



Version 1

Clinical User Guide



CE 1639

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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 hrs) is associated with increased morbidity, mortality & costs.

Extubation Advisor (EA) is the first clinical decision support tool developed to provide prediction of extubation outcomes and standardize the assessment of extubation readiness. It is a tool to assist in the complex decisions made in assessing extubation readiness and management of ventilated patients. It does not replace the clinical judgment of a Clinician.

EA combines a respiratory rate variability (RRV) derived predictive model of the risk of extubation failure called the WAVE score, the rapid shallow breathing index (RSBI), clinical impression of extubation failure risk, and a standardized extubation readiness checklist to generate an extubation report 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 minimise extubation failure and enhance care.

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
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The low-risk category corresponds to patients who have a risk estimate below the average population risk of 11.5%. Both average and high-risk categories have a risk estimate above the average population risk, with an incidence of extubation failures higher than 20% 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 standardised 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: high > 15% risk of extubation failure, average 5-15%, low < 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.

Low Risk	Average Risk	High Risk
RT perceived risk of extubation failure less than 5%	RT perceived risk of extubation failure is between 5 to 15%	RT perceived risk of extubation failure greater than 15%

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 properly trained clinicians. Extubation Advisor is for prescription use only.

Safety Information

OBS Medical products are designed to meet stringent safety standards. Users should read and adhere to all 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 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.

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.

Trademarks

Extubation Advisor™ is a registered Trademark of Therapeutic Monitoring Systems.

Symbols

Symbol	Title	Description
	Manufacturer	Indicates the medical device manufacturer
	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

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.

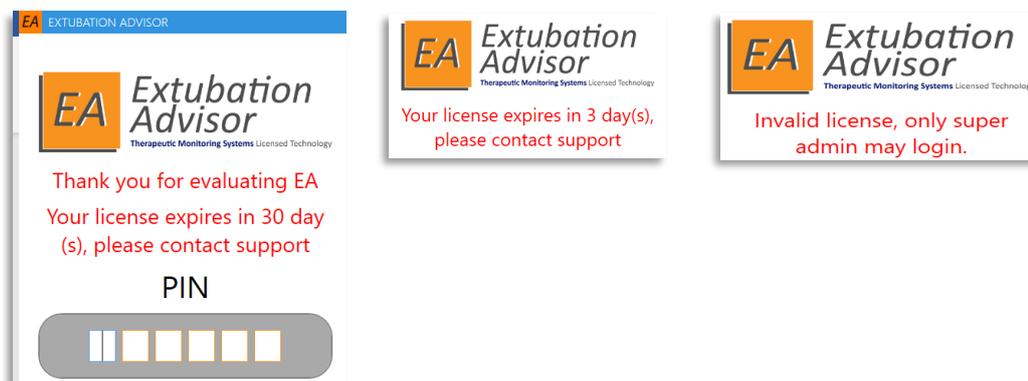
EA comes preinstalled with a 30-day trial license to facilitate set-up and configuration before requiring activation using a license key. The license key is specific to a given computer and cannot be used on any other computer.

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 licence expiration notification to minimise 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 devices 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 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)	
Super Admin	<p>Manages the overall installation and configuration of the systems Global or Local settings and its Users.</p> <ul style="list-style-type: none">- Adding, Editing or Deleting of Users- Patient Monitor Settings- Clinical Documentation Settings- SBT Synoptic Report Settings
Clinical: (Part No. 011-1014-LMAN)	
Respiratory Therapist (RT)	<p>Completes the various tasks associated with the documentation and reporting of an SBT.</p> <ul style="list-style-type: none">- 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- Reviewing and Generating the SBT Synoptic Report

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
 2. Patient Admit form
 3. Patient Demographic and Comorbidity information
 4. Admission Reason and associated dates information
 5. Intubation information
 6. SBT Snapshot 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
 - SBT Outcome
 - Risk Scores
 - **RSBI**
 - **WAVE**
 - **RT Impression**
 - EA Generated SBT Synoptic Report

The screenshot shows the EA Extubation Advisor interface. The top bar includes the EA logo, the title 'EXTUBATION ADVISOR', a 75% zoom level, the user name 'NICOLLE, Brett', and a 'Logout' button. The dashboard is divided into several sections:

- 1. PATIENT ROSTER SELECTION:** A table listing patients with columns for MRN, NAME, BED, SBT COUNT, LAST ADMISSION, PAT. STATUS, and SBT STATUS. The patient Mary Berry (MRN 47815) is highlighted in blue.
- 2. ADMIT NEW PATIENT TO ROSTER:** A form for adding a new patient, including fields for First name, Last name, Patient MRN, Initial Bed, Gender, and Date Of Birth.
- 3. PATIENT INFO:** A form for patient demographics, including Name (Mary Berry), MRN (47815), DOB (6/7/1941), Gender (Female), and Comorbidities (Cardiac Illness, Severe Cardiac Illness, Diabetes - Oral Hypoglycemics).
- 4. ADMISSION INFO:** A form for admission details, including Hosp. Admission (9/29/2020), ICU Admission (9/29/2020), and Reason for Admission (Shock - Septic, Post Surgery - Vascular).
- 5. INTUBATION INFO:** A table showing intubation events with columns for INTUBATED - EXTUBATED, VENT DAYS, #SBT, and STATUS. One entry is shown for 9/30/20 at 9:00 AM with 0 vent days, 1 SBT, and an 'Ongoing' status.
- 6. SBT SNAPSHOT:** A table showing SBT snapshots with columns for DATE, START - END, OUTCOME, RSBI, WAVE, RT, and REP. One entry is shown for 9/30/2020 from 10:00 AM to 10:02 AM with a 'Pass' outcome.

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.

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.

PATIENT ROSTER SELECTION							
Search (By Patient MRN or Name): <input type="text"/>						<input checked="" type="checkbox"/> Show discharged patients	
MRN	NAME	BED	SBT COUNT	LAST ADMISSION	PAT. STATUS	SBT STATUS	↓
65432	John Wilkinson	ICU-10	1 / 1	9/29/20 -	Awaiting MD Review	SBT > Report Generated	→ Perform SBT
87461	Paul Nichols	ICU-10	2 / 3	9/29/20 -	Intubated	SBT > Readiness	Extubate
32121	Linda Shields	ICU-09	0 / 0	9/25/20 -	Intubated	SBT > Outcome	Discharge
54621	Michael Rutter	ICU-07	0 / 0	9/29/20 -	Intubated	SBT > Analysis	Edit
47815	Mary Berry	ICU-11	0 / 3	9/29/20 -	Extubated (0 day(s) off vent)		Readmit
14781	Jamie Holland		0 / 0	9/29/20 - 10/6/20	Discharged		

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. <ul style="list-style-type: none"> Use the Perform SBT button to start the workflow.
	Intubated	Confirms the intubation date has now been inputted. <ul style="list-style-type: none"> 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. <ul style="list-style-type: none"> 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. <ul style="list-style-type: none"> 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. <ul style="list-style-type: none"> 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.

ADMIT NEW PATIENT TO ROSTER

First name:

Last name:

Patient MRN:

Initial Bed:

Gender: Male Female

Date Of Birth:

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 organisation.

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.

Warning

The selected patient Paul Nichols [87461] has completed reports.

If any changes are made to the patient details, previous reports will not be updated to reflect the changes.

Are you sure you wish to continue?

Edit Patient

Please note reports previously generated will NOT be updated

First Name:

Last Name:

Patient MRN:

DOB:

Gender: Male Female

Location: The patient's current location is set as part of each SBT.

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

INTUBATION INFO			
INTUBATED - EXTUBATED	VENT DAYS	#SBT	Status
28/06/20 22:18 - 10/07/20 15:00	11	5	Planned Extubation

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.

Intubate Patient

Please confirm the date & time patient Brett Nicolle [12345] was intubated.

Date/Time of Intubation:

Bed during Intubation:

July 2020

Su	Mo	Tu	We	Th	Fr	Sa
28	29	30	1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16		

12:00

01:00

02:00

03:00

04:00

05:00

06:00

07:00

08:00

09:00

10:00

11:00

(to nearest hour)

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

SBT SNAPSHOT						
DATE	START - END	OUTCOME	RSBI	Wave	RT	REPORT
13/07/2020	09:33 -		○	○	○	
12/07/2020	09:15 - 09:29	Pass	●	●	●	
11/07/2020	08:58 - 09:02	Pass	●	●	●	
10/07/2020	08:47 - 08:55	Equivocal	●	●	●	
09/07/2020	22:10 - 22:17	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.

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 Extubation** and **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 committing 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.

COMORBIDITIES AT TIME OF ADMISSION

Cardiac Illness: Yes
known CAD, cardiomyopathy, valvular disease, diastolic or systolic dysfunction No
 Unknown

Severe Cardiac Illness: Yes
Presence of ejection fraction < 45%, CCS Class III Angina (moderate limitation, with symptoms with everyday living activities), AHA Class III CHF (marked limitation of physical activity) No
 Unknown

Respiratory Illness: Yes
known COPD, emphysema, pulmonary fibrosis, asthma No
 Unknown

Severe Respiratory Illness: Yes
Presence of severe asthma/COPD with FEV1/FVC < 70% or FEV1 < 50%, or home oxygen use No
 Unknown

Diabetes: Insulin Dependent
 Oral Hypoglycemics
 Diet Controlled
 Not Diabetic

Other Major Illness:

PATIENT INFO

Name:

MRN:

DOB: **Gender:**

Comorbidities:

PATIENT INFO

Name:

MRN:

DOB: **Gender:**

Comorbidities:

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.

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**) (**cmH₂O**) settings prior to SBT.
2. Document the Positive end-expiratory pressure (**PEEP**) (**cmH₂O**) settings prior to SBT
3. Document the **Richmond Agitation-Sedation Scale (RASS)**
4. Select the **Proceed to SBT** button

The screenshot shows a software interface for documenting SBT settings. On the left, there are two sections: 'PATIENT INFO' and 'ADMISSION INFO'. 'PATIENT INFO' includes Name: Linda Shields, MRN: 32121, DOB: 4/12/1964 (56), Gender: Female, and Comorbidities: Respiratory Illness. 'ADMISSION INFO' includes Hosp. Admission: 7/31/2020, ICU Admission: 7/31/2020, and Reason for Admission: Post Surgery - Thoracic. The main area is titled 'CURRENT SBT [INTUBATION TIME :- 7/31/2020 8:00 AM]'. It features a red warning message: 'Please enter the ventilator settings prior the SBT'. Below this, there are input fields for PS (cmH₂O) with a range of 0-65, PEEP (cmH₂O) with a range of 0-40, and a dropdown for RASS Score. A checkbox labeled 'Patient not on Pressure Support Ventilation' is present. A 'Proceed to SBT' button is at the bottom. A status indicator shows 'Connecting Philips IntelliVue Series'.

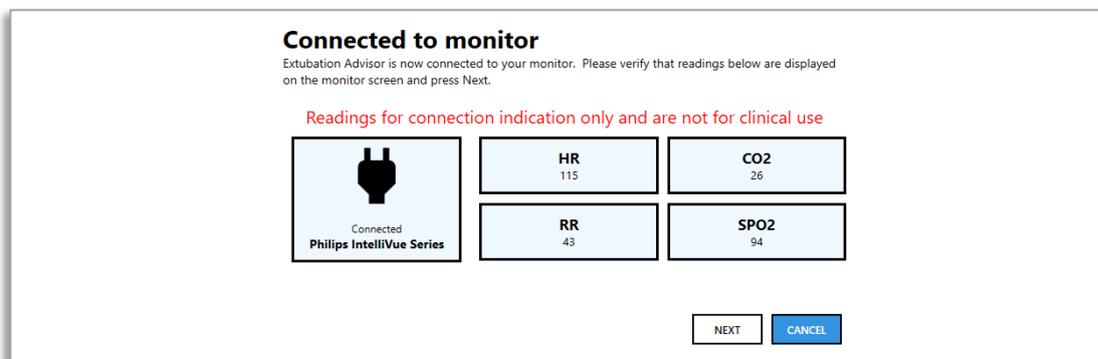
This is a close-up of the SBT recording interface. The red warning message is still present. The PS (cmH₂O) field is set to 'N/A', and the PEEP (cmH₂O) field is also set to 'N/A'. The RASS Score dropdown is set to '+1 Restless'. The 'Patient not on Pressure Support Ventilation' checkbox is now checked. The 'Proceed to SBT' button is highlighted in yellow. The status indicator now shows 'Connected Philips IntelliVue Series'.

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.

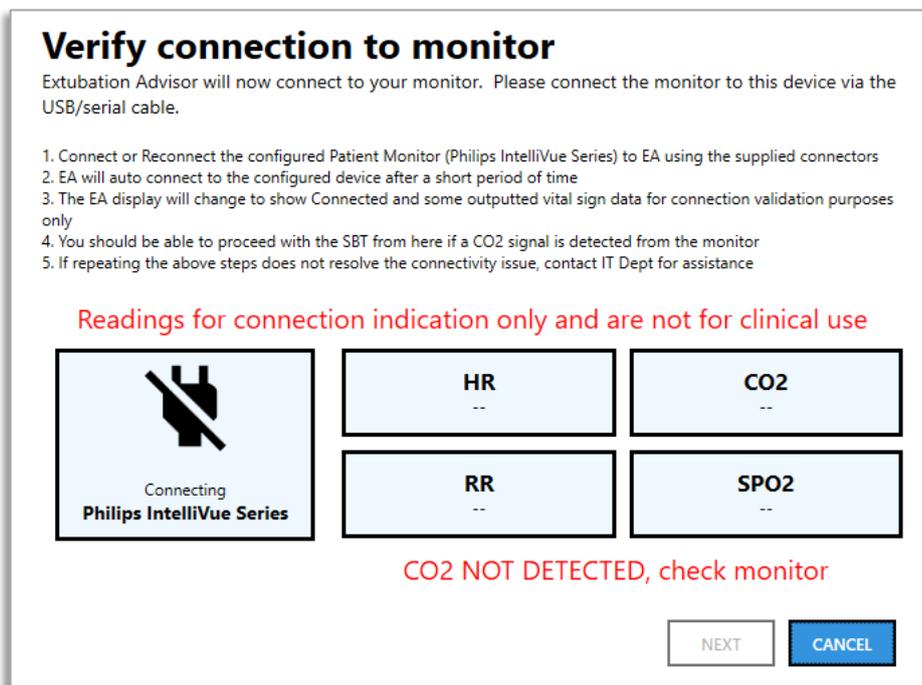
Connecting to a configured Patient Monitor

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 (cmH₂O) – During SBT**
- **PEEP (cmH₂O) – During SBT**
- **Fraction of inspired oxygen (FiO₂) (%) – During SBT**

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

The screenshot shows a software interface for starting an SBT recording. At the top, it displays 'PS (cmH₂O): 44 + -' and 'Patient not on'. The main heading is 'You are about to commence an SBT for patient Paul Nichols [87461]'. Below this, it says 'Please lower the PS/PEEP settings on the ventilator and record the new values below. Then press OK to begin the recording.' There is a 'Connected Philips IntelliVue Series' icon. The 'Date/Time of SBT' is set to '8/3/2020 3:10 PM'. The settings are as follows:

Setting	Value	Label
PS (cmH ₂ O)	44 + -	Prior to SBT (0 - 40)
PEEP (cmH ₂ O)	33 + -	Prior to SBT (0 - 40)
PS (cmH ₂ O)	+ -	During SBT (0 - 44)
PEEP (cmH ₂ O)	+ -	During SBT (0 - 33)
FiO ₂ (%)	+ -	During SBT (21 - 100)

Buttons for 'START RECORDING' and 'CANCEL' are at the bottom.

Review any error messages as displayed and correct as required.

This screenshot is identical to the previous one, but with an error message. The 'PS (cmH₂O)' value during SBT is set to 45 + -. A red error box appears to the right of the input field, containing the text: 'Please enter the PS value during the SBT which must be greater than 0 and less than the prior value'. The 'START RECORDING' and 'CANCEL' buttons are still visible at the bottom.

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.

The screenshot shows the Extubation Advisor (EA) interface. On the left, there are sections for Patient Info (Name: John Wilkinson, MRN: 65432, DOB: 5/4/1950, Gender: Male, Comorbidities: Respiratory Illness, Diabetes - Oral Hypoglycemics), Admission Info (Hosp. Admission: 7/27/2020, ICU Admission: 7/27/2020, Reason for Admission: Respiratory Failure - Hypercarbic, Post Surgery - Trauma), Intubation Info (table with columns: INTUBATED - EXTUBATED, VENT DAYS, #SBT, Status), and SBT Snapshot (table with columns: DATE, START - END, OUTCOME, ESEI, Wave, IT, REPORT). The main area is titled 'RECORDING - DO NOT CONNECT LAPTOP TO MAINS POWER' and shows a progress bar with stages: Admission, SBT, Extubation Readiness, and SBT Outcome. The current SBT is in progress, with a timer at 00:07:22. A 'REC' icon indicates recording is active. Parameters shown include PS (cmH₂O) at 33 (Prior to SBT), PEEP (cmH₂O) at 21 (Prior to SBT), PS (cmH₂O) at 15 (During SBT), PEEP (cmH₂O) at 9 (During SBT), FiO₂(%) at 21 (During SBT), and RASS Score at +2 Agitated. A checkbox for 'Patient not on Pressure Support Ventilation' is unchecked. At the bottom, there are buttons for 'End SBT' and 'Cancel Recording'. A red warning message states: 'A minimum of 15 minutes recording is required to end the SBT'. Navigation buttons 'Back to Roster' and 'Save & Proceed' are at the bottom.

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.



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 analyse the recorded data and to calculate the **WAVE Results**.
3. The Progress Bar for **SBT** will turn Green

EA EXTUBATION ADVISOR

PATIENT INFO

Name: Joules Holland
 MRN: 69751
 DOB: 21/01/1974 (46) Gender: Male
 Comorbidities: None Documented

ADMISSION INFO

Hosp. Admission: 29/06/2020
 ICU Admission: 29/06/2020
 Reason for Admission: Shock - Septic

INTUBATION INFO

INTUBATED - EXTUBATED	VENT DAY	#SBT	Status
30/06/20 10:00 -	5	0	Ongoing

SBT SNAPSHOT

DATE	START - END	OUTCOME	RSBI	Wave	RT	REPORT
05/07/2020	15:17 -		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

RECORDING - DO NOT CONNECT LAPTOP TO MAINS POWER

NICOLLE, Brett Logout

Admission → **SBT** → Extubation Readiness → SBT Outcome

CURRENT SBT [INTUBATION TIME :- 30/06/2020 10:00, SBT TIME :- 05/07/2020 15:17]

Recording Analysing Completed

REC
Recording

01:10:18

Time of SBT: 05/07/2020 15:17
Will be updated when you start SBT

PS (cmH₂O): 41 +-
Prior to SBT (0 - 45)

PEEP (cmH₂O): 32 +-
Prior to SBT (0 - 40)

PS (cmH₂O): 22 +-
During SBT (0 - 33)

PEEP (cmH₂O): 15 +-
During SBT (0 - 21)

FiO₂(%): 33 +-
During SBT (21 - 100)

RASS Score: +1 Restless

End SBT Cancel Recording

Back to Roster Save & Proceed



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

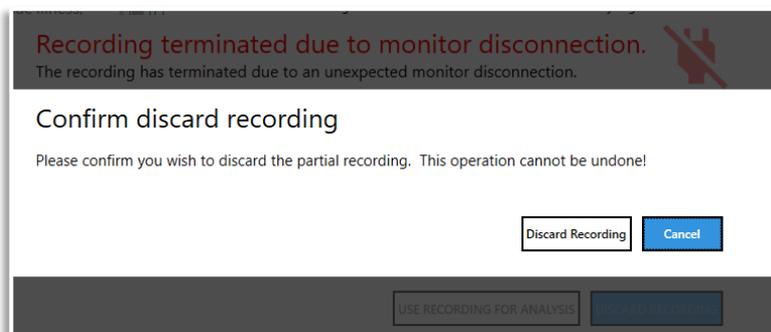
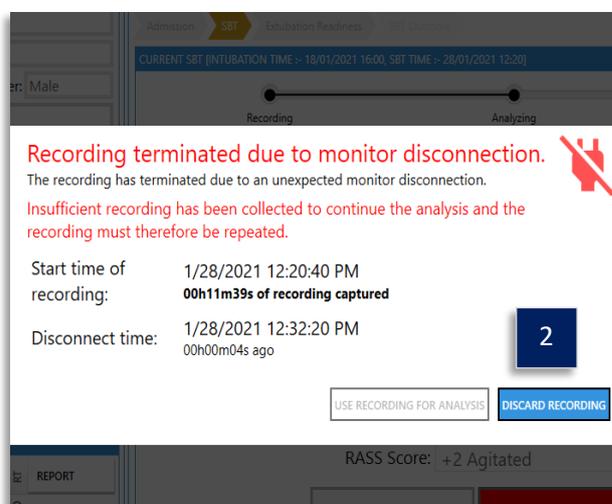
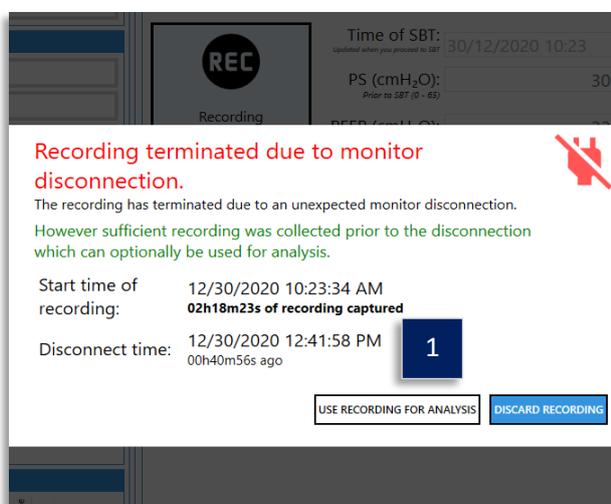
The cable connecting the Patient Monitor and the device running EA should **not be disconnected during an SBT Recording**.

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: RT’s 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 RT’s 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

Missing vital signs

The monitor has not provided all of the required vital signs during the recording. Please complete the form below with the values for the missing vital signs.

WAVE Results

Probability of extubation failure **Below Average**

Predicted risk of extubation failure 7%

Vitals Recorded during SBT

Avg. HR* 20.00

Avg. SpO2* 94.57

Avg. BP* 150 / 87

Avg. MAP* 108 **Estimate**

Avg. RR (CO2) 22.1

* Mandatory Value

SAVE **COMPLETE LATER**

CURRENT SBT [INTUBATION TIME - 02/02/2021 12:00, SBT TIME - 07/02/2021 10:31]

Recording Analyzing Completed

Time of SBT: 07/02/2021 10:31

PS (cmH₂O): 33

PEEP (cmH₂O): 17

PS (cmH₂O): 22

PEEP (cmH₂O): 12

FIO₂(%): 25

RASS Score: +2 Agitated

Analysis Complete

WAVE Results

Probability of extubation failure **Below Average**

Predicted risk of extubation failure 7%

Vitals Recorded during SBT

Avg. HR* 20.00

Avg. SpO2* 94.57

Avg. BP* 150 / 87

Avg. MAP* 108 **Estimate**

Avg. RR (CO2) 22.1

* Mandatory Value

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.

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

Admission SBT Extubation Readiness SBT Outcome

Complete the form below with details regarding the ongoing SBT. The SBT itself may be run before completing this information, however it must be completed to generate a final report.

RESPIRATORY

Airway:

- Test Not Done
- Cuff Leak Present
- No Cuff Leak Present

Coughs:

- Spontaneous
- Only Upon Request
- Only With Suctioning
- Unknown

Cough Strength:

- Strong
- Average
- Weak
- Unknown

SpO2 > 90%:

- Yes
- No
- Unknown

STRENGTH

Lift head off pillow for > 5 sec:

- Yes
- No
- Unknown

Firm Hand Grip:

- Yes
- No
- Unknown

RENAL

Negative Fluid Balance Last 24h:

- Yes
- No
- Unknown

NEURO

Gag:

- Present
- Not Present
- Unknown

Obeys Commands:

- Yes
- No
- Unknown

Back to Roster Save & Proceed



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.

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**.

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.

Admission SBT Extubation Readiness SBT Outcome

Complete the form below with details regarding the the outcome of the SBT.

CURRENT SBT (INTUBATION TIME - 02/02/2021 12:00, SBT TIME - 07/02/2021 10:31)

End time of SBT: 07/02/2021 10:34

SBT Completed as planned?: Yes No

Average RR (Breaths / min):

Average TV (mL):

Average RSBI: --

SBT Outcome: Pass Equivocal Fail

(Pass means absence of tachypnea, hypoxemia, hypercapnea, instability, ischemia, neuro deterioration, or bradypnea during SBT)

If patient were to be extubated, please provide your best professional assessment regarding the risk of extubation failure: High (i.e. risk > 15%) Average (i.e. risk is 5-15%) Low (i.e. risk is < 5%)

(Subjective assessment)

Comments to MD: Please include any additional information regarding the patient or the SBT, relevant to decision making. No Comments

Admission SBT Extubation Readiness SBT Outcome

Complete the form below with details regarding the the outcome of the SBT.

CURRENT SBT (INTUBATION TIME - 02/02/2021 12:00, SBT TIME - 07/02/2021 10:31)

End time of SBT: 07/02/2021 10:34

SBT Completed as planned?: Yes No

Average RR (Breaths / min):

Average TV (mL):

Average RSBI: --

SBT Outcome: Pass Equivocal Fail

(Pass means absence of tachypnea, hypoxemia, hypercapnea, instability, ischemia, neuro deterioration, or bradypnea during SBT)

If patient were to be extubated, please provide your best professional assessment regarding the risk of extubation failure: High (i.e. risk > 15%) Average (i.e. risk is 5-15%) Low (i.e. risk is < 5%)

(Subjective assessment)

Comments to MD: Please comment on why the SBT was not completed, as well as any additional information regarding the patient relevant to extubation decision making. No Comments

If SBT failed, equivocal or stopped early, please indicate why (check all that occurred during SBT)

Hypoxemia
Sustained O₂sat < 90% with FIO₂ > 60% and PEEP > 10 cm H₂O

Hypercapnia
Decreased alveolar ventilation, with >33% reduction in minute ventilation or arterial pH < 7.3

Tachypnea
RR > 25 AND / OR clinical respiratory distress (accessory muscle use, increased work of breathing, facies of distress)

Hemodynamic Instability
Drop in blood pressure requiring fluid bolus(es), or increased dose of vasopressors (norepinephrine > 15 µg/min or > 0.2 µg/kg/min or equivalent)

Cardiac Ischemia
Suspected myocardial ischemia based on ST changes on EKG and/or elevated Troponin

Decreased Level of Consciousness
Marked change in responsiveness due to hypoventilation or other cause

Bradypnea
RR < 10 breaths/min, related to sedation or other cause

Other
Please state other cause



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.

Report Preview

**Extubation Advisor™**
Therapeutic Monitoring Systems Licensed Technology
SBT Synoptic Report - 2021-02-07

Name: John Wilkinson
DOB: 1944-01-27 (77)
Days in ICU: 6
Sex: Male

Bed Number: ICU-10
MRN: 65432
Days on Vent: 5

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.

Assessment of Extubation Failure Risk:

RSBI: Low Risk	WAVE Score: Low Risk	RT Impression: Low Risk
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Means to Mitigate Extubation Failure Risk

- Suggest afterload reduction given elevated blood pressure and history of impaired left ventricular function
- Consider non-invasive ventilation post extubation given the history of Severe Cardiac Illness

Patient Information:
Comorbidities: Severe Cardiac Illness, Diabetes - Diet Controlled
Reason for Admission: Post Surgery - Vascular

Vent Settings prior to SBT: PS: 33 cmH ₂ O PEEP: 17 cmH ₂ O	Vent Settings during SBT: PS: 22 cmH ₂ O PEEP: 12 cmH ₂ O FiO ₂ : 25 %
--	---

SBT Information:
Start: 2021-02-07 10:31
End: 2021-02-07 10:34
Duration: 2 minutes
Completed as planned? Yes
RASS Score: +2 Agitated

Vitals during SBT from Monitor:
Average BP: 150 / 88 MAP: 108.7 mmHg
Average HR: 19.7 beats/min
Average RR (CO₂): 22.1 breaths/min
Average O₂ Sat: 94.6 %

Extubation Readiness Checklist:
 Cuff Leak Present
 Strong Cough
 Spontaneous Cough
 SpO₂ > 90%
 Negative Fluid Balance Last 24H
Concerns:
 No Gag Present
 Does Not Obey Commands
Not Reviewed:
Lifts Head
Hand Grip

Rapid Shallow Breathing Index (RSBI):
Average RR: 33 breaths/min
Average TV: 1500 mL
Average RSBI: 22 (< 60 = low risk; 60-110 = average risk; > 110 = high risk)

Respiratory Therapist's Subjective Assessment:
SBT Outcome: Pass
RT Perception of Risk of Extubation Failure: **Low (i.e. risk is < 5%)**

Weaning and Variability Evaluation (WAVE) Decision Support:
(WAVE Score is based on respiratory rate variability during the SBT, thought to reflect the patient's capacity to tolerate an increased respiratory workload.)
Probability of Extubation Failure: **Low Risk**
Predicted risk of extubation failure: 7 %

Please check the preview of the report above. The report will be emailed to nicolle@obsmedical.com on confirmation.

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.

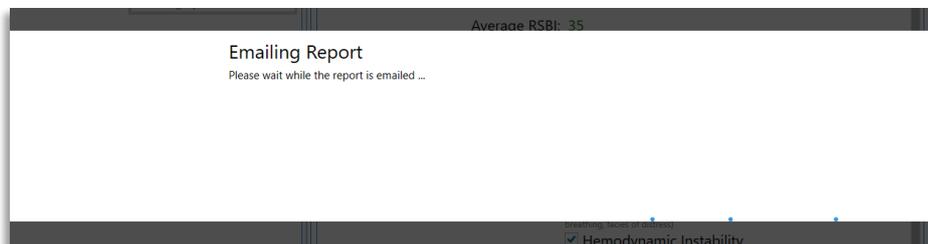
Note: The **Vent Settings prior to SBT** section will display a comment - **Patient not on Pressure Support Ventilation prior to SBT** if the corresponding checkbox for this section was selected.

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.

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

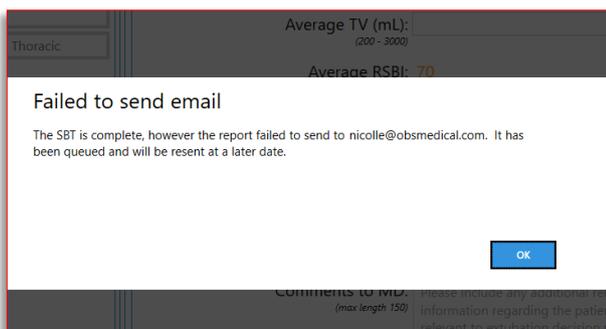


- Once successfully emailed, you will be returned to the Patient Roster.
 - The **Patient Status column** will advise – **Awaiting MD Review**
 - The **SBT Status column** will advise – **SBT > Report Generated**

MRN	NAME	BED	SBT COUNT	LAST ADMISSION	PAT. STATUS	SBT STATUS
32121	Linda Shields	ICU-09	0 / 0	9/25/20 -	Intubated	SBT > Analysis
65432	John Wilkinson	ICU-10	0 / 0	9/29/20 -	Intubated	SBT > Admission
54621	Michael Rutter	ICU-07	0 / 0	9/29/20 -	Intubated	SBT > Readiness
87461	Paul Nichols	ICU-10	0 / 1	9/29/20 -	Extubated (0 day(s) off vent)	
47815	Mary Berry	ICU-11	1 / 1	9/29/20 -	Awaiting MD Review	SBT > Report Generated
14781	Joules Holland	ICU-03	0 / 0	9/29/20 -	Admitted	

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.



DATE	START - END	OUTCOME	RSBI	Wave	RT	REPORT
13/07/2020	09:33 -		○	○	○	
12/07/2020	09:15 - 09:29	Pass	●	●	●	
11/07/2020	08:58 - 09:02	Pass	●	●	●	
10/07/2020	08:47 - 08:55	Equivocal	●	●	●	
09/07/2020	22:10 - 22:17	Fail	●	●	●	

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: <ul style="list-style-type: none"> Severe Cardiac Illness Respiratory Illness Severe Respiratory Illness 	Consider non-invasive ventilation post extubation given the history of <Comorbidities Selected>.
2	Comorbidity is: <ul style="list-style-type: none"> Severe Cardiac Illness and SBT Recording Analysis Results: <ul style="list-style-type: none"> Average Sys BP > 140 or MAP > 85 	Suggest afterload reduction given elevated blood pressure and history of impaired left ventricular function.
3	Extubation Checklist: <ul style="list-style-type: none"> Weak Cough and SBT Recording Analysis Results: <ul style="list-style-type: none"> FiO2 ≤ 40 	Consider high flow heated humidity nasal cannula O2 post extubation given weak cough strength.
4	Extubation Checklist: <ul style="list-style-type: none"> Weak Cough and SBT Recording Analysis Results: <ul style="list-style-type: none"> FiO2 > 40 	Consider high flow heated humidity nasal cannula O2 post extubation given FiO2 > 40% and weak cough strength.
5	Extubation Checklist: <ul style="list-style-type: none"> No Cuff Leak 	Consider steroid administration due to absence of cuff leak.
6	Extubation Checklist: <ul style="list-style-type: none"> No – Negative Fluid Balance Last 24H 	Consider diuresis given positive fluid balance in last 24h.
7	Patient is extubated and then, <ul style="list-style-type: none"> 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



Extubation Advisor™
Therapeutic Monitoring Systems Licensed Technology
SBT Synoptic Report - 2021-02-07

Name: John Wilkinson
DOB: 1944-01-27 (77)
Days in ICU: 6
Sex: Male

Bed Number: ICU-10
MRN: 65432
Days on Vent: 5

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.

Assessment of Extubation Failure Risk:

RSBI: Low Risk	WAVE Score: Low Risk	RT Impression: Low Risk
--------------------------	--------------------------------	-----------------------------------

Means to Mitigate Extubation Failure Risk

- Suggest afterload reduction given elevated blood pressure and history of impaired left ventricular function
- Consider non-invasive ventilation post extubation given the history of Severe Cardiac Illness

Patient Information:
Comorbidities: Severe Cardiac Illness, Diabetes - Diet Controlled
Reason for Admission: Post Surgery - Vascular

<p>Vent Settings prior to SBT: PS: 33 cmH₂O PEEP: 17 cmH₂O</p> <p>SBT Information: Start: 2021-02-07 10:31 End: 2021-02-07 10:34 Duration: 2 minutes Completed as planned? Yes RASS Score: +2 Agitated</p> <p>Vitals during SBT from Monitor: Average BP: 150 / 88 MAP: 108.7 mmHg Average HR: 19.7 beats/min Average RR (CO₂): 22.1 breaths/min Average O₂ Sat: 94.6 %</p> <p>Rapid Shallow Breathing Index (RSBI): Average RR: 33 breaths/min Average TV: 1500 mL Average RSBI: 22 (< 60 = low risk; 60-110 = average risk; > 110 = high risk.)</p>	<p>Vent Settings during SBT: PS: 22 cmH₂O PEEP: 12 cmH₂O FiO₂: 25 %</p> <p>Extubation Readiness Checklist: <input checked="" type="checkbox"/> Cuff Leak Present <input checked="" type="checkbox"/> Strong Cough <input checked="" type="checkbox"/> Spontaneous Cough <input checked="" type="checkbox"/> SpO₂ > 90% <input checked="" type="checkbox"/> Negative Fluid Balance Last 24H</p> <p>Concerns: <input checked="" type="checkbox"/> No Gag Present <input checked="" type="checkbox"/> Does Not Obey Commands</p> <p>Not Reviewed: Lifts Head Hand Grip</p>
---	--

<p>Weaning and Variability Evaluation (WAVE) Decision Support: <small>(WAVE Score is based on respiratory rate variability during the SBT, thought to reflect the patient's capacity to tolerate an increased respiratory workload.)</small> Probability of Extubation Failure: Low Risk</p>	<p>Respiratory Therapist's Subjective Assessment: SBT Outcome: Pass RT Perception of Risk of Extubation Failure: Low (i.e. risk is < 5%)</p>
--	---

RT Comments: None Documented

Print Report
Close

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

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 **colour 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.



Extubation Advisor™
Therapeutic Monitoring Systems Licensed Technology
SBT Synoptic Report - 2022-04-19

1

Name: Jane Doe
DOB: 1981-04-28 (40)
Days in ICU: 12
Sex: Female

Bed Number: ICU-02
MRN: 098761
Days on Vent: 12

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.

1

Patient Information:
Comorbidities: Cardiac Illness, Diabetes - Insulin Dependent
Reason for Admission: Shock - Septic

2

Assessment of Extubation Failure Risk:

RSBI: Low Risk	WAVE Score: Average Risk	RT Impression: Average Risk
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Means to Mitigate Extubation Failure Risk

- Consider diuresis given positive fluid balance in the last 24h

3

Vent Settings prior to SBT:
PS: 10 cmH₂O PEEP: 10 cmH₂O

4

SBT Information:
Start: 2022-04-19 11:38
End: 2022-04-19 11:48
Duration: 10 minutes
Completed as planned? Yes
RASS Score: +1 Restless

5

Vitals during SBT from Monitor:
Average BP: 120.7 / 47.8 MAP: 70.4 mmHg
Average HR: 72.3 beats/min
Average RR (CO₂): 27.1 breaths/min
Average O₂ Sat: 95 %

6

Vent Settings during SBT:
PS: 5 cmH₂O PEEP: 5 cmH₂O **FI_{O2}:** 30 %

7

Rapid Shallow Breathing Index (RSBI):
Average RR: 22 breaths/min
Average TV: 400 mL
Average RSBI: 55 (< 60 = low risk; 60-110 = average risk; > 110 = high risk)

8

Extubation Readiness Checklist:

- Cuff Leak Present
- Strong Cough
- Spontaneous Cough
- SpO₂ > 90%
- Gag Present
- Obeys Commands
- Able to lift head off pillow for > 5 sec
- Firm Hand Grip

Concerns:

- Positive Fluid Balance Last 24H

9

Respiratory Therapist's Subjective Assessment:
SBT Outcome: Pass
RT Perception of Risk of Extubation Failure: Average (i.e. risk is 5-15%)

10

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)
Probability of Extubation Failure: Average Risk
Predicted risk of extubation failure: 17 %
RT Comments: None Documented

Previous SBTs:

Date / Time	RSBI Risk	WAVE Risk	RT Impression Risk
2022-04-19 11:16 - 2022-04-19 11:35	Low Risk	Average Risk	Average Risk

Report Generated: 2022-04-19 11:49:05 **Respiratory Therapist:** Respiratory Therapist

No#	Section / Component	Description
1.	Patient Information	This section is extracted from the hospital admission and patient information found on the patient dashboard.

2.	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.
3.	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.
4.	SBT Information	This section details the Ventilator settings (PS/PEEP/FiO2) set before and during the SBT, as well as the SBT duration.
5.	Vitals	This section details the average vitals captured during the SBT.
6.	Extubation Readiness Checklist	This section details the standard readiness checklist completed by RTs on the patient's readiness for endotracheal tube removal.
7.	RSBI	RR and VT manually input by the RT as based on the recorded ventilator values during the SBT.
8.	Respiratory Therapist Assessment	The subjective assessment by the RTs on the patient's readiness for extubation (as extracted from the SBT Outcome checklist.
9.	WAVE Decision Support	The WAVE score value and probability of extubation failure.
10.	Historic SBT Table	The dates and times of previous SBT's for the same intubation session, along with the risk indices.

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

Hosp. Admission: 02/02/2021
ICU Admission: 02/02/2021

Outcome of last recorded SBT
The last recorded SBT for Patient John Wilkinson [65432] is displayed below.
Please select the current airway status

Date/Time of last intubation: 02/02/2021 12:00

Date/Time of last recorded SBT: 07/02/2021 10:31

Airway Status: <Please Select>

START SBT GO BACK

SBT SNAPSHOT

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 appropriate Airway Status.

Extubate patient Paul Nichols [87461]
Please select the status of the last attempted extubation

Date/Time of last intubation: 18/01/2021 16:00

Date/Time of last recorded SBT: None on record

Airway Status: <Please Select> Select a date: [calendar icon] Now

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.

MRN	NAME	BED	SBT COUNT	LAST ADMISSION	PAT. STATUS	SBT STATUS
32121	Linda Shields	ICU-09	0 / 0	9/25/20 -	Intubated	SBT > Analysis
65432	John Wilkinson	ICU-10	0 / 0	9/29/20 -	Intubated	SBT > Admission
54621	Michael Rutter	ICU-07	0 / 0	9/29/20 -	Intubated	SBT > Readiness
87461	Paul Nichols	ICU-10	0 / 1	9/29/20 -	Extubated (0 day(s) off vent)	
47815	Mary Berry	ICU-11	1 / 1	9/29/20 -	Awaiting MD Review	SBT > Report Generated
14781	Joules Holland	ICU-03	0 / 0	9/29/20 -	Admitted	

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.

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.

Intubate Patient
Please confirm the date & time patient Jim Lovell [554321] was intubated.

Date/Time of **PREVIOUS** Extubation: 20/08/2020 20:00 This Hour

Date/Time of Intubation: Select a date This Hour

Bed during Intubation: ICU-10

START SBT GO BACK

Caution - Re-intubated patient

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

I Understand Go Back

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**.

Discharge patient Michael Rutter [54621]

Please select the reason for discharge

Date of ICU admission:

Date/Time of last intubation:

Discharge reason: <Please Select>

<Please Select>

Discharged to Ward

Transferred to another ICU

Deceased

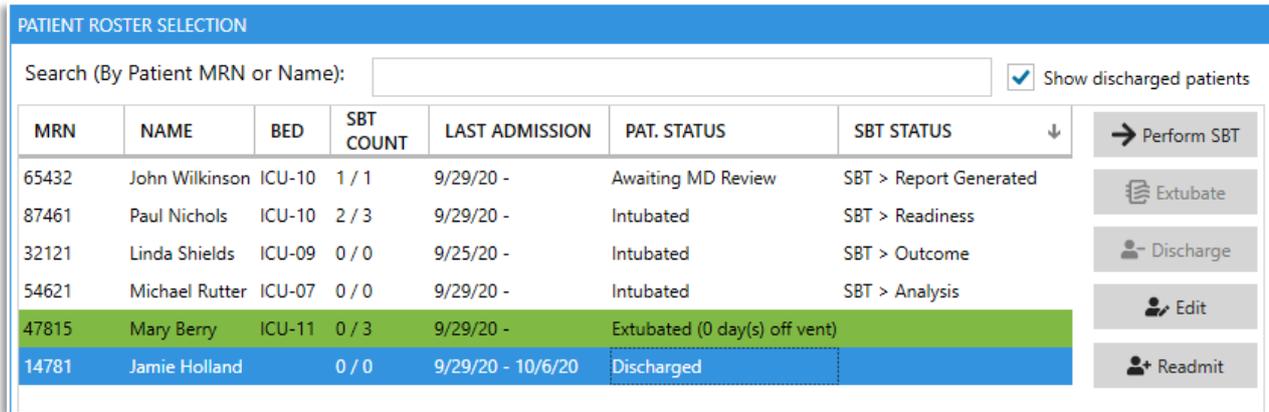
PATIENT ROSTER SELECTION						
Search (By Patient MRN or Name): <input type="text"/>						<input checked="" type="checkbox"/> Show discharged patients
MRN	NAME	BED	SBT COUNT	LAST ADMISSION	PAT. STATUS ↑	SBT STATUS
555555	Peter Doppelganger		0 / 0	8/20/20 - 8/20/20	Discharged	
335121	Mary Berry	ICU-07	0 / 0	8/20/20 -	Intubated	SBT > Admission
998765	Scott Stapp	ICU-09	0 / 0	8/15/20 -	Intubated	SBT > Admission
110101	Steve Jobs	ICU-08	0 / 0	8/10/20 -	Intubated	SBT > Admission
543211	John Wilkinson	ICU-15	0 / 1	8/20/20 -	Intubated	SBT > Analysis
554321	Jim Lovell	ICU-10	0 / 0	8/18/20 -	Self Extubated	

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

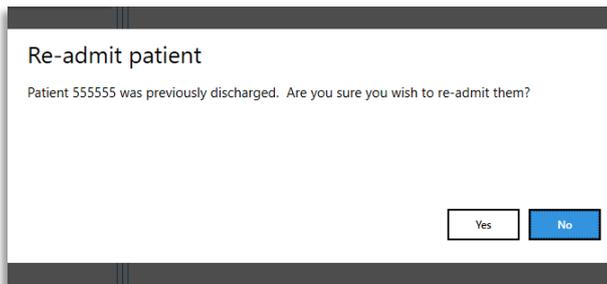
If for any reason you are required to **readmit a patient previously admitted and discharged using EA**, then you will need to action the following:

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



MRN	NAME	BED	SBT COUNT	LAST ADMISSION	PAT. STATUS	SBT STATUS	
65432	John Wilkinson	ICU-10	1 / 1	9/29/20 -	Awaiting MD Review	SBT > Report Generated	→ Perform SBT
87461	Paul Nichols	ICU-10	2 / 3	9/29/20 -	Intubated	SBT > Readiness	Extubate
32121	Linda Shields	ICU-09	0 / 0	9/25/20 -	Intubated	SBT > Outcome	Discharge
54621	Michael Rutter	ICU-07	0 / 0	9/29/20 -	Intubated	SBT > Analysis	Edit
47815	Mary Berry	ICU-11	0 / 3	9/29/20 -	Extubated (0 day(s) off vent)		Readmit
14781	Jamie Holland		0 / 0	9/29/20 - 10/6/20	Discharged		

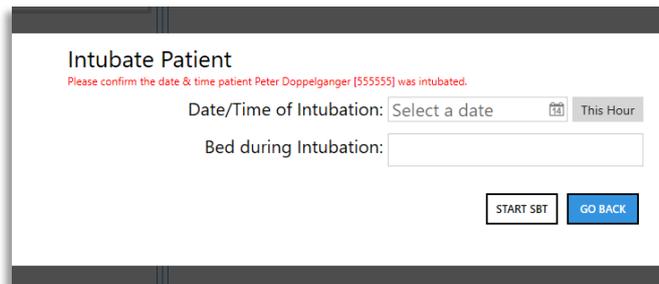
2. **Search for the discharged patient** using the Patient MRN or Name.
3. Select the patient you wish to readmit, and then **select the Readmit button**.
4. A dialogue message will be displayed asking you to confirm if you wish to **Re-admit the selected patient** [Their MRN will be displayed].
5. Select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



Re-admit patient

Patient 555555 was previously discharged. Are you sure you wish to re-admit them?

Yes No



Intubate Patient

Please confirm the date & time patient Peter Doppelganger [555555] was intubated.

Date/Time of Intubation: Select a date [calendar icon] This Hour

Bed during Intubation: [text input]

START SBT GO BACK

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.

Support

If you need any additional support using EA, please contact your local representative.

- 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.

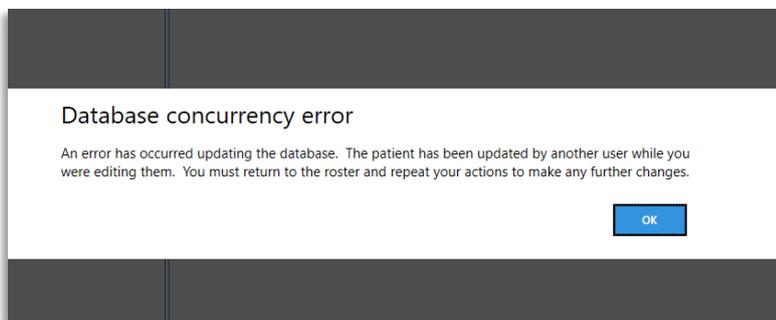
Centralized Database Connection Error

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.

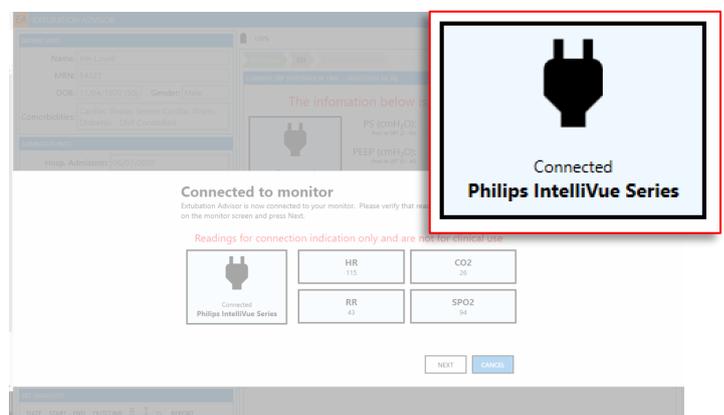
Note: Avoid updating the same patient from different systems.



EA – Patient Monitor Compatibility List

Your EA Administrator / IT Department will configure EA for the compatible patient monitors available within your department.

The configured monitor will be displayed in the “Connected to monitor” box when first Starting an SBT Recording.



Note: If you receive any error messages when attempting to connect a configured patient monitor, please contact your EA Administrator or Biomed Department to investigate and resolve.

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