

# Version 1

# **Clinical User Guide**



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

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

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

This combination of standardized SBT performance and reporting, along with optimal prediction of extubation outcomes aims to minimize extubation failure and enhance care.

## 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 16%. Both average and high-risk categories have a risk estimate above the average population risk, with an incidence of extubation failures higher than 24% for the high-risk group.

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

## **Rapid Shallow Breathing Index (RSBI)**

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

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

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

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

## **Respiratory Therapist's Clinical Impression**

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

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

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

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

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

#### **Intended Use**

The intended Use of the Extubation Advisor software is to provide

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

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

#### **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:

- A EA must not be used outside of its intended use.
- **A** 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.

## Symbols

Symbol	Title	Description		
	Manufacturer Indicates the medical device manufacturer			
LOT	Batch Code	Batch code so the lot or batch can be identified		
REF	Catalogue Number	Catalogue number so product can be identified		
i	Consult Instructions for Use	Indicates the need for user to refer to instructions for use		
<b>R</b> only	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 license expiration notification to minimize disruptions and to renew the license key as required for your computer.

# **Getting Started**

## Logging In

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

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

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



1. Start the EA Application.

2. Input your PIN using the 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 at the top right of every dashboard.

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

## **User Roles**

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

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

# **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
  - $\circ$   $\;$  Date the Patient was intubated
  - o Date the Patient was extubated
  - Number of days on a ventilator
  - Number of SBT's performed
  - Ventilation Liberation Status

#### 6. SBT Snapshot information

- o SBT Outcome
- Risk Scores
  - o RSBI
  - WAVE
  - o RT Impression
- EA Generated SBT Synoptic Report

PATIENT INFO	75%						NICOLLE, Brett	🕞 Logou
Name: Mary Berry 3	PATIENT ROSTE	R SELECTION		1				
MRN: 47815	Search (By Pa	atient MRN o	or Name	):			Show	discharged patient
DOB: 6/7/1941 (79) Gender: Female	MRN	NAME	BED	SBT	LAST ADMISSION	PAT. STATUS	SBT STATUS	→ Perform SBT
Comorbidition Cardiac Illness, Severe Cardiac Illness,	32121 L	inda Shields	ICU-09	0/0	9/25/20 -	Intubated	SBT > Analysis	E Eutubata
Diabetes - Oral Hypoglycemics	65432 J	ohn Wilkinson	ICU-10	0/0	9/29/20 -	Intubated	SBT > Admission	Excludate
	54621 N	lichael Rutter	ICU-07	0/0	9/29/20 -	Intubated	SBT > Readiness	🔓 Discharge
	87461 P	aul Nichols	ICU-10	0/1	9/29/20 -	Extubated (0 day(s) off vent)	l de la companya de l	• . mats
Hosp. Admission: 9/29/2020 4	47815 N	Aary Berry			9/29/20 -	Awaiting MD Review	SBT > Report Generated	er con
ICU Admission: 9/29/2020	14781 J	oules Holland	ICU-03	0/0	9/29/20 -	Admitted		💄 Readmit
Reason for Admission: Shock - Septic, Post Surgery - Vascular								
INTUBATION INFO INTUBATED - EXTUBATED VENT DAYS #5BT STATUS 9/30/20 9:00 AM - 0 1 Ongoing								
INTUBATION INFO INTUBATED - EXTUBATED VENT DAYS #SBT STATUS 9/30/20 9:00 AM - 0 1 Ongoing SBT SNAPSHOT DATE START - END OUTCOME B	ADMIT NEW PA	TIENT TO ROST	rer	2		Gender:	🔿 Male 🔵 Female	
ST SNAPSHOT DATE START - END OUTCOME 9/30/200 10:00 AM - 10:02 AM Pass	ADMIT NEW PA First nam Last nam	TIENT TO ROST	FER	2		Gender: Date Of Birt	◯ Male ◯ Female h: M/d/yyyy	
NTUBATION INFO INTUBATED - EXTUBATED VENT DAVS #SBT STATUS 9/30/20 9:00 AM - 0 1 Ongoing BT SNAPSHOT DATE START - END OUTCOME B A B B C REP 9/30/2020 10:00 AM - 10:02 AM Pass • • • • • •	ADMIT NEW PA First nam Last nam Patient N	TIENT TO ROST ne: [ ne: [ MRN: [	rer 1224	2		Gender: Date Of Birt	◯ Male ◯ Female	
STUBATION INFO INTUBATED - EXTUBATED VENT DAYS #SBT STATUS 9/30/20 9:00 AM - 0 1 Ongoing BT SNAPSHOT DATE START - END OUTCOME 9/30/2020 10:00 AM - 10:02 AM Pass • • • •	ADMIT NEW PA First nam Last nam Patient N	TIENT TO ROST TIE: [ e: [ IRN: [	<b>FER</b> e.g. 1234	2		Gender: Date Of Birt	◯ Male ◯ Female h: M/d/yyyy	
NTUBATION INFO INTUBATED - EXTUBATED VENT DAYS #SBT STATUS 9/30/20 9:00 AM - 0 1 Ongoing BT SNAPSHOT DATE START - END OUTCOME 9/30/2020 10:00 AM - 10:02 AM Pass • • • •	ADMIT NEW PA First nam Last nam Patient N Initial Be	TIENT TO ROST ne: [ ne: [ MRN: [ d: [	ER e.g. 1234	2		Gender: Date Of Birt	Male  Female h: M/d/yyyy	Clear

**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 RO	OSTER SELECTION							
Search (By Patient MRN or Name):						w discharged patients		
MRN	NAME	BED	SBT COUNT	LAST ADMISSION	PAT. STATUS	SBT STATUS	$^{\downarrow}$	→ Perform SBT
65432	John Wilkinson	ICU-10	1/1	9/29/20 -	Awaiting MD Review	SBT > Report Gen	erated	Evtubate
87461	Paul Nichols	ICU-10	2/3	9/29/20 -	Intubated	SBT > Readiness		E chabate
32121	Linda Shields	ICU-09	0/0	9/25/20 -	Intubated	SBT > Outcome		<b>a</b> - Discharge
54621	Michael Rutter	ICU-07	0/0	9/29/20 -	Intubated	SBT > Analysis		• . Eula
47815	Mary Berry	ICU-11	0/3	9/29/20 -	Extubated (0 day(s) off vent	)		ev Edit
14781	Jamie Holland		0/0	9/29/20 - 10/6/20	Discharged			<b>≜</b> + Readmit

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:
	Admitted	<ul> <li>Confirms the patient is admitted to EA, however the intubation date has not yet been inputted.</li> <li>Use the Perform SBT button to start the workflow.</li> </ul>
	Intubated	<ul> <li>Confirms the intubation date has now been inputted.</li> <li>Use the SBT Status column to determine weaning progress.</li> </ul>
Patient Status	Awaiting MD Review	<ul> <li>Confirms an SBT Synoptic Report has been generated. Awaiting MD review and decision regards extubation.</li> <li>Use Perform SBT button to restart the workflow.</li> </ul>
	Extubated	<ul> <li>Confirms the patient has been extubated and the number of days they have been ventilator free.</li> <li>Use Perform SBT button to restart the workflow and to document a re-intubation as required.</li> </ul>
	Discharged	<ul> <li>Confirms the patient has been discharged from EA. Only shown if "Show discharged patients" is enabled.</li> <li>Use Readmit button to re-admit the patient to ICU and to document a re-intubation as required.</li> </ul>
	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 Status	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				
Fields marked with * are required				
* First Name:		* Gender:	Male Female	
* Last name:		* Date Of Birth:	dd/MM/yyyy	14
* Patient MRN:	e.g. 12345			
* Initial Bed:			💄 Admit 👌 Cle	ear

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

Note: All dates will need to be entered in your local format. i.e. M/d/yyyy or dd/MM/yyyy Note: The format of the Patient MRN is a configurable option. Your EA Administrator can choose to display the watermark as a reminder to you of the expected MRN format used by your organization. Note: The patient's location (Unit/Bed) can be updated whenever a new SBT is performed.

	EA must not be used outside of its intended use.
Warnings	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	Edit Patient	
The selected patient Paul Nichols [87461] has completed reports.	Please note repo	orts previously generated will NOT be updated
If any changes are made to the patient details, previous reports will not be updated to reflect the changes.	First Name:	Paul
Are you sure you wish to continue?	Last Name:	Nichols
Yes No	Patient MRN:	87461
	DOB:	8/26/1977
	Gender:	Male     Female
	Location:	The patient's current location is set as part of each SBT.
		UPDATE CANCEL

**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.

	Planned Extubation
Ventilator	Self-Extubated
Outcome	Tracheostomy
	Deceased

INTUBATION INFO			
INTUBATED - EXTUBAT	ED VENT DA	YS #SBT	Status
28/06/20 22:18 - 10/07/2	0 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 I Please confirm the d	Patient ate & time patient Brett Nicolle [12345] was intu	ubated.					_					
	Date/Time of Intubation:	Sele	ct a d	late		14	] T	his Hou	r			
	Bed during Intubation:	•		Jul	y 20	20		•				
		Su	Мо	Tu	We	Th	Fr	Sa	12:00	01:00	02:00	03:00
		28	29	30	1	2	3	4	04:00	05:00	06:00	07:00
		5	6	7	8	9	10	11				
		12	13	14	15	16			08:00	09:00	10:00	11:00
									(to nearest l	hour) AN	PM	Close

**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 -		0	0	0		
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	y Information for RSBI, WAVE and RT Impression
	SBT Analysis not carried out yet
	Low risk of extubation failure
	Above average risk of extubation failure
	High risk of extubation failure
	Unable to calculate. Refer to the SBT Synoptic Report for more details.

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

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

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

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

# **Performing an SBT**

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

### 1. Admission Info, Reason and Comorbidity Info

- 2. SBT and recording of Patient Monitor waveform data for WAVE score
- 3. Extubation Readiness Checklist

## 4. SBT Outcome and SBT Synoptic Report Generation

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

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



**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.

ADMISSION DATE AND REASON	Date of Hospital Admission: 7/6/2020
Date of Hospital Admission: 7/16/2020	Date of ICU Admission: 7/8/2020 🔯 Today
Date of ICU Admission: 7/16/2020	Reason for ICU Admision:    July 2020  Su Mo Tu We Th Fr Sa
Reason for ICU Admision: 🗹 Shock	
Septic Shock Comments	12 13 14 15 16
• Other	
Respiratory Failure	Click on the Calendar Icon to
Hypoxemic	select the Hospital and ICU
Hypercarbic	Admission Dates.
Other	<ul> <li>Current date is</li> </ul>
© other	highlighted in hlue
Post Surgery	ing ingrited in blue.
Thoracic O Abdominal O Cardiac	<ul> <li>The selected Date has</li> </ul>
○ Vascular ○ Trauma ○ Ortho	blue border and text.
✓ Other	Select the <b>Today button</b> if
Other reason for ICU admission	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.

ADMISSION DATE AND REASON	Severe Cardiac Illness: (0) Voc
This form cannot be changed until the patient is re-admitted	
Date of Hospital Admission: 28/06/2020	Warning
Date of ICU Admission: 28/06/2020 📾 Today	The admission information has been used to generate previous reports.
Reason for ICU Admision: 🗌 Shock	If any changes are made to the admission information, previous reports linked to this admission
Respiratory Failure	will not be updated to reflect the changes.
✓ Post Surgery	Are you sure you wish to continue?
○ Thoracic ○ Abdominal ⑧ Cardiac ○ Vascular ○ Trauma ○ Ortho	Yes No
□ Other	III i Presence of severe asthma/COPD with FEV1/FVC <

If an error is made when documenting the various **Admission** and **Comorbitidy information** and a **SBT Synoptic Report** has subsequentely 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 **Comorbitities 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 commiting 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: known CAD, cardiomyopathy, valvular disease, diastolic or systolic dysfunction	● Yes ○ No	PATIENT INFO			
	O Unknown	Name: MRN:	John Wilki	nson	
Severe Cardiac Illness: Presence of ejection fraction < 45%, CCS Class III Angina (moderate limitation, with symptoms with	○ Yes ○ No	DOB:	27/01/194 Severe Ca	4 (77) rdiac Illr	Gender: Male
everyday living activities), AHA Class III CH- (marked limitation of physical activity)	Unknown	Comorbidities:	Controllec		
Respiratory Illness: known COPD, emphysema, pulmonary fibrosis, asthma	• Yes O No	PATIENT INFO Name:	Paul Nichols	;	
Sovere Perpiratory Illness	Unknown	MRN: DOB:	87461 8/26/1977 ( <sup>,</sup>	43)	Gender: Male
Presence of severe asthma/COPD with FEV1/FVC < 70% or FEV1 < 50%, or home oxygen use	O No	Comorbidities:	None Docu	mented	
Diabetes:	Unknown				
	Oral Hypoglycemics				
	<ul> <li>Diet Controlled</li> <li>Not Diabetic</li> </ul>				
Other Major Illness:	exclude GERD, HTN, HChol				

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



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

#### **Extubation Readiness Checklist**

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

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

Admission Extubation Readiness SBT SBT Our	tcome		
RESPIRATORY	itself may be run before completing this information, howe	ever it must be completed to generate a final report.	
Airway:	Coughs:	Secretions:	
Test Not Done	○ Spontaneous	○ None or minimal	
O Cuff Leak Present	Only Upon Request	Requiring suctioning every 3h or more	
O No Cuff Leak Present	Only With Suctioning	Requiring suctioning every 2h	
	O Unknown	Requiring suctioning every 1h	
		OUnknown	
Cough Strength:	O₂ Sat > 90% or baseline target	<b>t</b> :	
Strong	○ Yes		
Average	No		
○ Weak	O Unknown		
○ Unknown			
STRENGTH		Firm Hand Color	
Lift head off pillow for > 5 sec:		Firm Hand Grip:	
No		No	
RENAL		NEURO	
Negative Fluid Balance Last 24h:		Gag:	
○ Yes		○ Present	
• No		Not Present	
O Unknown		O Unknown	
		Obeys Commands:	
		⊖ Yes	
		• No	
		O Unknown	
Eack to Roster		Save 8	ि & 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.

## **Documenting Ventilator Settings prior to SBT**

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

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

Otherwise proceed to document the PS and PEEP values.

- 1. Document the Pressure Support (PS) (cmH<sub>2</sub>O) settings prior to SBT.
- 2. Document the Positive end-expiratory pressure (PEEP) (cmH<sub>2</sub>O) settings prior to SBT.
- 3. Document the Fraction of inspired Oxygen (FiO<sub>2</sub>) (%) prior to SBT.
- 4. Document the Most abnormal Richmond Agitation-Sedation Scale (RASS) value.
- 5. Select the Proceed to SBT button.



	A When conn to mains po	ected to a Patier wer.	nt Monitor, the device running EA cannot be connected		
Cautions	A When not in be used on	n use, the device running EA should be kept on charge to ensure it can battery when connected to a Patient Monitor.			
Please note if you attempt to connect mains power during an SBT recording, 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		A Battery Low	Consider sourcing a different device running EA that has a fully charged battery.		
Battery Critica	l Warning Message	A Battery Critical	Stop using device running EA and connect it to mains power to fully recharge battery.		

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

## **Connecting to a configured Patient Monitor**

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.

Extubation Advisor is now connected to on the monitor screen and press Next. Readings for connection	your monitor. Please verify	that readings below are displayed are not for clinical use	
	HR 115	<b>CO2</b> 26	
Connected Philips IntelliVue Series	<b>RR</b> 43	<b>SPO2</b> 94	
		NEXT CANCEL	

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.

Verify connection to monitor Extubation Advisor will now connect to your monitor. Please connect the monitor to this device via the USB/serial cable.						
<ol> <li>Connect or Reconnect the configured Patient Monitor (Philips IntelliVue Series) to EA using the supplied connectors</li> <li>EA will auto connect to the configured device after a short period of time</li> <li>The EA display will change to show Connected and some outputted vital sign data for connection validation purposes only</li> <li>You should be able to proceed with the SBT from here if a CO2 signal is detected from the monitor</li> <li>If creating the above steps does not resolve the connectivity issue contact IT Dent for assistance</li> </ol>						
Readings for connection indication only and are not for clinical use						
<b>X</b>	HR 	CO2				
Connecting Philips IntelliVue Series	Connecting RR SPO2 Philips IntelliVue Series					
	CO2 NOT DETECTED, check monitor					
	NEXT CANCEL					

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

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

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

#### **Documenting the Ventilator Settings during the SBT**

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

- PS (cmH<sub>2</sub>O) During SBT
- PEEP (cmH<sub>2</sub>O) During SBT
- Fraction of inspired oxygen (FiO<sub>2</sub>) (%) During SBT

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

Щ	Date/Time of SBT: 20/0	02/2023 13:46	
<b>–</b>	PS (cmH <sub>2</sub> O):	30 + -	
Connected Philips IntelliVue Series	PEEP (cmH <sub>2</sub> O): Prior to SBT (0 - 40)	25 +	
	FiO <sub>2</sub> (%): Prior to SBT (21 - 100)	41 + -	
	PS (cmH <sub>2</sub> O): During SBT (0 - 30)	+ -	
	PEEP (cmH <sub>2</sub> O): During SBT (0 - 25)	+ -	
	FiO <sub>2</sub> (%):	+ -	

Review any error messages as displayed and correct as required.

Ц	Date/Time of SBT: 20/02/2023 13:4	6 11	
•	PS (cmH <sub>2</sub> O): Prior to SBT (0 - 65)	30 +	
Connected Philips IntelliVue Series	PEEP (cmH <sub>2</sub> O): Prior to 587 (0 - 40)	25 + -	
	FiO <sub>2</sub> (%): Prior to SBT (21 - 100)	41 + -	
	PS (cmH <sub>2</sub> O): During S87 (0 - 30)	35 + -	Please enter the PS value during the S8T which must be greater than 0 and less than the prior value.
	PEEP (cmH <sub>2</sub> O): During SBT (0 - 25)	22 +	value
	FiO₂ (%):	41 + -	

Press the Start Recording button.



## **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.

EA EXTUBATION ADVISOR		40 ×, 3 –	- 🗆 🗙
PATIENT INFO	RECORDING - DO NOT CONNECT LAPTOP TO MAINS POWER	THERAPIST, Respiratory	Test Console
Name: Lina Shields	Admission Extubation Readiness SBT SBT Outcome		
MRN: 32121	CURRENT SBT [INTUBATION TIME :- 20/02/2023 13:00, SBT TIME :- 20/02/20	2023 13:48]	
DOB: 17/02/1983 (40) Sex: Female	•	0	
Relevant Comorbidities: Diabetes	Recording Analyzin	ng Complete	
ADMISSION INFO	Time of SBT: 20/02/2023 13:4	48 13	
Hosp. Admission: 20/02/2023	PS (cmH <sub>2</sub> O):	30 + - Patient not on	
ICU Admission: 20/02/2023	Prior to SBT (0 - 65)	Pressure Support	
Reason for Admission: Shock - Septic, Post Surgery - Thoracic	PEEP (cmH <sub>2</sub> O): Prior to SBT (0 - 40)	25 + - Ventilation	
	00:00:22 FiQ <sub>2</sub> (%): Prior to SBT (21 - 100)	41+-	
	PS (cmH <sub>2</sub> O): During S87 (0 - 30)	28 + -	
	PEEP (cmH <sub>2</sub> O): During S87 (0 - 25)	21 + -	
INTUBATION INFO	FiO <sub>2</sub> (%):	42 +	
INTUBATED - EXTUBATED VENT DAYS #SBT STATUS	During 581 (21 - 100)		
20/02/23 I3/00 - 0 0 Ongoing	RASS:	Ť	
SBT SNAPSHOT	End SBT Canc	cel Recording	
DATE START - END OUTCOME	A minimum of 15 minutes recordin	ng is required to	
20/02/2023 13:48 - OOO	end the recording		
	L		
	Back to Roster		Save & Proceed

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

Restart the recording when ready.



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

#### **Ending an SBT Recording**

Cautions

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

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

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

Admission Extubation Readiness SBT SET Outcome	
CURRENT SBT [INTUBATION TIME :- 20/02/2023 13:00, SBT TIME :- 20/02/2023 13:55]	
Recording Analyzing Complete	
Time of SBT: 20/02/2023 13:55	
PS (cmH <sub>2</sub> O): 30 + - Patient not on Prior to SET (0 - 65) Pressure Support	
Recording PEEP (cmH <sub>2</sub> O): 25 + - Ventilation	
00:21:17 FiQ <sub>2</sub> (%): 41+-	
PS (cmH <sub>2</sub> O): 28 + -	
PEEP (cmH <sub>2</sub> O): 21 + -	
FiO <sub>2</sub> (%): 42 + -	
Most abnormal RASS: +4 Combative *	
End SBT Cancel Recording	
Back to Roster	Save & Proceed



▲ 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.

Time of SBT: Updated where you proceed to SBT 30/12/2020 10:23		
PS (cmH <sub>2</sub> O): 30	er: Male	CURRENT SBT [INTUBATION TIME :- 18/01/2021 16:00; SBT TIME :- 28/01/2021 12:20]
Recording       Description         Recording terminated due to monitor disconnection.       Image: Control of the disconnection.         The recording has terminated due to an unexpected monitor disconnection.       Image: Control of the disconnection.         However sufficient recording was collected prior to the disconnection which can optionally be used for analysis.       Start time of 12/30/2020 10:23:34 AM recording:         Start time of Disconnect time:       12/30/2020 12:41:58 PM 1	Recording to The recording has Insufficient record recording must to Start time of recording: Disconnect time	Recording       Analyzing         terminated due to monitor disconnection.       Image: Comparison of the second sec
USE RECORDING FOR ANALYSIS DISCARD RECORDING	E REPORT	USE RECORDING FOR ANALYSIS DISCARD RECORDING RASS Score: +2 Agitated
Recording terminated due to monitor disconnection. The recording has terminated due to an unexpected monitor disconnection.		
Confirm discard recording		
Please confirm you wish to discard the partial recording. This operation cannot be undone!		
Discard Recording	Cancel	
USE RECORDING FOR ANALYSIS	RECORDING	

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

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

#### **Reviewing the SBT Analysis Results**

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

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

1. Input all required (\* Mandatory Values) for **Vital Signs** not automatically acquired from the connected device.

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

he monitor has not provided all of the requir ne values for the missing vital signs	ed vital sigr	ns during the recording. Please complete the form below with
	WAY	VE Results
Probability of extuba	tion failure	High
Predicted risk of ex failure	tubation	24%
Ā	/itals Reco	orded during SBT
* Avg. HR/PR	114.30	
* Avg. SpO2	93.80	
* Avg. BP	120	+ - / 80 + -
* Avg. MAP		+ - Estimate
Avg. RR (CO2)	36.8	
	* Mandat	tory Value
		SAVE COMPLETE LATER

CURRENT SBT [INTUBATION TIME :- 02/02/2021 12:00,	SBT TIME :- 07/02/2021 10:31]		
Recording	Analyzing	9	Completed
	Time of SBT:         07/02/2021 10::           PS (cmH <sub>2</sub> O);	31 33 + - 33 + - 17 + - 22 + - 12 + - 25 + - •	Wave Results       Probability of extubation failure     Below Average       Predicted risk of extubation failure     7%       Vitals Recorded during SBT     Vitals Recorded during SBT       Avg. HR*     20.00       Avg. SpO2*     94.57       Avg. BP*     150     +     /       Avg. BP*     108     +     Estin       Avg. RR (CO2)     22.1     *

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



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

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

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

#### **SBT Outcome Information**

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

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

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

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





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

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

## **SBT Synoptic Reports**

#### **Generating the SBT Synoptic Report**

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

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

Incrapeutic Autoritoring Systems Licensed Technology			Name: Lina Shields DOB (Age): 1983-0 Days in ICU: 1	9 02-17 (40)	Report Date: 2023-02-20 MRN: 32121 Days on Vent: 0 Location (Unit/Bed): BED01	
OBS Medical			Sex: Female			
se of this Clinical De his Extubation Advisor report mplex and should incorpo	cision Support Tool ort is derived from assessment during rate all relevant information (including	a spontaneous breathing trial (SBT but not limited to patient history, ill	) to aid the clinical assessment of extubation r ress and values), some of which may not be in	eadiness of ventilated patients, ncluded in this report.	recognizing that extubation decision making is	
atient Information: elevant Comorbidities: D eason for Admission: Sh	biabetes lock - Septic, Post Surgery - Thoracic					
ssessment of Extuba	tion Failure Risk:					
	RSBI 🔺		WAVE Score		RT Impression •	
	Low Risk		High Risk		Average Risk	
R	SBI = 15 (RR/TV = 3/0.2)	Esti	nated risk of extubation failure: 24%	Estima	ted risk of extubation failure: 5-20%	
2 Strong Cough 2 Strong Cough 3 Secretions requiring suc	tioning every 3h or more		Concerns: Cough Only Upon Request O <sub>2</sub> Sat < 90% or baseline te No Gag Present Does Not Obey Commands Unable to lift head off pillow Weak Hand Grip Positive Fluid Balance Last Not Performed or Not Releva Cuff Leak not performed	irget for > 5 sec 24H <b>nt:</b>		
Consider diuresis give     Consider high-flow heat	n positive fluid balance in the last 24h ated humidity nasal cannula O <sub>2</sub> post e	xtubation given FiO <sub>2</sub> > 40%				
BT Start/End: 2023-02-20	0 13:55-14:17 (22 minutes)		Vent Settings prior to SB	т:		
ASS (most abnormal du	no ring SBT): +4 Combative		PS: 30 cmH <sub>2</sub> O	PEEP: 25 cmH <sub>2</sub> O	FiO <sub>2</sub> : 41 %	
verage Vitals during P: 120.7 / 47.8 MAP: 70.4 R: 72.3 beats/min R (From capnograph): 2 b Sat: 22 %	SBT from Monitor: mmHg 7.2 breaths/min		PS: 28 cmH <sub>2</sub> O	PEEP: 21 cmH <sub>2</sub> O	FiO <sub>2</sub> : 42 %	
Rapid Shallow Brea verage RR: 3 breaths/mir	thing Index (RSBI):					
verage TV: 201 mL						
verage TV: 201 mL verage RSBI: 15 (< 60 = lov	v risk; 60-110 = average risk; > 110 = high risk.)					

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

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

Warnings

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

## **Emailing the SBT Synoptic Report**

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

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

	Average RSBI: 35
Emailing Report	
Please wait while the report is emailed	
	heathan torus of organity
	Hemodynamic Instability

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

PATIENT RO	OSTER SELECTION							
Search (B	Search (By Patient MRN or Name):						Sho	w discharged patients
MRN	NAME	BED	SBT COUNT	LAST ADMISSION	PAT. STATUS 4	SBT STATUS		→ Perform SBT
32121	Linda Shields	ICU-09	0/0	9/25/20 -	Intubated	SBT > Analysis		Evtubate
65432	John Wilkinson	ICU-10	0/0	9/29/20 -	Intubated	SBT > Admission		E
54621	Michael Rutter	ICU-07	0/0	9/29/20 -	Intubated	SBT > Readiness		💄 Discharge
87461	Paul Nichols	ICU-10	0/1	9/29/20 -	Extubated (0 day(s) off vent)			• . Edit
47815	Mary Berry	ICU-11	1/1	9/29/20 -	Awaiting MD Review	SBT > Report Ger	nerated	er Edit
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.

Average TV (mL): (200-3000)	SBT SNAPSHOT
Average RSBI: 70 Failed to send email	DATE START - END OUTCOME
The SBT is complete, however the report failed to send to nicolle@obsmedical.com. It has	13/07/2020 09:33 - O O O
been queued and will be resent at a later date.	12/07/2020 09:15 - 09:29 Pass • • •
	11/07/2020 08:58 - 09:02 Pass • • • 1
ок	10/07/2020 08:47 - 08:55 Equivocal • • Em
(maximum 150) Please include any additional r (maximum 150) information regarding the pati relevant to extubation decision	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: • Severe Cardiac Illness • Respiratory Illness • Severe Respiratory Illness	Consider non-invasive ventilation post extubation given the history of <comorbidities selected="">.</comorbidities>
2	Comorbidity is: • Severe Cardiac Illness and SBT Recording Analysis Results: • Average Sys BP > 140 or MAP > 85	Suggest afterload reduction given elevated blood pressure and history of impaired left ventricular function.
3	<ul> <li>Extubation Checklist:</li> <li>Weak Cough</li> <li>and SBT Recording Analysis Results:</li> <li>FiO2 During SBT ≤ 40</li> </ul>	Consider high flow heated humidity nasal cannula O2 post extubation given weak cough strength.
4	Extubation Checklist: • Weak Cough and SBT Recording Analysis Results: • FiO2 During SBT > 40	Consider high flow heated humidity nasal cannula O2 post extubation given FiO2 > 40% and weak cough strength.
5	Extubation Checklist: • No Cuff Leak	Consider steroid administration due to absence of cuff leak.
6	Extubation Checklist: • No – Negative Fluid Balance Last 24H	Consider diuresis given positive fluid balance in last 24h.
7	Patient is extubated and then, <ul> <li>Re-intubated</li> </ul>	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.

Therapeutic Systems OBS Medical Jee of this Clinical Decision This Extubation Advisor report is d somplex and should incorporate all	Extubation Advisor Therapeutic Monitoring Systems Licensed Tech Support Tool arived from assessment during a spontanee relevant information (including but not limit	nology bus breathing trial (SBT) to aid the clin ed to patient history, illness and value	Name: Lina Shields DOB (Age): 1983-02-17 Days in ICU: 1 Sex: Female	(40) ness of ventilated patients, ed in this report.	Report Date: 2023-02-20 MRN: 32121 Days on Vent: 0 Location (Unit/Bed): BED01 recognizing that extubation decision making is
Patient Information: Relevant Comorbidities: Diabete Reason for Admission: Shock - S	s Septic, Post Surgery - Thoracic				
Assessment of Extubation F	Failure Risk:			] [	
F LOT RSBI = 1	RSBI▲ W Risk 5 (RR/TV = 3/0.2)	WAVE S High Estimated risk of extr	core Risk	Estima	RT Impression • Average Risk led risk of exturbation failure: 5-20%
Extubation Readiness Chec Strong Cough Secretions requiring suctioning Means to Mitigate Extubation Consider diuresis given posit Consider digrams and the such as the su	klist: I every 3h or more In Failure Risk: ve fluid balance in the last 24h midify nasal cannula 0 <sub>2</sub> post extubation giv	ren FiO₂ > 40%	Concerns: Cough Only Upon Request Solat < 90% or baseline target No Gap Present Does Not Obey Commands Unable to lift head of pillow for : Weak Hand Grip Weak Hand Grip Not Performed or Not Relevant: Cuff Leak not performed	- 5 sec	
BT Start/End: 2023-02-20 13 55 Completed as planned?: No RASS (most abnormal during SI Average Vitals during SBT I BP: 120.7 / 47.8 MAP: 70.4 mmHg HR: 72.3 beats/min RR (From capnograph): 27.2 bre O <sub>2</sub> Sat: 22 %	5-14:17 (22 minutes) BT): +4 Combative f <b>rom Monitor:</b> 9 aths/min		Vent Settings prior to SBT: PS: 30 cmH <sub>2</sub> O Vent Settings during SBT: PS: 28 cmH <sub>2</sub> O	PEEP: 25 cmH <sub>2</sub> O PEEP: 21 cmH <sub>2</sub> O	FiO <sub>2</sub> : 41 % FiO <sub>2</sub> : 42 %
▲ Rapid Shallow Breathing Average RR: 3 breaths/min Average TV: 201 mL Average RSBI: 15 (< 60 = tow risk; 60- ■ Weaning and Variability E	Index (RSBI): 110 = average risk; > 110 = high risk.) valuation (WAVE) Decision Suppo	rt:			Print Report

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

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

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

#### **Overview of the EA Generated SBT Synoptic Report**

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

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

OBS Medical     Extubatio     Therapeutic Monitorin     Systems	n Advisor g Systems Licensed Technology	Name Lina Shields DOB (Age): 1983-02- Days in ICU: 1 Sex: Female	17 (40)	Report Date: 2023-02-20 MRN: 32121 Days on Vent: 0 Location (Unit/Bed): BED01
Use of this Clinical Decision Support Tool This Extubation Advisor report is derived from assessm complex and should incorporate all relevant information	ent during a spontaneous breathing trial (including but not limited to patient histo	(SBT) to aid the clinical assessment of extubation reading in the clinical assessment of extubation reading in the inclusion of which may not be inclusion.	diness of ventilated patients uded in this report.	, recognizing that extubation decision mak
Patient Information: Relevant Comorbidities: Diabetes Reason for Admission: Shock - Septic. Post Surgery.	- Thoracic			
Assessment of Extubation Failure Risk:				
RSBI 🔺		WAVE Score		RT Impression •
Low Risk		High Risk		Average Risk
RSBI = 15 (RR/TV = 3/0.2)		Estimated risk of extubation failure: 24%	Estim	ated risk of extubation failure: 5-20%
RT Comments				
Extubation Readiness Checklist:				
<ul> <li>✓ Strong Cough</li> <li>✓ Secretions requiring suctioning every 3h or more</li> </ul>		Concerns: ⊠ Cough Only Upon Request ⊠ O <sub>2</sub> Sat < 90% or baseline targe ⊠ No Gag Present ⊠ Does Not Obey Commands ⊠ Unable to lift head off pilow for ⊠ Weak Hand Grip ⊠ Positive Fluid Balance Last 24!	et r > 5 sec H	
		Not Performed or Not Relevant:		
Means to Mitigate Extubation Failure Risk: • Consider diuresis given positive fluid balance in th • Consider high-flow heated humidity nasal cannula	ie last 24h O <sub>2</sub> post extubation given FiO <sub>2</sub> > 40%	Li Cuil Leak not performed		
SBT Start/End: 2023-02-20 13:55-14:17 (22 minutes)		Vent Settings prior to SBT:		
RASS (most abnormal during SBT): +4 Combative		Vent Settings during SBT:	PEEP: 25 cmH <sub>2</sub> O	FIO <sub>2</sub> : 41 %
BP: 120.7 / 47.8 MAP: 70.4 mmHg HR: 72.3 beats/min RR (From capnograph): 27.2 breaths/min O <sub>2</sub> Sat: 22 % ▲ Rapid Shallow Breathing Index (RSBI): Average RR: 3 breaths/min Average TV: 201 mL Average TV: 201 mL				
Weaning and Variability Evaluation (WAVE The WAVE score is based on respiratory rate variability (RRV) d efferences below.) Probability of Extubation Failure (Based on RRV): !	Decision Support: erved from interbreath intervals obtained from c tinh Risk	apnography waveforms recorded during the SBT; RRV is thoug	ght to reflect the patient's capacity	y to tolerate an increased respiratory workload. Si
Predicted risk of extubation failure (Based on RRV)	24% (population-based categories: low: 5%; avera	ige: 16%; high: 24%)		
• Respiratory Therapist's Subjective Assess SBT Outcome: Pass RT Perception of Risk of Extubation Failure: Averag	sment: ie (i.e. risk is 5-20%)			
Current and Previous SBTs:				
Date / Time	RSBI Risk	WAVE Risk	×	RT Impression Risk
2023-02-20 13:55-14:17 (22 minutes) [Current]	RSBI Low Risk RSBI = 15 (RR/TV = 3/0	VAVE Scol High Ris 12) Estimated risk of extubatio	re Sk n failure: 24%	RT Impression Average Risk Estimated risk of extubation failure: 5-20'
RT Comments: Not Documented				
References: • Seely AJE, Bravi A, Herry C, et al. (2014) Do heau • Godard S, Herry C, Westergaard P, et al. (2016) F • Zheno Z, Kumar S, Sarti A et al. (2022) Early Eco	t and respiratory rate variability improve Practice Variation in Spontaneous Breath nomic Evaluation of a Novel Tool to Assi	prediction of extubation outcomes in critically ill patien ing Trial Performance and Reporting. <u>Can Respir J</u> 20 st Extubation Decision-Making. <u>Int J Technol Assess H</u>	nts? <u>Crit Care</u> 18:R65. <u>doi</u> 016:9848942. <u>doi</u> Health Care 38(1):e66. <u>doi</u>	
<ul> <li>Sarti Å, Żheng K, Herry CL, et al. (2021). Feasibili 11(8), e045674. doj</li> </ul>	ty of Implementing Extubation Advisor, a	Clinical Decision Support Tool to Improve Extubation	Decision-making in the ICO	a Mixed-Methods Observational Study.

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

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

## Warnings

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

## Subsequent SBTs, Extubation, Reintubation and Discharge

#### **Documenting Subsequent SBTs**

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

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

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

Hosp. Admission: 02/02/2021	
ICU Admission: 02/02/2021	
Outcome	e of last recorded SBT
The last record	rded SBT for Patient John Wilkinson [65432] is displayed below.
Please select t	the current airway status
Date/Tim inti	ne of last tubation: 12:00
Date/Tim record	ne of last rded SBT:
Airway	ay Status: <please select=""> 🔹</please>
	START SBT GO BACK
SBT SNAPSHOT	

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

	Still Intubated
Airwey Status	Planned Extubation
Airway Status	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:

	Planned Extubation
Ainway Status	Self Extubation
All way Status	Tracheostomy
	Deceased

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



- 3. Select the **Extubate** button. You will then be returned to the Patient Roster.
- 4. The Patient Roster will then display the **updated extubation status** under the **Pat. Status column.**

PATIENT ROSTER SELECTION										
Search (	By Patient MRN o	or Name	):				Show	discharged patients		
MRN	NAME	BED	SBT COUNT	LAST ADMISSION	PAT. STATUS 4	SBT STATUS		→ Perform SBT		
32121	Linda Shields	ICU-09	0/0	9/25/20 -	Intubated	SBT > Analysis		Evtubate		
65432	John Wilkinson	ICU-10	0/0	9/29/20 -	Intubated	SBT > Admission		E criabate		
54621	Michael Rutter	ICU-07	0/0	9/29/20 -	Intubated	SBT > Readiness		💄 Discharge		
87461	Paul Nichols	ICU-10			Extubated (0 day(s) off vent)			💂 Edit		
47815	Mary Berry	ICU-11	1/1	9/29/20 -	Awaiting MD Review	SBT > Report Gener	ated	Eure		
14781	Joules Holland	ICU-03	0/0	9/29/20 -	Admitted			💄 Readmit		

**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 patien	ıt Jim Lovell [554321] was intubate	d.		
Date/Time of <b>PR</b>	EVIOUS Extubation:	20/08/2020 20:00	14	This Hour
Date	/Time of Intubation:	Select a date	14	This Hour
Be	d during Intubation:	ICU-10		
		START S	SBT	GO BACK
) Gender: Male ; Diabetes - Oral s				
Caution - Re-int	ubated patient			
While WAVE was derived fo prediction would be unchar extubation failed), and thus extubation.	r patients undergoing their first iged when assessing readiness can be helpful when assessing	extubation, the physiologic bas for subsequent extubations (if t a patient's readiness for a secon	sis for tł he first nd	he
However, the reasons for fa extubation vs. tracheostom	iling the first extubation need to /	be addressed in planning a se	cond	
		I Understand	Go B	ack
			_	

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



## **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:

<b>D:</b> 1	Discharged to Ward
Discharge	Transferred to another ICU
Reason	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:	8/3/2020							
Date/Time of last intubation:	None on record							
Discharge reason:	<please select="">  Select a date  This Hour</please>							
	<please select=""></please>							
	Discharged to Ward DISCHARGE GO BACK							
	Transferred to another ICU							
	Deceased							

PATIENT ROSTER SELECTION									
Search (By Patient MRN or Name):							✓ Show	discharged patients	
MRN	NAME	BED	SBT COUNT	LAST ADMISSION	PAT. STATUS 🛧	SBT STATUS		→ Perform SBT	
555555	Peter Doppelganger			8/20/20 - 8/20/20	Discharged			E Evtubate	
335121	Mary Berry	ICU-07	0/0	8/20/20 -	Intubated	SBT > Admission		Exclubate	
998765	Scott Stapp	ICU-09	0/0	8/15/20 -	Intubated	SBT > Admission		<b>a</b> - Discharge	
110101	Steve Jobs	ICU-08	0/0	8/10/20 -	Intubated	SBT > Admission		● a Edit	
543211	John Wilkinson	ICU-15	0/1	8/20/20 -	Intubated	SBT > Analysis		er Eure	
554321	Jim Lovell	ICU-10	0/0	8/18/20 -	Self Extubated			よ Readmit	

**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.

PATIENT ROSTER SELECTION									
Search (By Patient MRN or Name):							Show discharged patients		
MRN	NAME	BED	SBT COUNT	LAST ADMISSION	PAT. STATUS	SBT STATUS	Ψ	→ Perform SBT	
65432	John Wilkinson	ICU-10	1/1	9/29/20 -	Awaiting MD Review	SBT > Report Gen	erated	Extubate	
87461	Paul Nichols	ICU-10	2/3	9/29/20 -	Intubated	SBT > Readiness		E trabate	
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)			er Ealt	
14781	Jamie Holland		0/0	9/29/20 - 10/6/20	Discharged			💄 Readmit	

- 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	Intubate Patient Please confirm the date & time patient Peter Doppelganger [555555] was intubated.			
ratent 555555 was previously alsonarged. Are you sure you wish to re during arent	Date/Time of Intubation: Select a date			
	Bed during Intubation:			
Ves No	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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Doc Reference: 011-1014-LMAN-R8 Issue Date: 20 Feb 2023 Copyright © 2023 OBS Medical