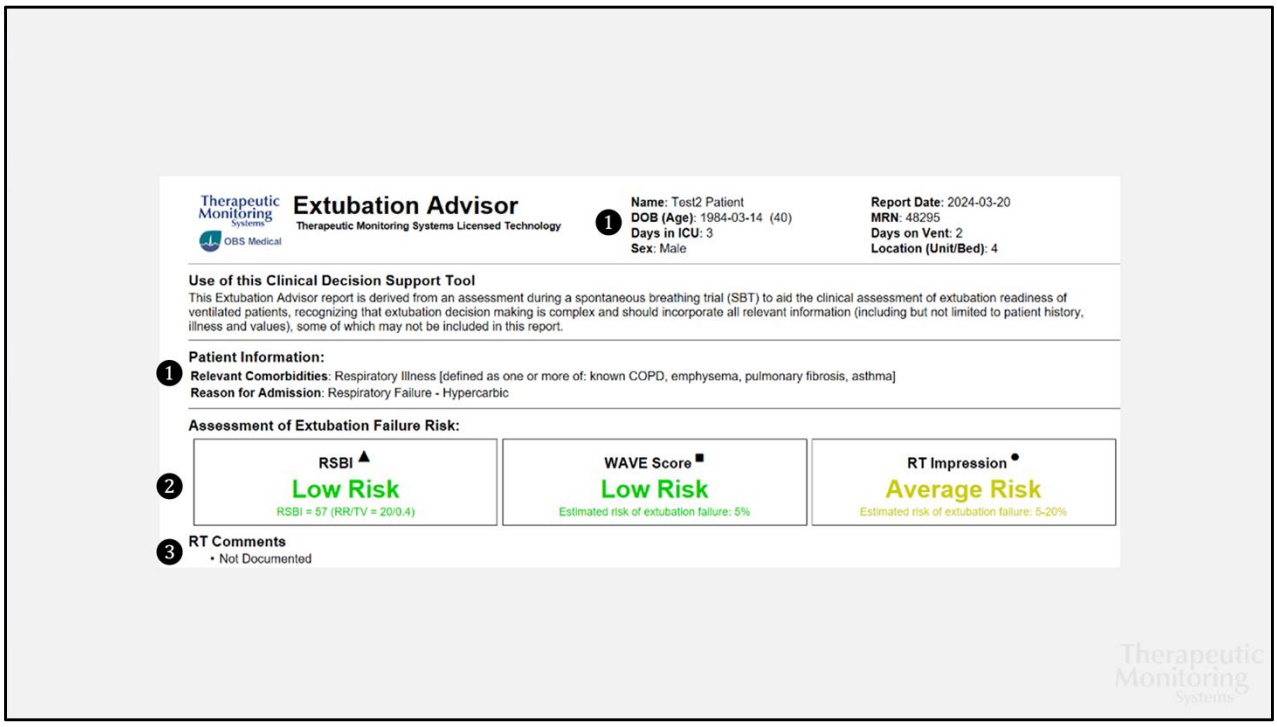
Preview the report and the patient's overall performance for the SBT. If all data is correctly documented, **Save** the report as required.

If information is incorrect, **cancel**, and return to the **Extubation Readiness** checklist or **SBT Outcome** page to correct the information and re-generate the report.

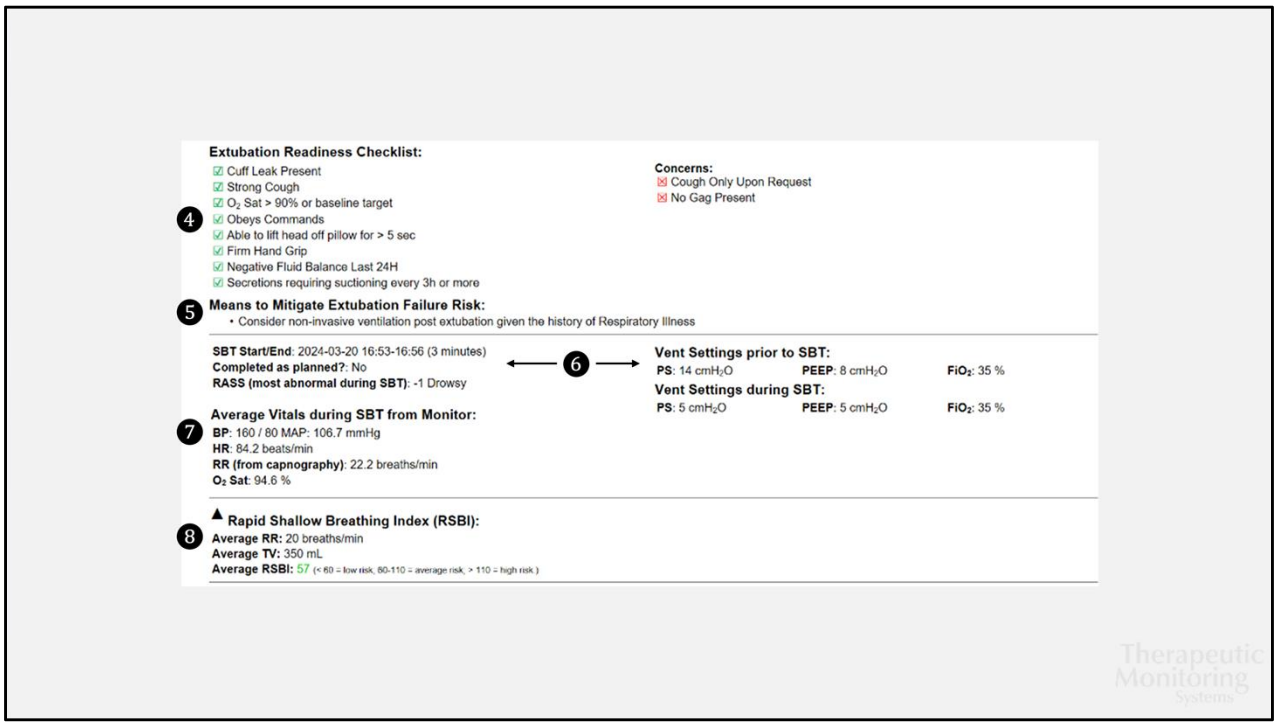
Once the report is saved, you will be re-directed to the EA homepage.



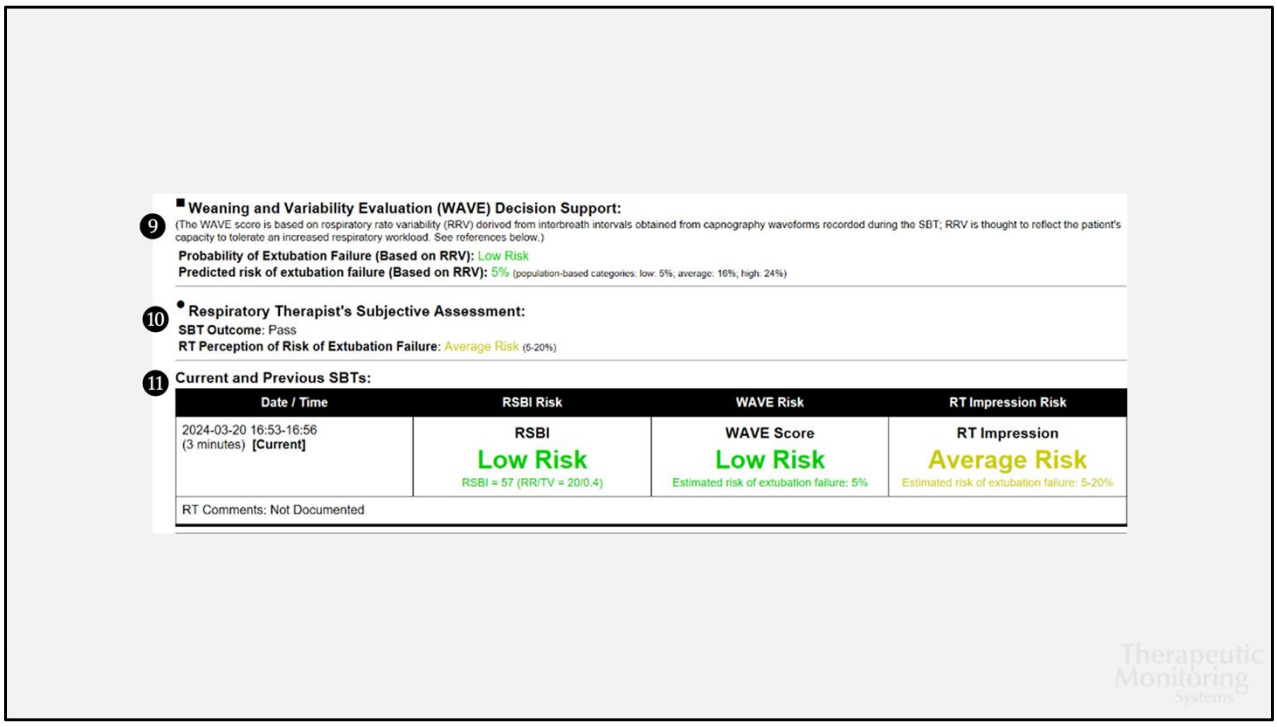
The EA **Generated Report**



1) **Patient Information** – This section is extracted from the hospital admission input
2) **Clinical Indices** of extubation failure risk recorded during the SBT - a RR 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
3) **RT Comments** – Any comments concerning SBT performance or extubation risk factors not highlighted in the EA checklist (free-text)



4) **Extubation Readiness Checklist** - 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 associated suggestions) are only displayed if certain criteria is met that may increase patient risk for extubation failure (as pulled from the patients documented comorbidities, extubation readiness checklist options and the SBT recordings analysis). 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** – Ventilator settings (PS/PEEP/FiO2) set before and during the SBT, as well as SBT duration
7) **Vitals** – 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 - WAVE score value and probability of extubation failure

10) Respiratory Therapist Assessment – subjective assessment by the RT on patient Type equation here.readiness for extubation (as extracted from the **SBT Outcome** checklist)

11) Results of prior SBTs – allows multidisciplinary team to compare current outcome risks to previous SBT performances to assess whether a patient is moving closer towards extubation

The WAVE Score

- Based on *respiratory rate variability* (interval between successive breaths, as captured through capnography waveforms)
- RR variability is a marker of the ability of the cardiopulmonary system to tolerate / adapt to an increased workload, in this case, reduced PS/PEEP during a SBT
- Greater variability/adaptability to workload = stronger pulmonary status and better predictive outcomes
- Lower the WAVE score = lower probability for extubation failure

Unique to EA, capnography waveforms are recorded and analyzed during the SBT to provide a *Weaning And Variability Evaluation (WAVE)* score. The WAVE score evaluates respiratory rate variability, an indicator of pulmonary function, when a patient is subject to an increased respiratory workload during a SBT to provide a probabilistic estimate of the risk of extubation failure.

The WAVE score and associated predictive model was derived from a large multicenter international study of 800 patients. (DOI: 10.1186/cc13822)

Scoring Criteria

WAVE Scoring

Low Risk	Average Risk	High Risk
<16% failure risk	16-24% failure risk	>24% failure risk

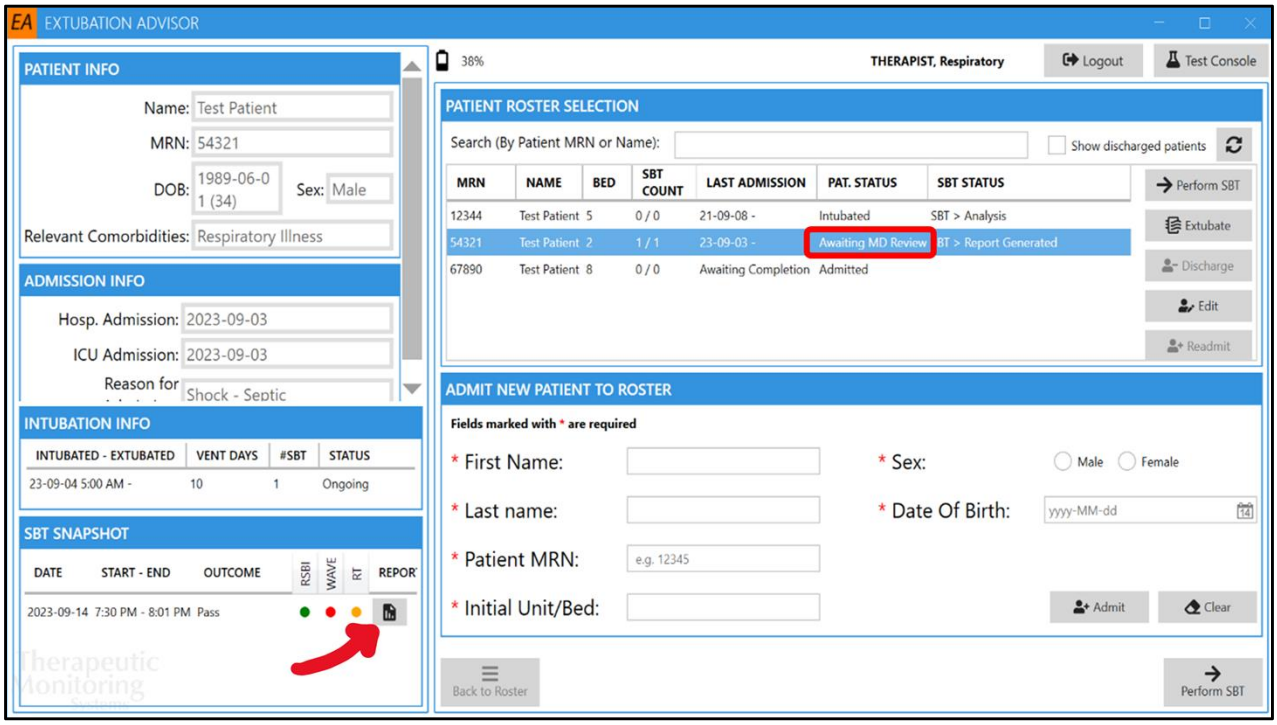
RSBI Scoring

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

RT Impression Scoring

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%

Therapeutic Monitoring Systems



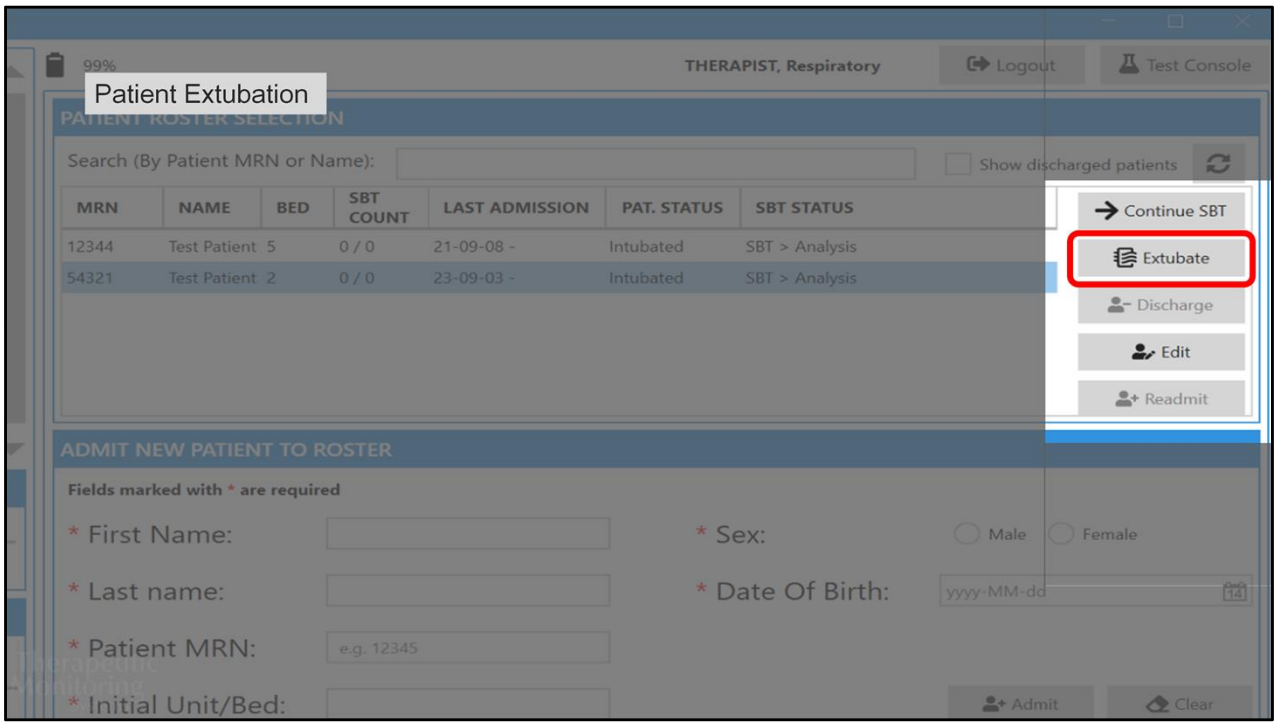
The generated report is available via the **SBT Snapshot** on the bottom left panel of the homepage. To print the report (for MD review), select the **Report** icon beside the desired SBT recording.

The three clinical indicators assessed for extubation readiness during the SBTs (RSBI / WAVE score / RT impression) are also available for quick reference in the SBT Snapshot, based on a colorimetric grading scale – green indicating *low* risk, yellow indicating *average* risk, and red indicating a *high* predictive risk for extubation failure.

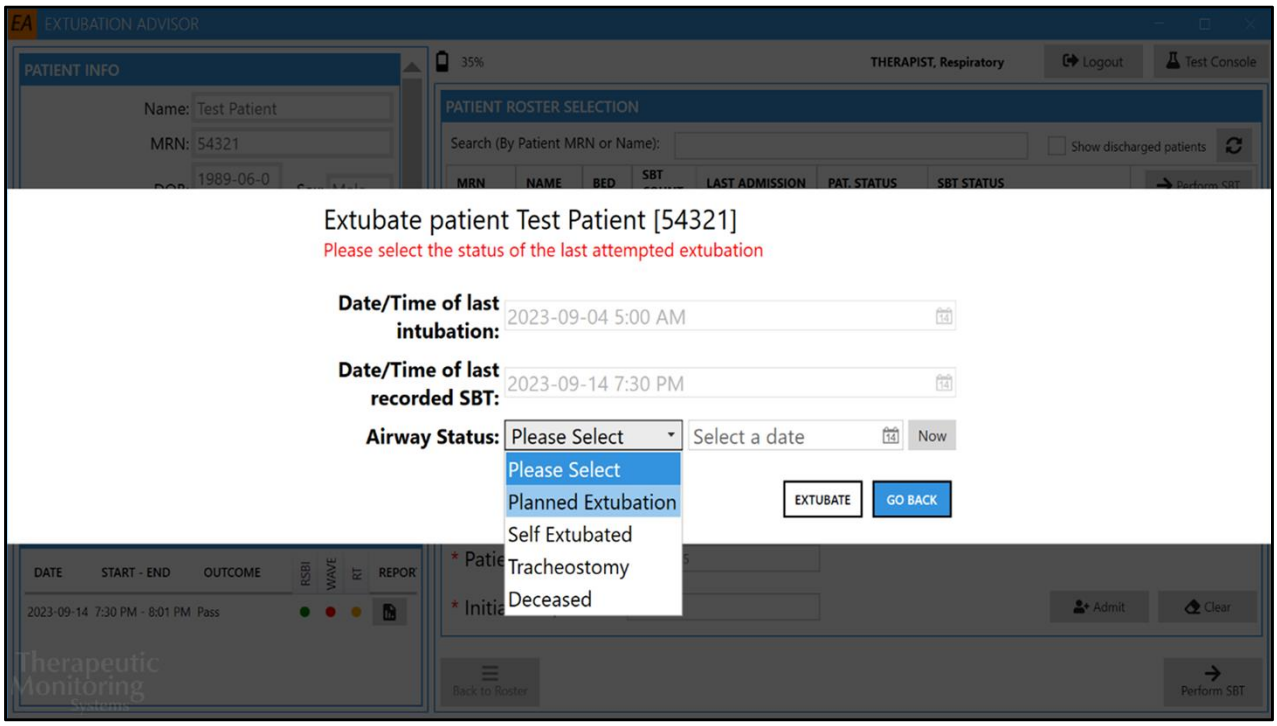
Once the patient is ready for a successive SBT, select **Perform SBT** and repeat steps 4-7. If the patient is ready for extubation, select **Extubate**.

Repeat steps above for subsequent SBTs (as per designated study group) until:

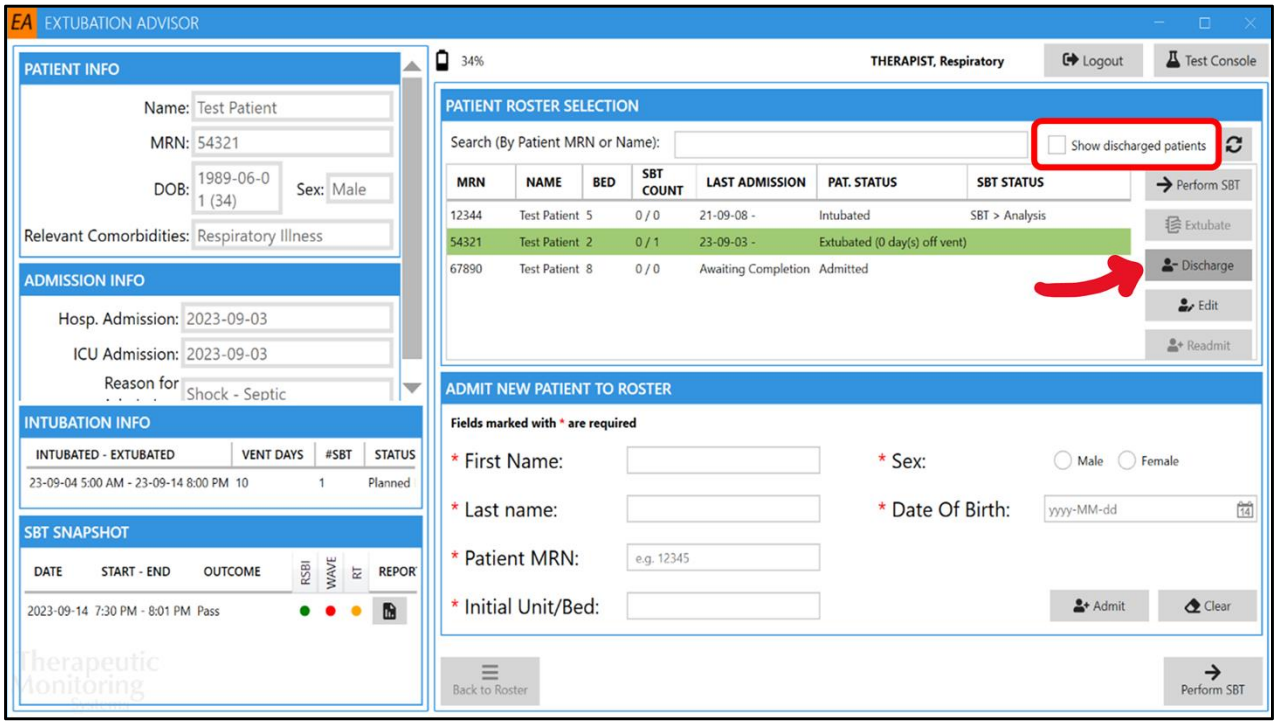
- *Successful extubation with liberation from MV*
- *Transfer / discharge from ICU on mechanical ventilation*
- *Tracheostomy*
- *Deemed Ventilator Dependent (on ventilator at study day 45)*
- *Terminal Extubation*
- *Death*



Extubation - When the patient is ready for extubation, select the “extubate” button on the R-side toolbar. This will ensure patient status is current (ex. intubated, extubated, #days off vent) for app users.



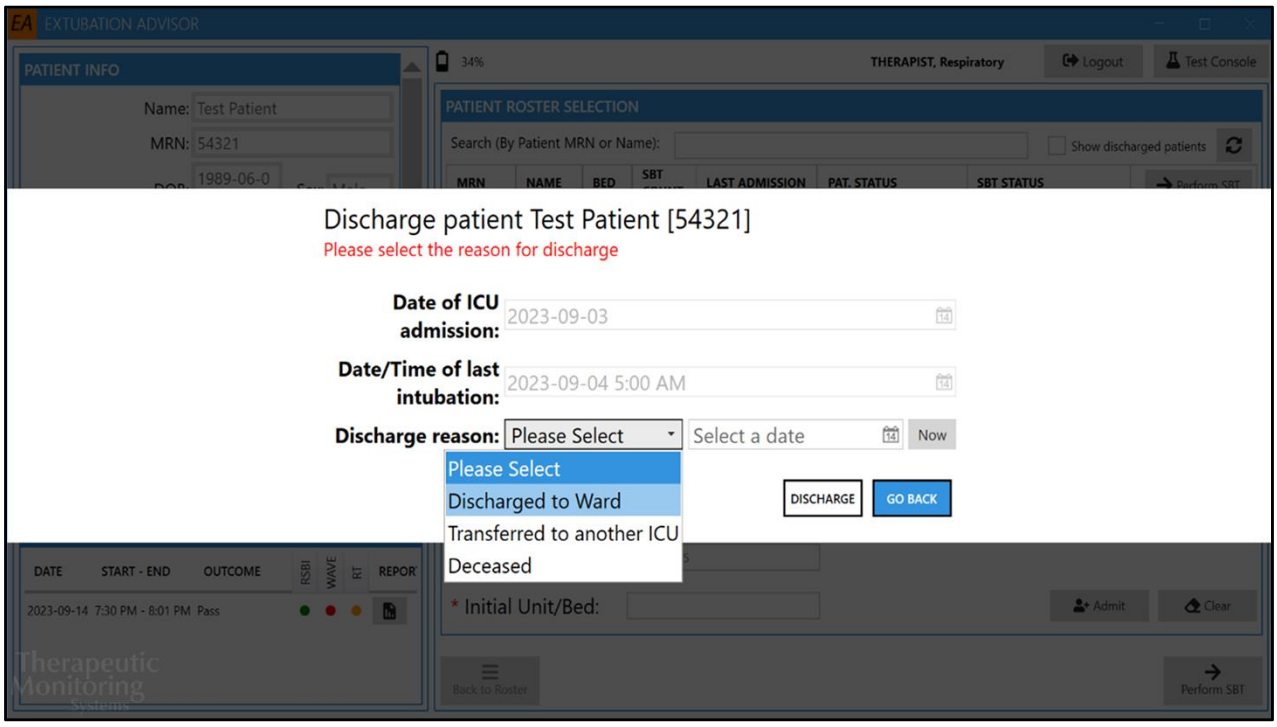
When “Extubate” is selected, users will complete a brief extubation form (above).



Once extubated, the *Patient Status* and *Intubation Info* will update on the dashboard.

To remove the patient off the active roster list, select **Discharge**.

The **Show Discharged Patients** box at the top right-corner allows users to review a complete list of all patients entered in the app (active and discharged).


EXTUBATION ADVISOR
PATIENT INFO
Name: Test Patient
MRN: 54321
34%
THERAPIST, Respiratory
Logout
Test Console
PATIENT ROSTER SELECTION
Search (By Patient MRN or Name):
Show discharged patients
MRN
NAME
BED
LAST ADMISSION
PAT. STATUS
SBT STATUS
Discharge patient Test Patient [54321]
Please select the reason for discharge
Date of ICU admission:
2023-09-03
Date/Time of last intubation:
2023-09-04 5:00 AM
Discharge reason:
Please Select
Select a date
Now
Please Select
Discharged to Ward
Transferred to another ICU
Deceased
DISCHARGE
GO BACK
DATE
START - END
OUTCOME
RSBI
WAVE
RT
REPOR
2023-09-14 7:30 PM - 8:01 PM Pass
* Initial Unit/Bed:
Admit
Clear
Back to Roster
Perform SBT

The LEADS Study – Checklist Summary for RTs

1. Bedside set-up with EA
2. Perform SBT using EA (ref. 7-Step Guide)
3. Generate SBT Report - Review with MD *prior to extubation decision making*
4. *Complete Case Report Forms:*
   - ✓ *MD: Complete "Usefulness Scale Questionnaire"*
   - ✓ *RT: Complete "Form 6: Intervention (EA) Daily Data Form"*
     - ✓ *+/- Form 8: Protocol Violations, Form 11: Extubation Advisor Related Adverse Events, Form 9:* Adverse Event/Serious Adverse Events
5. Repeat (until patient is successfully extubated, need for tracheostomy, discharge on MV, or death)

1. Perform SBT <u>without</u> EA
2. Extubation decision
3. *RT: Complete "Form 6: Standard-of-care Daily Data Form"*
   - ✓ *+/- Form 8: Protocol Violations, Form 11: Extubation Advisor Related Adverse Events, Form 9:* ***Adverse Event/Serious Adverse Events***
4. Repeat (until patient is successfully extubated, need for tracheostomy, discharge on MV, or death)

Therapeutic Monitoring Systems

Estimated RT Workload

LEADS Trial
Extubation Advisor

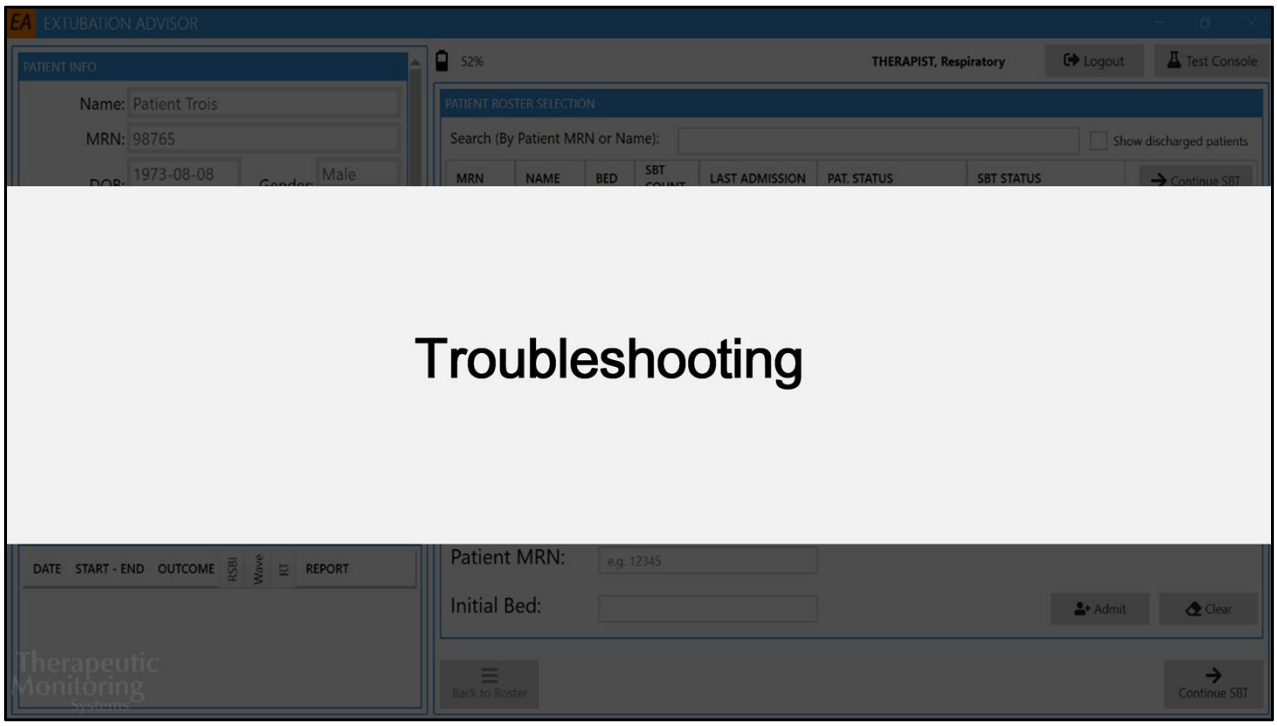
INTERVENTION GROUP

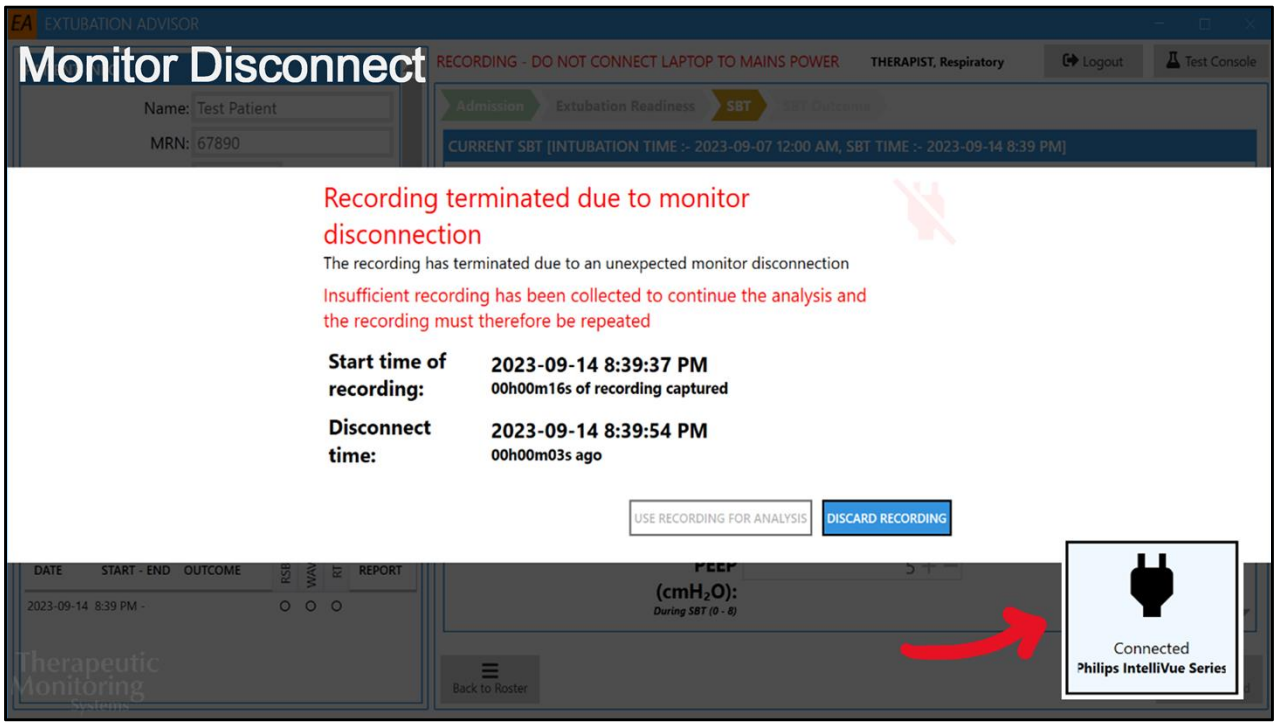
**Time will depend on the RT's comfort level with using EA.*

- 1st SBT - for patients enrolled - anticipate approximately **30 mins** in addition to the time spent performing the SBT
  - → During the SBT, the RT can simultaneously perform the following tasks:
    - ❑ Complete EA data entry: admission data and the extubation readiness checklist
- For subsequent SBTs - approximately **20 mins**

CONTROL GROUP - complete the paper CRF - **5 mins**

Therapeutic Monitoring Systems


EA EXTUBATION ADVISOR
PATIENT INFO
Name: Patient Trois
MRN: 98765
1973-08-08
Male
52%
THERAPIST, Respiratory
Logout
Test Console
PATIENT ROSTER SELECTION
Search (By Patient MRN or Name):
Show discharged patients
MRN
NAME
BED
SBT COUNT
LAST ADMISSION
PAT. STATUS
SBT STATUS
Continue SBT
Troubleshooting
DATE
START - END
OUTCOME
RSBI
Wave
RT
REPORT
Patient MRN:
e.g. 12345
Initial Bed:
Admit
Clear
Therapeutic Monitoring Systems
Back to Roster
Continue SBT

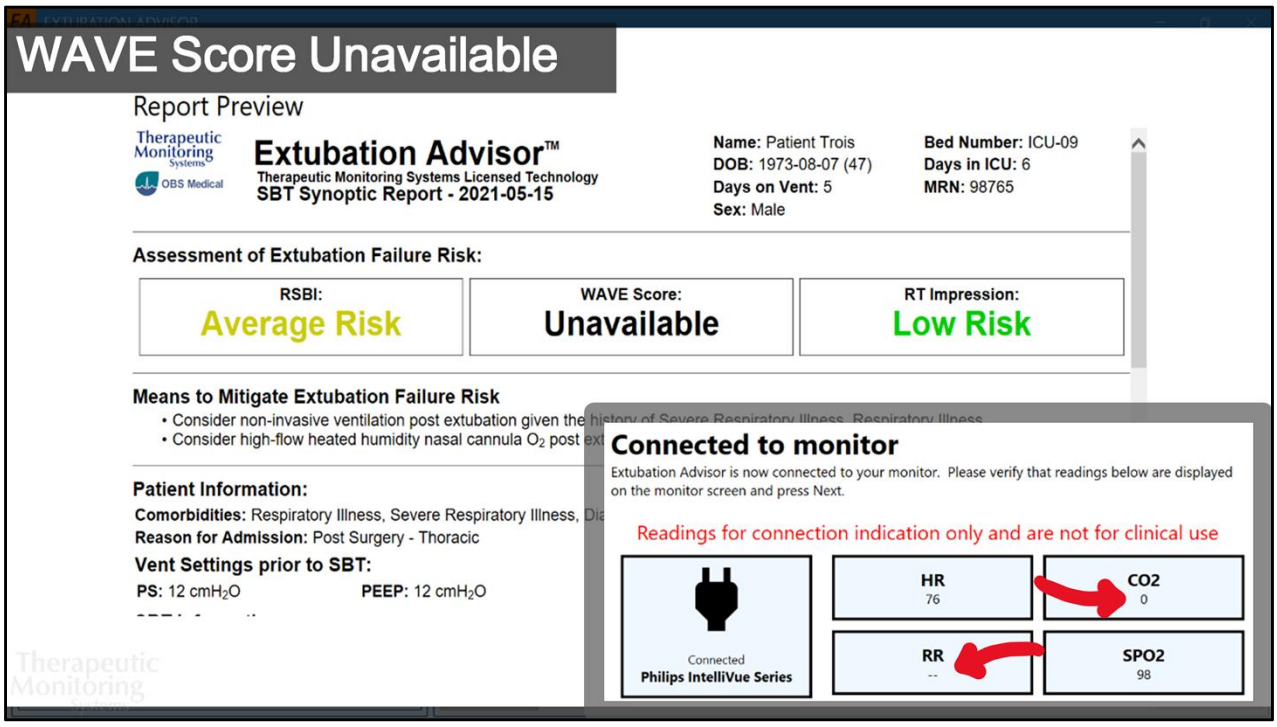


MONITOR DISCONNECT

The following **Error Recording message** will appear along with an audible alarm in the event there is an unexpected disconnect between the EA device and the patient monitor during a SBT recording.

- If there is a disconnect before the minimum 15-minute recording period, the SBT will need to restart and only the **Discard Recording** button is available.
- If the disconnect occurs after 15 minutes, users *may* proceed to keep the recorded data captured by selecting **Use Recording for Analysis** OR discard the results and restart the trial. Decision to keep the data or restart the trial collection is up to the user's discretion, however data used should best represent the patient's SBT performance.

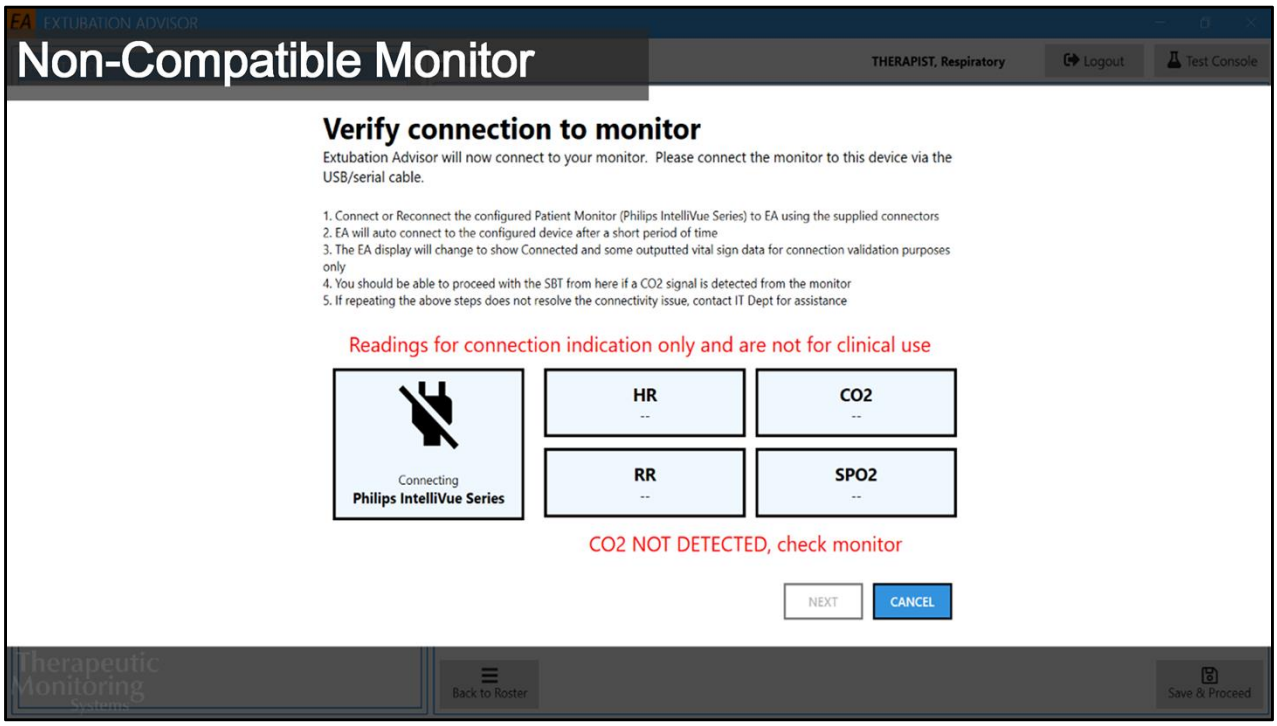
To proceed with the SBT, check system connections and verify the patient monitor data is being recorded again – this can be verified by the plug icon on the SBT recording page (arrow) and by the live vitals capture screen presented prior to SBT recording.



WAVE SCORE UNAVAILABLE

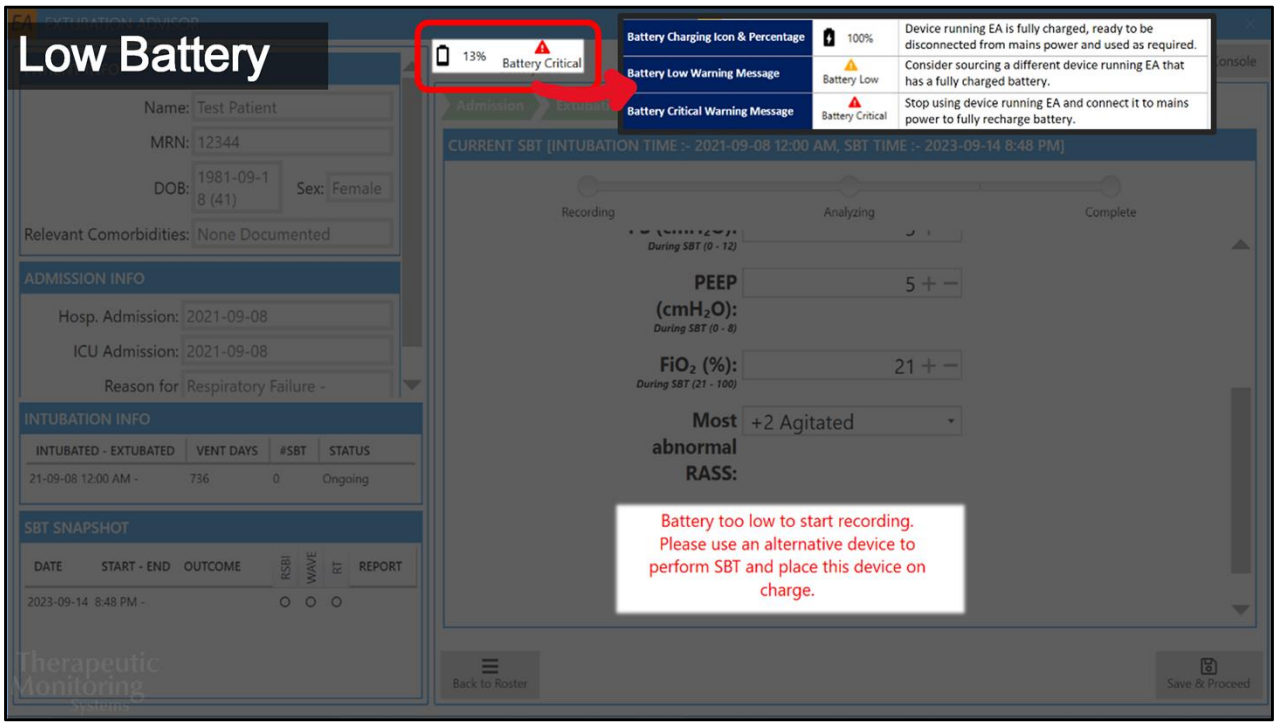
The WAVE Score is extracted from respiratory waveforms via capnography recorded during the patient's SBT. If the capnography is not in-line, EA will not proceed to the recording. If the capnography module is not functioning properly, EA might not be able to complete the WAVE analysis for that patient and it will be **unavailable** in the generated report.

To ensure EtCO2 and RR are being recorded, verify values are present for CO2 and RR in the live vitals capture screen (as highlighted above) *before* proceeding with the SBT. Also ensure the capnography module is placed firmly in the patient monitor and the monitoring device is within close proximity to the patient in the ventilator circuit.



NON-COMPATIBLE MONITOR
The EA software works with the GE (B850, B450, B650), Philips (MP50, MP70, MP90, MX600-800), or Medtronic Capnostream20 patient monitoring devices.

If the laptop/tablet is connected to a patient monitor that is not compatible with EA or is not connected properly to a compatible patient monitor, the **Verify Connection to Monitor** error may appear in addition to no vital signs being recorded. In this case, disconnect the patient monitor and replace with a compatible device. This error may also appear if the connections are too loose or there is poor cord integrity (fraying, twisted, etc.).



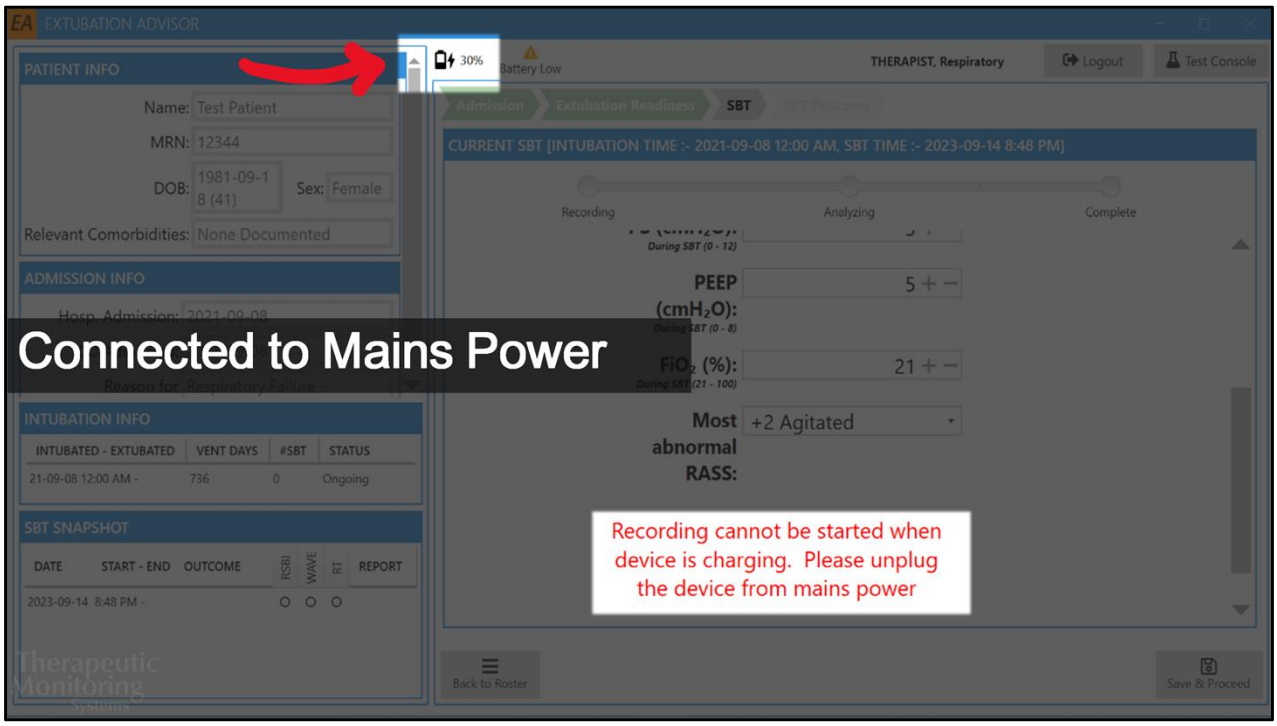
LOW BATTERY

To run the EA software, the laptop battery should be as close to fully charged as possible. To run the software, the battery must be at least ***15%*** - we suggest running SBTs with at least 30-40% charge (at minimum). Below this amount, the battery is considered **critical** and the SBT will not run - as indicated with the following error message (above).

When not in use, the device running EA should be kept charging to ensure it is ready for the next SBT. If the battery dies during the SBT, recorded data will be lost.

Battery low (yellow icon) = ≤30%
Batter critical (red icon) = ≤15%

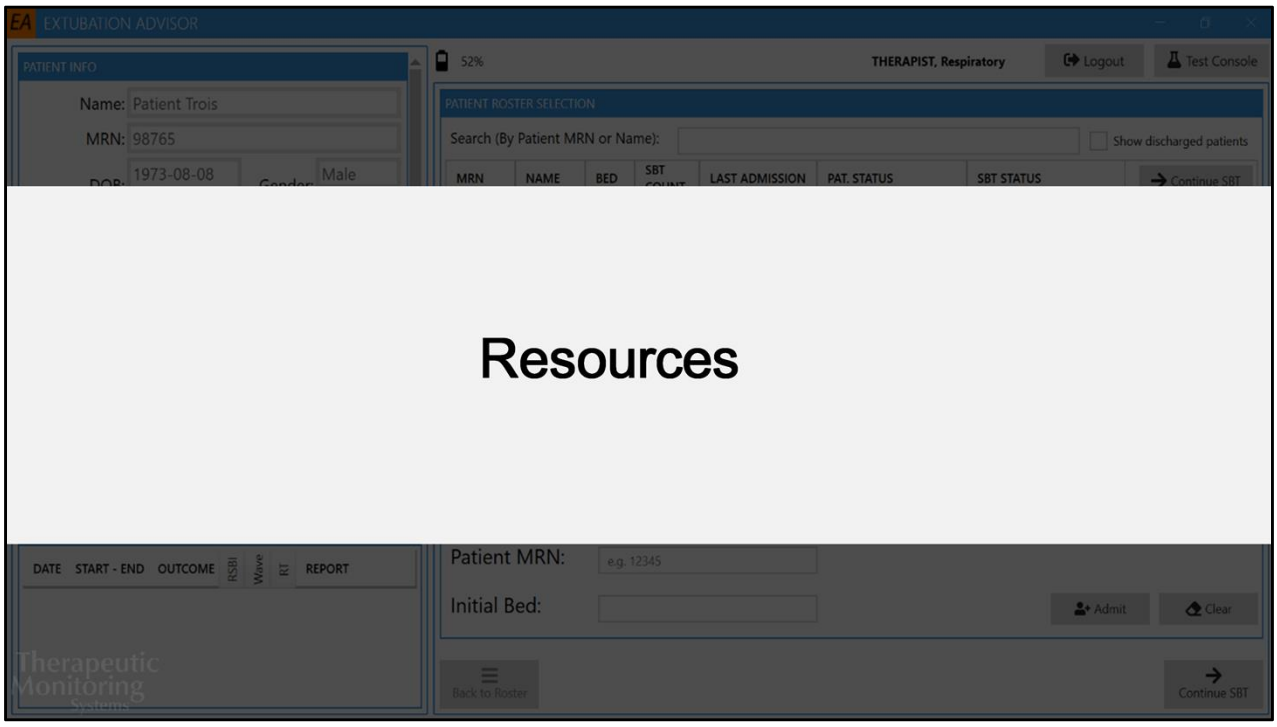
Note: Use of an alternative device will require recreating the patient record (EA enrollment is locally saved), which will not sync to other devices. We suggest keeping the device charged between uses to prevent creating multiple unsynchronous records for a given patient.



DEVICE PLUGGED IN
Connection to a mains power supply can be seen by the lightening bolt beside the battery icon.

Some sites may prohibit electronics to be connected to an electrical outlet at the patient's bedside (site and policy-dependent). If connection to mains power is prohibited, EA is configured to prevent users from running SBTs if the laptop/tablet is connected to a mains power source. This feature is disabled if connection to mains power is acceptable.

Note: If connection to a mains power is prohibited and the device is plugged in during a SBT recording, all data recorded to that point will be lost.


EXTUBATION ADVISOR
PATIENT INFO
Name: Patient Trois
MRN: 98765
1973-08-08
Male
52%
THERAPIST, Respiratory
Logout
Test Console
PATIENT ROSTER SELECTION
Search (By Patient MRN or Name):
Show discharged patients
MRN
NAME
BED
LAST ADMISSION
PAT. STATUS
SBT STATUS
Continue SBT
Resources
DATE
START - END
OUTCOME
RSBI
Wave
RT
REPORT
Patient MRN:
e.g. 12345
Initial Bed:
Admit
Clear
Therapeutic Monitoring Systems
Back to Roster
Continue SBT

The LEADS Trial – Resources

RT Resource Binder

7-Step Guide
(attached to EA device)

Index Cards
(to attach to RT badges)

Randomization Magnets
(to identify participants)

WhatsApp – RT Support

Monthly Virtual RT
Office Hours and FAQs

Website: www.leadstrial.ca

ClinicalTrials.gov: https://www.clinicaltrials.gov/study/NCT05506904

Additional resources

The LEADS Trial – Contacts

PROJECT LEADS

Study Principal Investigator: Dr. Karen Burns – Unity Health (karen.burns@unityhealth.to)
Study Co-Investigator: Dr. Andrew Seely – The Ottawa Hospital (aseely@toh.ca)

For specific study inquiries, please email: leadstrial@ohri.ca

RESEARCH STAFF

Multicenter Research Coordinator: Jill Allan
Multicenter RT Support: Emma Lee

EA SOFTWARE SUPPORT:

Biomedical Engineers: Christophe Herry and Nathan Scales

Additional Support:

Site-specific WhatsApp group
RT LEAD Champions (super-users)
Monthly (virtual) study forums
FAQs (updated list found on: www.leadstrial.ca)

Therapeutic Monitoring Systems