Instructions for Use

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The T3 Platform software is a medical device complying with the Regulation (EU) 2017/745 (EU MDR) concerning Medical Devices.

⚠ **CAUTION**: This medical device is to be sold by or on the order of a physician and is for clinical use only.

Please note that you can access the user manual from your local T3: Access T3 and log in. Click Help in the upper-right title bar to get T3 Help and Resources. Click on the user manual link to view this user manual. The compatible PDF format is viewable in commonly used browsers or a PDF reader.

1 Indications for Use

The T3 Platform software features the T3 Data Aggregation & Visualization software module version 5.0 and the T3 Risk Analytics Engine software module version 7.0.

The T3 Data Aggregation & Visualization software module is intended for the recording and display of multiple physiological parameters of the adult, pediatric, and neonatal patients from supported bedside devices. The software module is not intended for alarm notification or waveform display, nor is it intended to control any of the independent bedside devices to which it is connected. The software module is intended to be used by healthcare professionals for the following purposes:

- To remotely consult regarding a patient's status, and
- To remotely review other standard or critical near real-time patient data in order to utilize this information to aid in clinical decisions and deliver patient care in a timely manner.

The T3 Data Aggregation & Visualization software module can display numeric physiologic data captured by other medical devices:

- Airway flow, volume, and pressure
- Arterial blood pressure (invasive and non-invasive, systolic, diastolic, and mean)
- Bispectral index (BIS, signal quality index, suppression ratio)
- Cardiac Index
- Cardiac output
- Central venous pressure
- Cerebral perfusion pressure

- End-tidal CO2
- Heart rate
- Heart rate variability
- Intracranial pressure
- Left atrium pressure
- Oxygen saturation (intravascular, regional, SpO2)
- Premature ventricular counted beats
- Pulmonary artery pressure (systolic, diastolic, and mean)
- Pulse pressure variation
- Pulse Rate
- Respiratory rate
- Right atrium pressure
- Temperature (rectal, esophageal, tympanic, blood, core, nasopharyngeal, skin)
- Umbilical arterial pressure (systolic, diastolic, and mean)

The T3 Data Aggregation & Visualization software module can display laboratory measurements including arterial and venous blood gases, complete blood count, and lactic acid.
The T3 Data Aggregation & Visualization software module can display information captured by the T3 Risk Analytics Engine software module.

The T3 Risk Analytics Engine software module calculates four indices: the IDO2 Index for inadequate delivery of oxygen, the IVCO2 Index for inadequate ventilation of carbon dioxide, the ACD Index for acidemia, and the HLA Index for hyperlactatemia.

The IDO2 Index is indicated for use by health care professionals with patients aged zero days to twelve years weighing 2 kg or more under intensive care. The IDO2 Index is derived by mathematical manipulations of the physiologic data and laboratory measurements received by the T3 Data Aggregation & Visualization software module, version 5.0 or higher. When the IDO2 Index is increasing, it means that there is an increasing risk of inadequate oxygen delivery and attention should be brought to the patient. The IDO2 Index presents partial quantitative information about the patient's cardiovascular condition, and no therapy or drugs can be administered based solely on the interpretation statements.

The IVCO2 Index is indicated for use by health care professionals with invasively ventilated patients aged 29 days to 12 years weighing 2 kg or more under intensive care. The IVCO2 Index is derived by mathematical manipulations of the physiologic data and laboratory measurements received by the T3 Data Aggregation and Visualization software module, version 5.0 or higher. When the IVCO2 Index is increasing, it means that there is an increasing risk of inadequate carbon dioxide ventilation and attention should be brought to the patient. The IVCO2 Index presents partial quantitative information about the patient's respiratory condition, and no therapy or drugs can be administered based solely on the interpretation statements.

The ACD Index is indicated for use by health care professionals with invasively ventilated patients aged 29 days to 12 years weighing 2 kg or more under intensive care. The ACD Index is derived by mathematical manipulations of the physiologic data and laboratory measurements received by the T3 Data Aggregation and Visualization software module, version 5.0 or higher. When the ACD Index is increasing, it means that there is an increasing risk of acidemia and attention should be brought to the patient. The ACD Index presents partial quantitative information about the patient's respiratory condition, and no therapy or drugs can be administered based solely on the interpretation statements.

The HLA Index is indicated for use by health care professionals with patients aged zero days to twelve years weighing 2 kg or more under intensive care. The HLA Index is derived by mathematical manipulations of the physiologic data and laboratory measurements received by the T3 Data Aggregation & Visualization software module, version 5.0 or higher. When the HLA Index is increasing, it means that there is an increasing risk of hyperlactatemia and attention should be brought to the patient. The HLA Index presents partial quantitative information about the patient's cardiovascular condition, and no therapy or drugs can be administered based solely on the interpretation statements.

WARNING:

- Do not use the T3 Platform software as an active patient monitoring system.
- Do not use the T3 Platform software to replace any part of the hospital's device monitoring.
- Do not rely on the T3 Platform software as the sole source of patient status information.
- Do not use any of the T3 Platform indices as a substitute for taking blood samples.
- The indices present qualitative and potentially imperfect information of the patient's condition and in certain scenarios, the indices may contradict each other. The primary data should be reviewed as part of standard patient evaluations and no decisions should be solely based on the indices.

2 Overview

The Tracking, Trajectory, and Trigger tool abbreviated T3 was developed for clinical use with patients being closely monitored. The aims of the T3 Software are to:

1. Capture and store continuous physiologic data streams from monitored patients.
2. Provide meaningful visualization of near real-time data to make informed decisions through data integration, analytics, and calculations.
3. Develop algorithms and models from stored and shared data to reduce practice variability and unnecessary resource utilization.

This user manual describes the User Interface (UI) and the fundamental features of the Etiometry Platform. The features, layout, and appearance of the application may differ in future releases.

3 Introduction

A Application Icon

Etiometry's T3 Software (hereafter referred to as "T3") is a web-based application designed to leverage near real-time patient data by presenting complex information in an elegant display to improve clinical decision-

making. The application may be accessed online by clicking on the following icon (see Figure 1) on a network computer's desktop or by navigating a web browser to the hospital's installed instance of the T3.

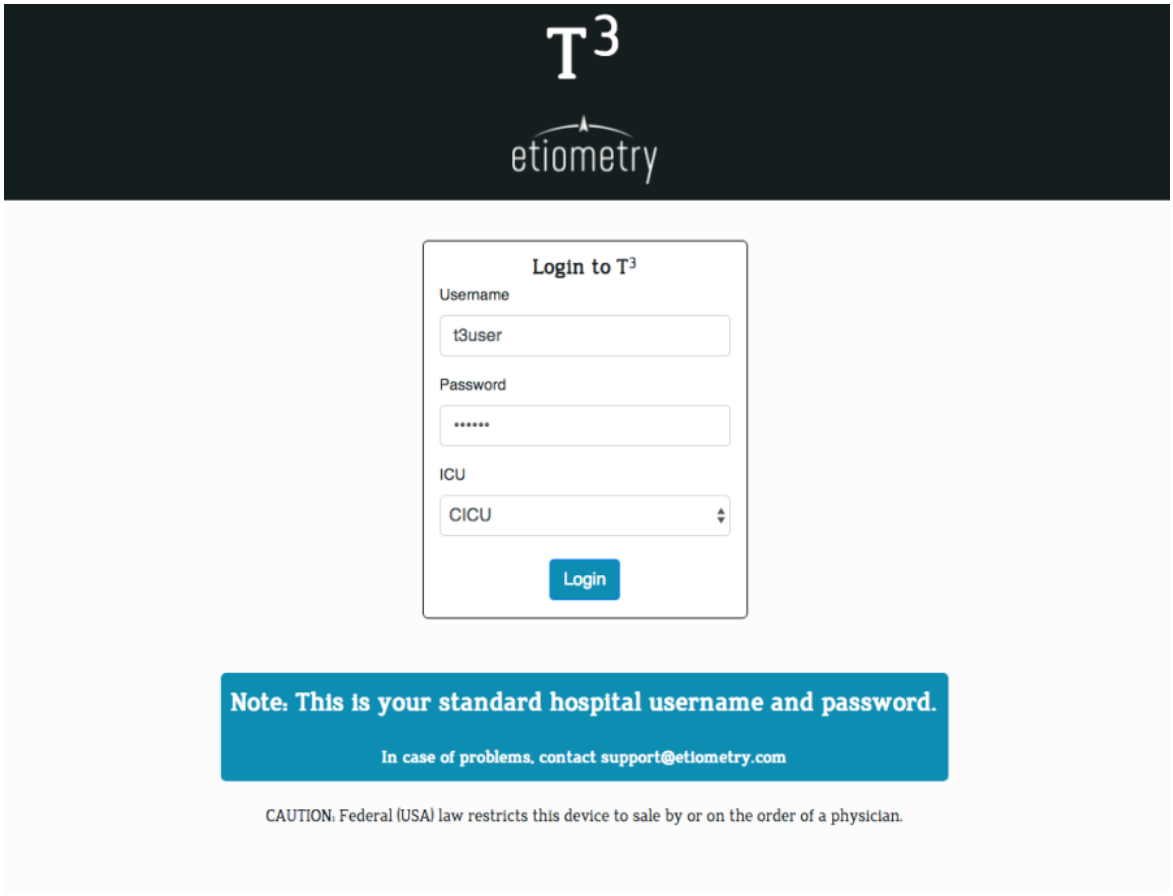
User Interface (UI) Overview - The following sections describe the User Interface - what each feature is, and how the user can interact with the application. These sections are separated by functionality. When a key element or concept is initially defined, it will appear in **bold.** These key elements and concepts can also be found in the glossary.

4 Modes of Operation

T3 functions in either **Persistent Display mode** or **Individual User mode**.

- The Persistent Display mode displays data about the patient in a particular bed-space. It continues to show information about whatever patient is currently in that location, even as patients are discharged, transferred and admitted. Having a dedicated persistent display monitor for a bed space saves clinicians the time and effort of logging in and navigating to the patient's data.
- The Individual User mode is for people logging in through a web browser for a defined period of time. This document will describe Individual User mode first, then later will discuss the differences introduced by Persistent Display mode.

5 Login Screen



B Login Screen

The login screen is the first page accessed when T3 initially launches (see Figure 2). If a login attempt is made with an incorrect username or password, an error message will be displayed.

T3 authenticates with Lightweight Directory Access Protocol (LDAP). Contact your Help Desk if you cannot log in.

6 Advanced indices

As the Etiometry Platform continuously collects patient physiologic measures and laboratory test results, the Advanced Indices are computed by employing Bayes' theorem to interpret the newly acquired data given its own previous assessment of the physiologic state of the patient. It then uses the interpreted data to update its assessment of the patient state. The patient state is represented as a set of patient physiologic variables, each of which is modeled with a probability distribution to account for patient-to-patient variations and measurement uncertainty. Physiologic variables representing the patient state are also related to one another using established relationships of human physiology. Finally, the physiologic variables are related to the physiologic measures and laboratory test results collected by T3 using models of the measurement collection devices and sensors that account for potential errors in the data. These elements make up the software

physiology model. Note that some of the parameters of the physiology model are continuously dependent on the patient's age.

Mixed venous oxygen saturation (SvO2), partial pressure of carbon dioxide (PaCO2), whole blood lactate concentration (LA), and arterial blood pH (pHa) are four of the patient physiologic variables that the algorithm keeps updated given new data. These four variables are then used to compute four distinct indices in the following way:

- Inadequate delivery of oxygen index (IDO2 Index) by calculating the cumulative probability of the SvO2 probability distribution between 0% and 30%, 0% and 40%, or 0% and 50% depending on the threshold chosen by the user.
- Inadequate ventilation of carbon dioxide index (IVCO2 Index) by calculating the cumulative probability of the PaCO2 probability distribution above 50 mmHg or 60 mmHg depending on the threshold chosen by the user.
- Acidemia index (ACD Index) is computed by the probability density estimated of pHa, by computing the cumulative probability of pHa being below 7.25.
- Hyperlactatemia index (HLA index) is computed by the probability density estimated of LA, by computing the cumulative probability of LA being above 4 mmol/L.

WARNING:

- The IDO2 Index should not be used as a substitute for taking central or mixed venous blood gas samples.
- The IVCO2 Index should not be used as a substitute for taking arterial blood gas samples.
- The ACD Index should not be used as a substitute for taking arterial blood gas samples.
- The HLA Index should not be used as a substitute for taking measurements of the whole blood concentration of lactate.

In certain scenarios, the interrelationships between indices may provide additional information, for example:

- The IDO2 Index and the HLA Index afford comprehensive tracking of adequate oxygen delivery, including the downstream effect of lactate production due to anaerobic metabolism.
- The ACD Index and the IVCO2 Index affords comprehensive tracking of adequate ventilation, including periods when the patient is managed with permissive hypercapnia.

In certain scenarios, discordance may be observed, for example:

- Elevated lactate post-cardiac surgery (**High HLA**) without impaired oxygen delivery (**Low IDO2**)
- Hypercapnia (**High IVCO2**) which is compensated (**Low ACD**)
- Rising lactate detecting by a series of lactate measurements (**High HLA**) due to impaired elimination (e.g., liver failure) and normal oxygen delivery (**Low IDO2**)
- Decreasing pH detected by a series of blood gas measurements (**High ACD**) during normocapnia (**Low IVCO2**) due to metabolic reasons

As a result of the model-based approach used, the indices exhibit the following properties:

- The indices can continue to be computed based on previously acquired data even when data is missing at particular points in time.

- The algorithm used for the indices computation can incorporate and reconcile multiple measurements of the same physiologic variable (e.g., heart rate can be derived both from ECG and from the arterial line waveform) because it accounts for the noise and common errors inherent in each possible measurement source.
  - If redundant sources of measurements are available of the same physiologic variable, and one of the sources is producing erroneous measurements, in general, the indices will be more accurate than if only the erroneous source was available.
- The algorithm used for the indices computation analyzes the likelihood of particular measurement values given other collected data values and its current patient state assessment and can reject potential measurement artifacts that contradict the physiology model or the other physiologic measurements.
- If a measurement source is producing erroneous measurements, e.g. faulty blood pressure measurements from an arterial line, the algorithm performance will benefit from the redundant sources and maintain accurate performance in most instances.

The model incorporates the following physiological effects:

- Oxygen and Carbon Dioxide gas exchange dynamics circulating in three interconnected compartments: alveolar, arterial, and venous. Ventilation rate, *V*, and cardiac output, *Q*, drive this exchange.
- *V-Q* mismatch using alveolar variables for dead-space and pulmonary shunting, which represent idealized portions of the lung that are respectively ventilated but not perfused and perfused but not ventilated.
- Mixed venous oxygen saturation depends on oxygen consumption, oxygen delivery (Stroke Volume x Heart Rate x Oxygen Content), and arterial oxygen saturation.
- The nominal value of oxygen consumption used by the model depends on the current body temperature.
- Heart rate, systemic vascular resistance, and unstressed venous blood volume are affected by autonomic regulation.
- Stroke volume depends on mean arterial pressure, central venous pressure, and ventricular function.
- Pulse pressure depends on stroke volume
- A dynamic relationship accounts for kidney response to increases in CO2 and decreasing blood pH. The dynamic response model is focused on accounting for HCO3 retention and as a result gradual compensation of respiratory failure and respective acidemia.
- A dynamic relationship between computed oxygen delivery and lactic acid production tracks the likelihood of increased whole blood concentration of lactate as a function of changes to the patient perfusion status.

The model incorporates the following measurement effects:

- Physiologic measurements are modeled as corrupted by the noise that is normally distributed with a zero mean, and a standard deviation specific to the measurement source.
- The model accounts for a potential persistent bias between arterial oxygen saturation derived from arterial blood gas and pulse oximetry.
- The model utilizes regional oxygenation measurements from Near-Infrared Spectroscopy sensors to inform the algorithm's estimate of the patient's current mixed venous oxygen saturation level.
- Error mechanisms in EtCO2 measurements, which make that measurement source less reliable.

The model utilizes adaptable parameters that adjust to the individual patient to account for the patient to patient variability.

The algorithm employed for indices computation classifies venous oxygen saturation measurements as either validated or non-validated and incorporates the measures under different conditions based on that classification. The algorithm will always incorporate validated samples. Non-validated samples will only be incorporated if a central venous, a right atrial, or a pulmonary artery catheter is present at the time the sample was taken, as determined by pressure measurements from one of these sources. The validation process is to continually assess a site's adherence to a protocol of correctly labeling true mixed venous (or central venous) oxygen saturation measurements within their laboratory system.

⚠ **Note:** Inaccurate labeling of venous blood gas samples, e.g. labeling arterial samples as venous samples, will degrade the indices' accuracy and overall performance.

⚠ **Note:** The IVCO2 Index and the ACD Index are only computed if the patient is invasively ventilated at a particular time. The algorithm determines this based on whether or not the algorithm has received FiO2, EtCO2, Airway Respiration Rate, and Tidal Volume measurements from the patient in the past 10 minutes.

Table 1 summarizes the data which can be ingested by the algorithms and the minimum frequency required for the display of each index:

Physiologic variables	Employed measurements	Minimally Required for IDO2 Index	Minimally Required for HLA Index	Minimally Required for IVCO2 Index	Minimally Required for ACD Index
Heart rate	HR (ECG)	Yes, at least every minute	Yes, at least every minute	Yes, at least every minute	Yes, at least every minute
	HR (Pulse)				
Mean blood pressure	(ABPm/ARTm) Arterial line	Yes, at least every 10 minutes	Yes, at least every 10 minutes	Yes, at least every 60 minutes	Yes, at least every 60 minutes
	(NiBPm) Blood pressure cuff				
Systolic blood pressure	(ABPs/ARTs) Arterial line				
	(NiBPs) Blood pressure cuff				
Diastolic blood pressure	(ABPd/ARTm) Arterial line				
	(NiBPd) Blood pressure cuff				

Physiologic variables	Employed measurements	Minimally Required for IDO2 Index	Minimally Required for HLA Index	Minimally Required for IVCO2 Index	Minimally Required for ACD Index
Filling pressure	RAPm (Right atrium pressure) CVPm (Central venous pressure)	No	No	No	No
SpO2	SpO2 SpO2 (Left) SpO2 (Right) SpO2 (Pre-ductal) SpO2 (Post-ductal)	Yes, at least every 10 minutes	Yes, at least every 10 minutes	Yes, at least every 10 minutes	Yes, at least every 10 minutes
Hemoglobin	Laboratory result	No	No	No	No
SvO2	Venous blood gas	No	No	No	No
SaO2	Arterial blood gas	No	No	No	No
Temperature	Temp Temp (Skin) Temp (Rectal) Temp (Core) Temp (Oral) Temp (Esophagus)	No	No	No	No

Physiologic variables	Employed measurements	Minimally Required for IDO2 Index	Minimally Required for HLA Index	Minimally Required for IVCO2 Index	Minimally Required for ACD Index
	Temp (Blood)				
Respiration rate (Airway)	RR (Airway)	No	No	Yes, at least every minute	Yes, at least every minute
Respiration rate (ECG)	RR (ECG)	No	No	No	No
Tidal volume	TV (Expired)	No	No	Yes, at least every minute	Yes, at least every minute
	TV (Inspired)				
Fraction of inspired oxygen	FIO2	No	No	Yes, at least every minute	Yes, at least every minute
PaCO2	Arterial blood gas	No	No	No	Yes, interchangeably with PvCO2, every 24 hours
End Tidal CO2	etCO2	No	No	Yes, at least every minute	Yes, at least every minute
Arterial pH	Arterial blood gas	No	No	No	Yes, interchangeably with venous pH, every 24 hours
PvCO2	Venous blood gas	No	No	No	Yes, interchangeably with PaCO2, every 24 hours
Venous pH	Venous blood gas	No	No	No	Yes, interchangeably with arterial pH, every 24 hours
Whole blood concentration of lactate	Various blood panels	No	Yes, every 24 hours	No	No

Physiologic variables	Employed measurements	Minimally Required for IDO2 Index	Minimally Required for HLA Index	Minimally Required for IVCO2 Index	Minimally Required for ACD Index
Mean Airway Pressure	Mean Airway Pressure	No	No	Yes, at least every minute	Yes, at least every minute
Regional Oxygenation	NIRS (channel 1)	No	No	No	No
	NIRS (channel 2)				
	NIRS (channel 3)				
	NIRS (channel 4)				

1 Advanced Indices Measurements

⚠ **Note:** The indices' performance, as assessors of physiologic states implied by their associated biomarkers, improves as more data becomes available (see Table 1 for all of the data types considered for the indices computation.)

The following provides a more detailed explanation and performance characteristics for each of the specific indices:

7 The Inadequate Delivery of Oxygen Index (IDO2 Index)

Thresholds for the IDO2 Index and their associated notations are described as follows:

Risk	Threshold	Description
IDO2	IDO2_30	Likelihood that SvO2 < 30%
	IDO2_40 *	**Likelihood that SvO2 < 40% ***
	IDO2_50	Likelihood that SvO2 < 50%
	*** Default threshold**	

2 Various risk thresholds

⚠ **Note:** The IDO2_30 Index threshold is not available or validated for patients above 2 years of age.

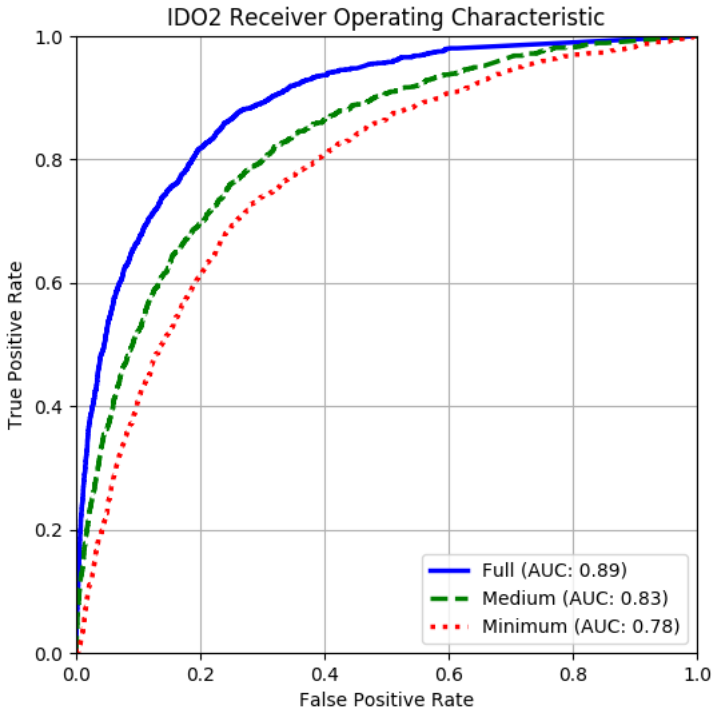
7.1 The IDO2 Index performance

The association of IDO2 Index with inadequate oxygen delivery was established through a retrospective study of a patient population that included neonates (0-28 days of age), infants (29 days to 2 years of age), and children (2-12 years of age) from multiple institutions and intensive care units. This validation patient population group included 3018 patients.

The study used periodic measurements of proxies of mixed venous oxygen saturation (SvO2proxy) measurements sampled from various access points, e.g. superior vena cava catheter, or right atrium catheters. A total of 20,424 measurements were included in the reported performance assessment.

For each SvO2proxy measurement in the first 10 postoperative days, the average IDO2 Index was computed in the 30 minute period immediately prior to the measurement and used as a predictor score for the different selectable thresholds of the index, i.e. SvO2proxy < 30%, SvO2proxy < 40%, or SvO2proxy < 50%. The resulting Receiver Operating Characteristic (ROC) curve was generated and the Area Under the Curve (AUC) was computed.

7.2 Default IDO2 Index configuration (IDO2_40)



C ROC curves for Minimum, Medium and Full Data sets for the IDO2 Index

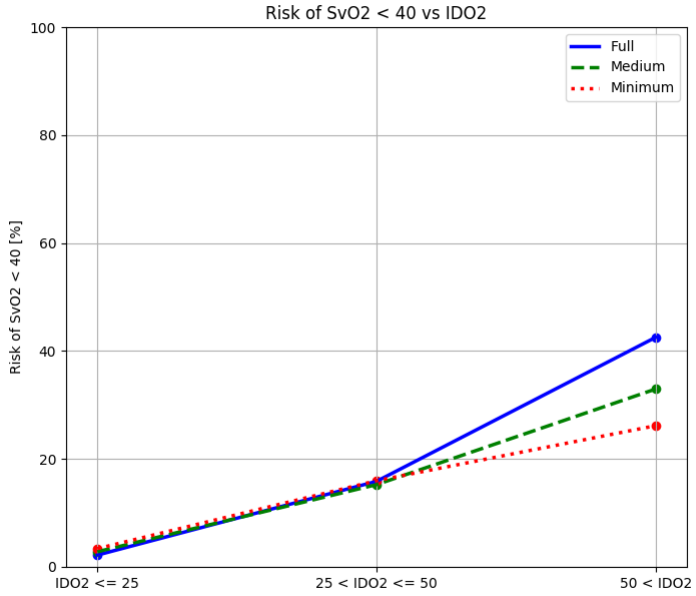
The figure (see Figure 3) shows the receiver operating characteristic with SvO2proxy < 40% by using the IDO2 Index computed by the model-based IDO2 algorithm. There were three datasets examined. In the first dataset, full measurement data composed of all possible measures listed above were used by the algorithm for the IDO2 computation, which included past mixed venous oxygen saturation measurements. In the second dataset, a "medium" dataset was curated by removing all SvO2 lab measurements. In the third dataset, only the minimum measurement data was used by the algorithm for the computation, i.e., heart rate every 60 seconds, SpO2 every 10 minutes, and blood pressure every 10 minutes. Note, these datasets are defined below in Table 3. The area under the curve (AUC) for the prediction with the full set of data is AUC = 0.89 with a 95% confidence interval of 0.87-0.89. The AUC for using the medium set of data is AUC = 0.83 with a 95% confidence interval of 0.82-0.84. The AUC for the minimum set of data is AUC = 0.78 with a 95% confidence interval of 0.76- 0.79. This is shown in the figure. There were 20,424 total SvO2 measurements with 3,602 measurements that were below 40% in the dataset.

Data set	Downsampling
Full	No downsampling - all data sources are fully available, see Table 1
Medium	No downsampling - all data sources are fully available, with the removal of all SvO2 lab measurements

Data set	Downsampling
Minimum	Reduced data rates for the minimal set (eleven measurements): • The following measures downsampled to 1 data point every 10 minutes - SpO2 and Arterial Blood Pressure • The following measures downsampled to 1 data point every 60 seconds - Heart rate No other measurements, above the minimal measurements, are processed through the algorithm (i.e. excluding central venous pressure, Hemoglobin, SvO2, and temperature)

3 The data sets employed in the analysis

The significance of different values of the IDO2 Index is illustrated (see Figure 4), by calculating the risk for SvO2 < 40% in various bins of the index. The figure shows a consistent increase in the risk in bins with higher values.



D The risk of SvO2 < 40% for different bins of the IDO2 Index

Data Set	IDO2 ≤ 25	p-value	25 < IDO2 ≤ 50	p-value	50 < IDO2
Full	2.19	<0.0001	15.85	<0.0001	42.53
Medium	2.01	<0.0001	15.24	<0.0001	32.95

Data Set	IDO2 ≤ 25	p-value	25 < IDO2 ≤ 50	p-value	50 < IDO2
Minimum	3.38	<0.0001	15.97	<0.0001	26.16

4 Statistics of the increase of risk of SvO2 < 40% between different bins of the IDO2 Index

The risk of SvO2 < 40% for different IDO2 bins is summarized in the table above for all three datasets (see Table 4). The dataset is shown in the left-hand column and the risk for each bin is shown under the corresponding bin label. The p-values listed specify whether the increases in risk between two adjacent bins are statistically significant.

7.3 Additional IDO2 index thresholds (IDO2_30 and IDO2_50)

Table 5 below depicts the AUC performance of the additional thresholds selectable for the index denoted as IDO2_30, for SvO2 < 30% and IDO2_50 for SvO2 < 50%.

Threshold	Data set	AUC	95% Confidence Interval
IDO2_30	Full	0.9019	[0.8797 - 0.9226]
	Medium	0.8418	[0.8147 - 0.8662]
	Minimum	0.8106	[0.7829 - 0.8363]
IDO2_50	Full	0.8558	[0.8489 - 0.862]
	Medium	0.7763	[0.7676 - 0.7853]
	Minimum	0.7208	[0.7112 - 0.7308]

5 AUCs for each data set type given with 95% confidence bounds - IDO2_30 and IDO2_50

Table 6 shows how the risk of SvO2 < 30% and SvO2 < 50% change for different ranges of the index thresholds. Note, the p-values demonstrates the risk increase is significant between the different ranges, the only notable exception being the increase of the IDO2 Index between the 25-50 and 50-100 range in the minimum data set.

Threshold	Data Set	IDO2 ≤ 25	p-value	25 < IDO2 ≤ 50	p-value	50 < IDO2
IDO2_30	Full	0.83	<0.0001	14.29	<0.0001	34.25
	Medium	1.07	<0.0001	10.23	=0.0006	20.6
	Minimum	1.33	<0.0001	11.29	=0.0665	4.4

Threshold	Data Set	IDO2 ≤ 25	p-value	25 < IDO2 ≤ 50	p-value	50 < IDO2
IDO2_50	Full	5.6	<0.0001	23.04	<0.0001	54.99
	Medium	7.64	<0.0001	18.88	<0.0001	45.29
	Minimum	8.07	<0.0001	19.83	<0.0001	41.53

6 AUCs for each data set type given with 95% confidence bounds - IDO2_30 and IDO2_50

7.4 The IDO2 Index Limitations

Healthcare professionals should consider the following limitations when employing the IDO2 Index for evaluation of indicated patients:

- The IDO2 Index cannot be used to diagnose or treat a disease or condition.
- The IDO2 Index is a trend monitor and as such has been validated and intended to be interpreted in the context of its entire range not versus a specific threshold.
- The IDO2 Index accuracy depends on the intensity of patient monitoring. The more measurements that are collected as inputs to T3, the more accurate the IDO2 Index will be. See the table in the Measurements section for all the data types considered by the algorithm.
- The IDO2 Index will not be displayed if the following minimum measurements are not available:
  - Heart rate from ECG or pulse at a minimum of once every 60 seconds.
  - SpO2 from pulse oximetry at a minimum of once every 10 minutes.
  - Blood Pressure (mean/diastolic/systolic) at a minimum of once every 10 minutes.
- The IDO2 Index has not been validated for patients weighing less than two kilograms.
- When the IDO2 Index is at its minimum value and not trending there is still a residual risk for inadequate oxygen delivery.
- When the IDO2 Index is at its maximum value and not trending there is still a residual risk for adequate oxygen delivery.
- The IDO2 Index uses the patient's date of birth to compute the patient's age and continuously update certain parameters of the physiology model.
- The IDO2 Index requires initialization time to calibrate to a particular patient once data starts streaming. The IDO2 Index will not be displayed during the initial calibration period of five minutes. If the patient's heart rate is subsequently lost for one hour, the algorithm will wait for at least the minimum set of measurements to be restored and will re-enter a calibration period prior to reporting a new value. No IDO2 Index will be displayed while the index is calibrating.
- The IDO2_30 is not available or validated for patients above 2 years of age.

- At extreme data sparsities (minimally available data sets), the IDO2_30 may not increase throughout its range.

⚠ **Note:** The scale for the IDO2 Index is the opposite of the saturation scale for oxygen saturation measurements such as those provided by pulse oximetry. When the index is increasing, it means that there is an increasing risk of inadequate oxygen delivery and attention should be brought to the patient.

8 The Inadequate Ventilation of Carbon Dioxide Index (IVCO2 Index)

The following table summarizes the available thresholds respected notation for the IVCO2 Index:

Risk	Threshold	Description
IVCO2	**IVCO2_50 ***	**Likelihood that PaCO2 > 50 mmHg ***
	IVCO2_60	Likelihood that PaCO2 > 60 mmHg
	*** Default threshold**	

7 Various risk thresholds

8.1 The IVCO2 Index Performance

The performance of the IVCO2 Index was established based on a validation dataset, which was independent of the dataset used during the index development. It included a total of 972 patients with 13,476 PaCO2 measurements.

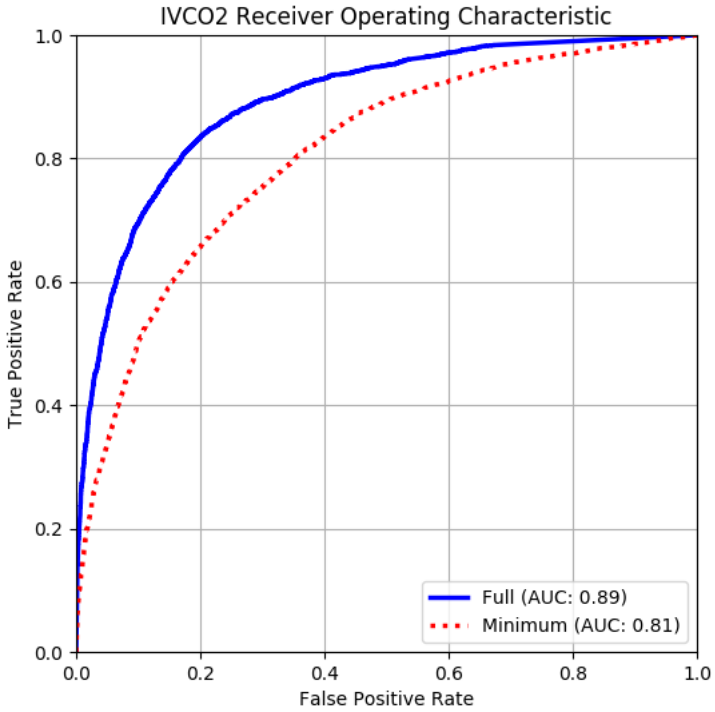
Data set	Downsampling
Full	No downsampling - all data sources are fully available, see Table 1
Minimum	Reduced data rates for the minimal set (eleven measurements): • The following measures downsampled to 1 data point every 60 minutes - Arterial Blood Pressure • The following measures downsampled to 1 data point every 10 minutes - SpO2 • The following measures downsampled to 1 data point every 60 seconds - FiO2, Heart rate, Respiratory rate, Tidal Volume, EtCO2, and Mean Airway Pressure No other measurements, above the minimal measurements, are processed through the algorithm (i.e. excluding central venous pressure, Hemoglobin, SvO2, and temperature)

8 The data sets employed in the analysis

Two different sets (see Table 8) were derived from the original data: 1) a *full data set*, which included the unaltered original data for the available patients and 2) a *minimum data set*, which was derived by down-sampling the original dataset to include only the minimum data required for the computation of the IVCO2 Index, which was used to evaluate the robustness of the performance of the IVCO2 Index under limited monitoring levels.

8.2 Default IVCO2 Index configuration (IVCO2_50)

Figure 5 illustrates the ROC curves and respective AUC values for detecting points positive for inadequate ventilation of carbon dioxide (PaCO2 > 50 mmHg) under the two different datasets.



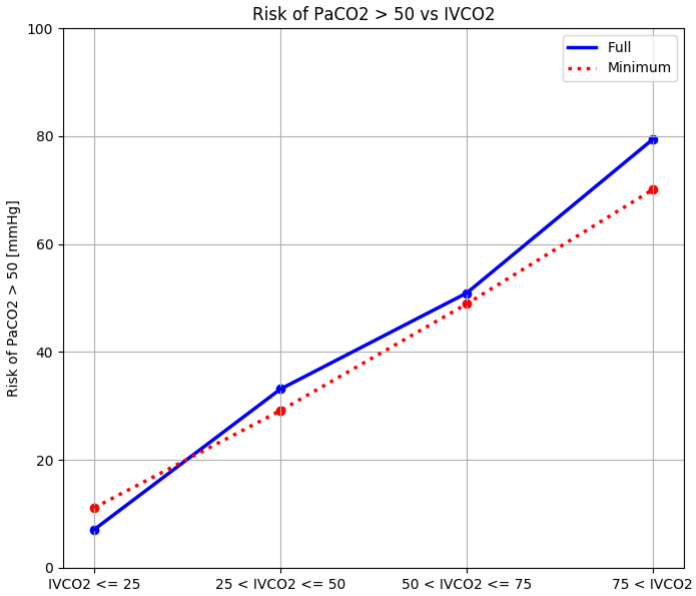
E the ROC for detecting points positive for inadequate ventilation of carbon dioxide for all validation patients when run with full and minimum data sets

These results are also summarized in Table 9, which includes the error around the means of the reported AUCs.

Data set	AUC	95% Confidence Interval
Minimum	0.8065	[0.7979 - 0.8153]
Full	0.8921	[0.8864 - 0.8985]

9 AUCs for each data set type, given with confidence bounds

The risk for PaCO2>50mmHg (the fraction of positive points) in different bins of the index is summarized in Figure 6, which shows a monotonically increasing risk between bins in all of the three datasets, which, as summarized in Table 10, is statistically significant.



F The risk of inadequate ventilation of carbon dioxide for different bins of the IVCO2 index

Data Set	0-25	p	25-50	p	50-75	p	75-100
Minimum	11.15	<0.0001	29.13	<0.0001	48.49	<0.0001	70.07
Full	7.13	<0.0001	33.13	<0.0001	50.91	<0.0001	79.39

10 Statistics of the increase of inadequate ventilation of carbon dioxide risk between different bins of the IVCO2 index

Note that when the IVCO2 Index is below its minimum value, i.e. IVCO2 < 1, or above its maximum value, i.e. IVCO2 > 99, there is still a residual risk for inadequate ventilation of carbon dioxide (i.e. PaCO2 > 50 mmHg), or for adequate ventilation of carbon dioxide (i.e. PaCO2 ≤ 50 mmHg) in the latter case. The following approach is used to quantify this limitation:

- The risk for inadequate ventilation of carbon dioxide is evaluated given IVCO2 Index < 1
- The risk for adequate ventilation of carbon dioxide is evaluated given the IVCO2 Index > 99
- The relative risk between these risks and the total risks (prevalence) in the study population is quantified with its 95% confidence interval

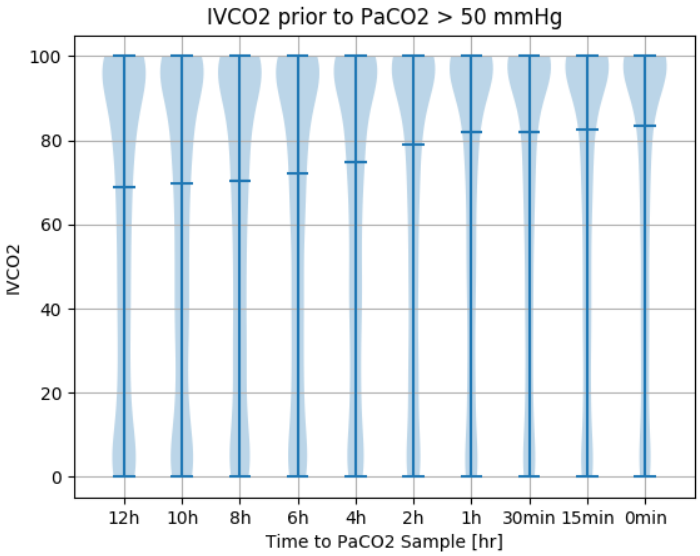
Table 11 shows the computed relative risk of PaCO2 > 50 at IVCO2 Index < 1 defined as the minimum relative risk, and PaCO2 ≤ 50 mmHg at IVCO2 Index > 99 defined as the maximum relative risk.

Data Set	Minimum relative risk	95% Confidence Interval	Maximum relative risk	95% Confidence Interval
Minimum	0.19	[0.11-0.33]	0.13	[0.09-0.19]
Full	0.11	[0.09-0.13]	0.10	[0.07-0.12]

11 The minimum relative risk for patients in the validation data set

The following conclusion can be drawn from these results:

- When a patient has both an IVCO2 Index < 1 and a **full** set of observations (see Table 8), this patient is 9-**times** less likely to have inadequate ventilation of carbon dioxide than the patient population (i.e. 1/0.11 = 9, where 0.11 is the minimum relative risk value from the full dataset, Table 11).
- When a patient has both an IVCO2 Index > 99 and a **full** set of observations (see Table 8), this patient is 10-**times** less likely to have adequate ventilation of carbon dioxide than the patient population (i.e. 1/0.10 = 10, where 0.15 is the maximum relative risk value from the full data set, Table 11).



G IVCO2 Distribution Prior to PaCO2 > 50 mmHg

The IVCO2 index is intended to be used as a trend monitor. Figure 7 summarizes the trend of the IVCO2 index before an arterial blood gas with PaCO2 > 50 mmHg, which illustrates the following key elements of the index:

- Prior to a PaCO2 measurement associated with inadequate ventilation of carbon dioxide (PaCO2 > 50 mmHg), from 12 hours to 4 hours, the distribution of IVCO2 values is bi-modal with the larger portion

from 60-100 and the smaller portion from 0 - 20. This illustrates the fact that some patients experience chronic hypercapnia with chronically elevated IVCO2, while others experience acute periods of hypercapnia, and as a result have lower IVCO2 values further away from a blood gas sample.

- From 4 hours to the draw time of an ABG with PaCO2 > 50 mmHg, Figure 7 depicts a rise in the median IVCO2 value, as well as a shift of the distribution from bi-modal to uni-modal with the majority of density > 60 indicating that an increasing IVCO2 Index correctly identifies increasing risk for inadequate ventilation of carbon dioxide.

8.3 Additional IVCO2 threshold (IVCO2_60)

Table 12 summarized the AUC values for IVCO2_60 in detecting points positive for inadequate ventilation of carbon dioxide (PaCO2 > 60 mmHg) under the two different datasets.

Data set	AUC	95% Confidence Interval
Minimum	0.8294	[0.8155 - 0.8433]
Full	0.9097	[0.8991 - 0.919]

12 AUCs for each data set type, given with confidence bounds

The risk for PaCO2 > 60 mmHg (the fraction of positive points) in different bins of the index is summarized in Table 13, which shows a monotonically increasing risk between bins in all of the two datasets.

Data Set	0-25	p	25-50	p	50-75	p	75-100
Minimum	4.03	<0.0001	18.39	<0.0001	34.61	<0.0001	55.50
Full	2.65	<0.0001	26.65	<0.0001	37.42	<0.0001	70.96

13 Statistics of the increase of inadequate ventilation of carbon dioxide risk between different bins of the IVCO2 index

Table 14 shows the computed minimum and maximum relative risks for inadequate ventilation of carbon dioxide, which was 0.02 and 0.08 for the minimum, and full datasets respectively. Given these performance metrics:

- When a patient has both an IVCO2 Index < 1 and a **full** set of observations (see Table 8), this patient is 7-**times** less likely to have inadequate ventilation of carbon dioxide than the patient population (i.e. 1/0.15 = 7, where 0.15 is the minimum relative risk value from the full dataset, Table 14).

- When a patient has both an IVCO2 Index > 99 and a **full** set of observations (see Table 8), this patient is 3-**times** less likely to have adequate ventilation of carbon dioxide than the patient population (i.e. 1/0.32 = 3, where 0.32 is the maximum relative risk value from the full data set, Table 14).

Data Set	Minimum relative risk	95% Confidence Interval	Maximum relative risk	95% Confidence Interval
Minimum	0.25	[0.21-0.29]	0.25	[0.09-0.44]
Full	0.15	[0.12-0.18]	0.32	[0.10-0.23]

14 The minimum relative risk for patients in the validation data set

8.4 The IVCO2 Index Limitation

Healthcare professionals should consider the following limitations when employing the IVCO2 Index for evaluation of indicated patients:

- The IVCO2 Index cannot be used to diagnose or treat a disease or condition.
- The IVCO2 Index is a trend monitor and as such has been validated and intended to be interpreted in the context of its entire range not versus a specific threshold.
- The precision and accuracy of the IVCO2 Index algorithm improve as more data becomes available. The performance of the IVCO2 Index shows a statistically significant improvement in the presence of arterial blood gases. (See Table 9.)
- When the IVCO2 Index is at its minimum value and not trending, there is still a residual risk for inadequate ventilation of carbon dioxide.
- When the IVCO2 Index is at its maximum value and not trending, there is still a residual risk for adequate ventilation of carbon dioxide.
- The IVCO2 Index will not be displayed if the following minimum measurements are not available:
  - Heart rate from ECG or pulse, respiration rate, tidal volume, end-tidal-CO2, the fraction of inspired oxygen, and mean airway pressure at a minimum of once every 60 seconds
  - SpO2 from pulse oximetry at a minimum of once every 10 minutes
  - Blood Pressure (mean/diastolic/systolic) at a minimum of once every 60 minutes
- The IVCO2 Index requires initialization time to calibrate to a particular patient once data starts streaming. The IVCO2 Index will not be displayed during the initial calibration period of five minutes. If the patient's heart rate is subsequently lost for one hour, the algorithm will wait for at least the minimum set of measurements to be restored and will re-enter a calibration period prior to reporting a new value. No IVCO2 Index will be displayed while the index is calibrating.
- The IVCO2 Index has not been validated for patients weighing less than two kilograms.
- The IVCO2 Index uses the patient's date of birth to compute the patient's age and continuously update certain parameters of the physiology model.

9 The HLA Index

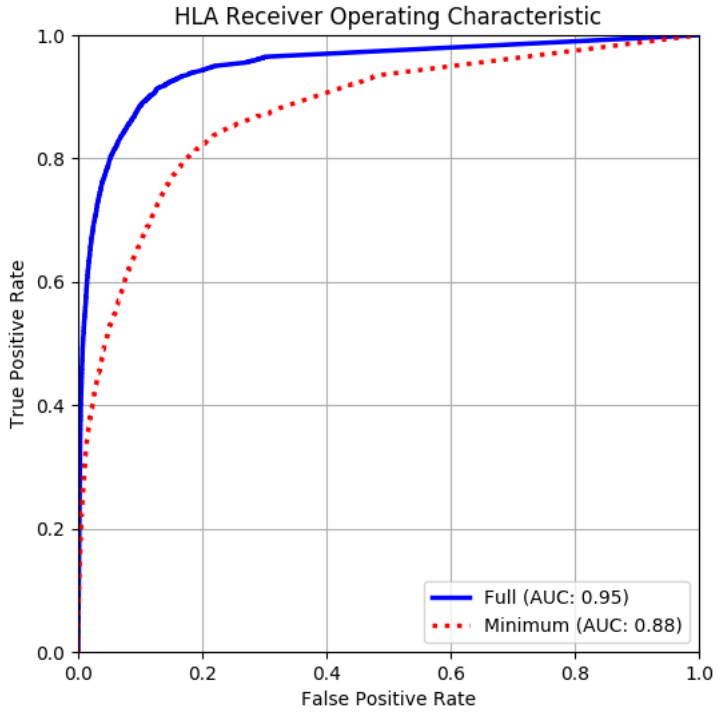
9.1 The HLA Index performance

The association of the HLA Index with hyperlactatemia was established through a retrospective study of a patient population that included neonates (0-28 days of age), infants (29 days to 2 years of age), and children (2-12 years of age) from multiple institutions and intensive care units. This validation patient population group included 4524 patients.

The study used periodic measurements of whole blood concentration of lactate sampled from various blood panels, e.g. Point-of-Care diagnostics, blood chemistry. A total of 63,914 measurements were included in the reported performance assessment.

For each lactate measurement in the first 10 postoperative days, the average HLA index was computed in the 30 minute period immediately prior to the measurement and used as a predictor score for LA > 4 mmol /L. The resulting Receiver Operating Characteristic (ROC) curve was generated and the Area Under the Curve (AUC) was computed.

9.2 The HLA ROC Performance



H ROC Curves for Full and Minimum Validation sets for the HLA Index

The figure (see Figure 8) shows the receiver operating characteristic with LA > 4 mmol/L by using the HLA Index computed by the model-based Risk Analytics algorithm. There were two datasets examined. In the first dataset, full measurement data composed of all possible measures listed above were used by the algorithm for the HLA computation. In the second dataset, only the minimum measurement data was used by the algorithm for the computation, i.e., heart rate every 60 seconds, SpO2 every 10 minutes, and blood pressure every 10 minutes, and whole blood lactate once every 24 hours. Note, these datasets are defined below in Table 15.

Data set	Downsampling
Full	No downsampling - all data sources are fully available, see Table 1

Data set	Downsampling
Minimum	Reduced data rates for the minimal set (eleven measurements): • The following measures downsampled to 1 data point every 10 minutes - SpO2 and Arterial Blood Pressure • The following measures downsampled to 1 data point every 60 seconds - Heart rate • The following measures downsampled to 1 data point every 24 hours - Whole blood lactate No other measurements, above the minimal measurements, are processed through the algorithm

15 The data sets employed in the HLA analysis

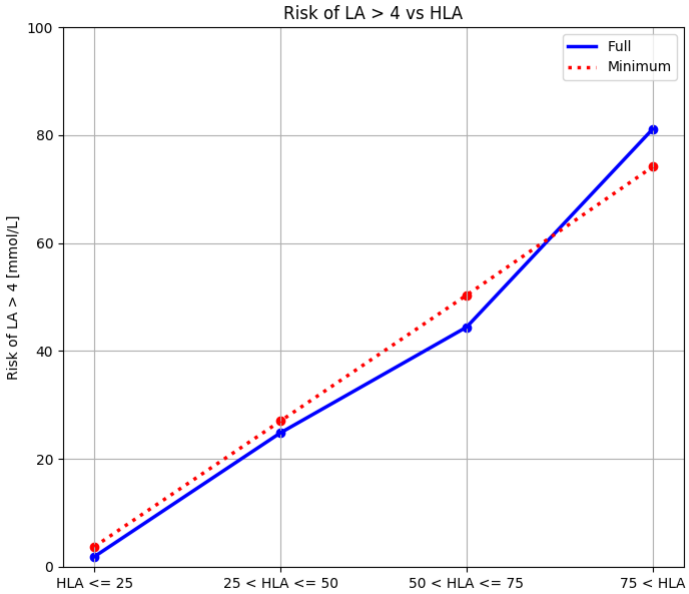
Table 16below depicts the resulting AUCs and 95% confidence intervals.

Data set	AUC	95% Confidence Interval
Full	0.9493	[0.9461 - 0.9523]
Minimum	0.8755	[0.8691 - 0.8819]

16 AUCs for each data set type given with 95% confidence bounds for the HLA Index

9.3 The HLA Risk Performance

The risk for LA > 4 mmol/L in different bins of the HLA Index is summarized in Figure 9. Note the monotonic increase of risk between bins in both data sets, which, as summarized in Table 17, is statistically significant.



I The risk of LA > 4 mmol/L for different bins of the HLA Index

Data Set	HLA ≤ 25	p-value	25 < HLA ≤ 50	p-value	50 < HLA ≤ 75	p-value	75 < HLA
Full	1.9	<0.0001	24.84	<0.0001	44.42	<0.0001	81.12
Minimum	3.75	<0.0001	27.02	<0.0001	50.34	<0.0001	74.12

17 Statistics of the increase of hyperlactatemia risk between different bins of the HLA Index

Note that when the HLA Index is below its minimum value, i.e. HLA < 1, or above its maximum value, i.e. HLA > 99, there is still a residual risk for hyperlactatemia (i.e. LA > 4 mmol / L), or LA ≤ 4 mmol / L in the latter case. The following approach is used to quantify this limitation:

- The risk for hyperlactatemia is evaluated given HLA Index < 1
- The risk for LA LA ≤ 4 mmol / L is evaluated given the HLA Index > 99
- The relative risk between these risks and the total risks (prevalence) in the study population is quantified with its 95% confidence interval

Table 18 describes the minimum relative risk for hyperlactatemia, which is 0.16 and 0.07 for the minimum and full data sets respectively. These numbers can be interpreted as a patient with a minimum value of the HLA Index and a full set of observations is **14 times less likely** to have hyperlactatemia than their peers. The table also describes the maximum relative risk for Lactate < 4 mmol/L, which is 0.12 and 0.10 for both the minimum and full data sets respectively. These numbers can be interpreted as a patient with a maximum value of the HLA Index and a full set of observations is **10 times less likely** to have Lactate ≤ 4 mmol/L than their peers.

Data Set	Minimum relative risk	95% Confidence Interval	Maximum relative risk	95% Confidence Interval
Minimum	0.16	[0.14-0.18]	0.12	[0.09-0.16]
Full	0.07	[0.06-0.08]	0.10	[0.09-0.11]

18 The minimum and maximum relative risk for patients in the validation data set for the HLA Index

9.4 The HLA Index Limitations

Healthcare professionals should consider the following limitations when employing the HLA Index for evaluation of indicated patients:

- The HLA Index cannot be used to diagnose or treat a disease or condition.
- The HLA Index is a trend monitor and as such has been validated and intended to be interpreted in the context of its entire range not versus a specific threshold.
- The HLA Index accuracy depends on the intensity of patient monitoring. The more measurements that are collected as inputs to T3, the more accurate the HLA Index will be. See the table in the Measurements section for all the data types considered by the algorithm.
- The HLA Index will not be displayed if the following minimum measurements are not available:
  - Heart rate from ECG or pulse at a minimum of once every 60 seconds.
  - SpO2 from pulse oximetry at a minimum of once every 10 minutes.
  - Blood Pressure (mean/diastolic/systolic) at a minimum of once every 10 minutes.
  - Whole blood concentration of lactate acquired at a minimum of every 24 hours
- The HLA Index has not been validated for patients weighing less than two kilograms.
- When the HLA Index is at its minimum value and not trending there is still a residual risk for hyperlactemia.
- When the HLA Index is at its maximum value and not trending there is still a residual risk for LA ≤ 4 mmol / L.
- The HLA Index uses the patient's date of birth to compute the patient's age and continuously update certain parameters of the physiology model.
- The HLA Index requires initialization time to calibrate to a particular patient once data starts streaming. The HLA Index will not be displayed during the initial calibration period of five minutes. If the patient's heart rate is subsequently lost for one hour, the algorithm will wait for at least the minimum set of measurements to be restored and will re-enter a calibration period prior to reporting a new value. No HLA Index will be displayed while the index is calibrating.

10 The ACD Index

10.1 The ACD Index Performance

The association of the ACD Index with acidemia was established through a retrospective study of a patient population that included neonates infants (29 days to 2 years of age) and children (2-12 years of age) from multiple institutions and intensive care units. This validation patient population group included 898 patients.

The study used periodic measurements of pH sampled from arterial blood gas. A total of 12,653 measurements were included in the reported performance assessment.

For each arterial pH measurement (pHa), the average ACD index was computed in the 30 minute period immediately prior to the measurement and used as a predictor score for pHa < 7.25. The resulting Receiver Operating Characteristic (ROC) curve was generated and the Area Under the Curve (AUC) was computed.

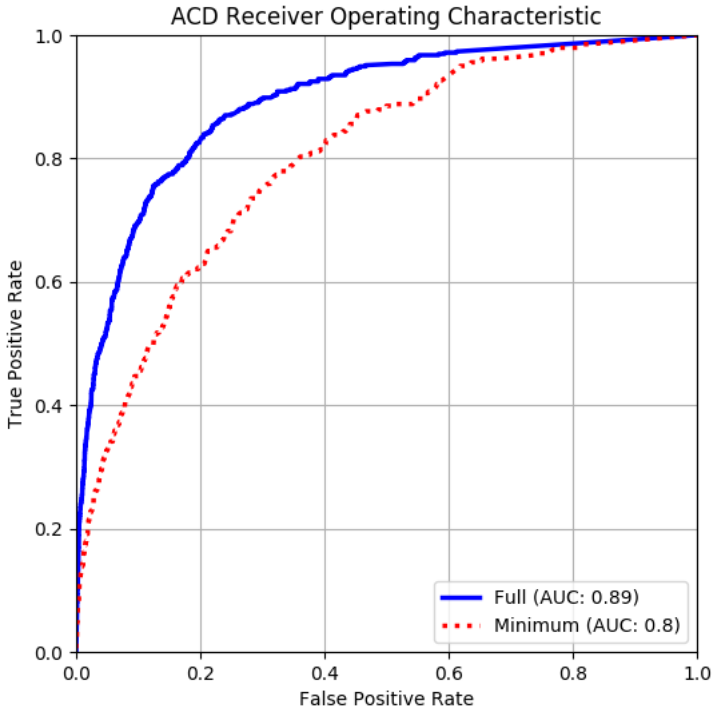
10.2 The ACD ROC Performance

The figure below (see Figure 10) shows the receiver operating characteristic of predicting pHa < 7.25 by using the average of the ACD Index averaged over the 30 minutes prior to an arterial blood gas sample.

Data set	Downsampling
Full	No downsampling - all data sources are fully available, see Table 1
Minimum	Reduced data rates for the minimal set (eleven measurements): • The following measures downsampled to 1 data point every 60 minutes - Arterial Blood Pressure • The following measures downsampled to 1 data point every 10 minutes - SpO2 • The following measures downsampled to 1 data point every 60 seconds - FiO2, Heart rate, Respiratory rate, Tidal Volume, EtCO2, and Mean Airway Pressure • The following measures downsampled to 1 data point every 24 hours - PaCO2 or PvCO2 • The following measures downsampled to 1 data point every 24 hours - arterial pH or venous pH No other measurements, above the minimal measurements, are processed through the algorithm

19 The data sets employed in the analysis

Two different sets (see Table 8) were derived from the original data: 1) a *full data set*, which included the unaltered original data for the available patients and 2) a *minimum data set*, which was derived by down-sampling the original dataset to include only the minimum data required for the computation of the ACD Index, which was used to evaluate the robustness of the performance of the ACD Index under limited monitoring levels.



J ROC Curves for Full and Minimum Validation sets of the ACD Index

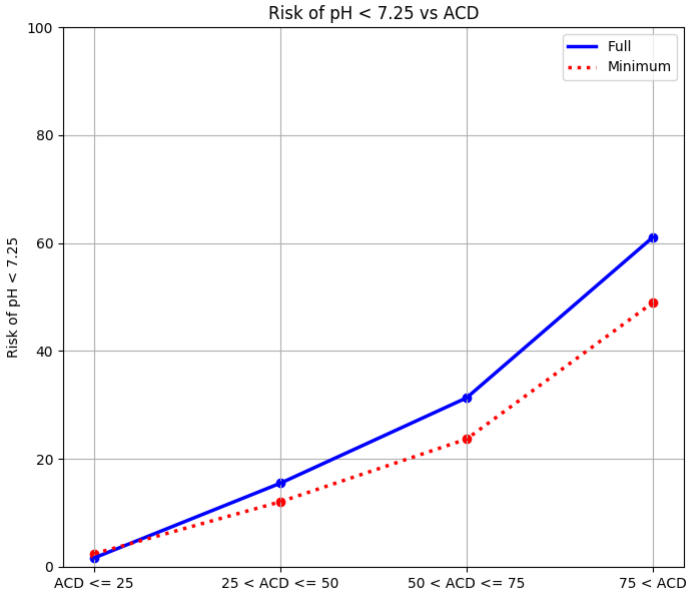
Table 20 below depicts the resulting AUCs and 95% confidence intervals. Note that all intervals are above the 0.7 AUC acceptance criterion.

Data set	AUC	95% Confidence Interval
Full	0.8907	[0.8754 - 0.9067]
Minimum	0.8005	[0.776 - 0.8236]

20 AUCs for each data set type given with 95% confidence bounds for the ACD Index

10.3 ACD Risk Performance

The risk for pHa < 7.25 in different bins of the ACD Index is summarized in Figure 11. Note the monotonic increase of risk between bins in both data sets, which, as summarized in Table 21, is statistically significant.



K The risk of pH < 7.25 for different bins of the ACD Index

Data Set	ACD ≤ 25	p-value	25 < ACD ≤ 50	p-value	50 < ACD ≤ 75	p-value	75 < ACD
Full	1.68	<0.0001	15.51	<0.0001	31.32	<0.0001	61.05
Minimum	2.45	<0.0001	12.07	=0.0003	23.68	=0.0005	48.94

21 Statistics of the increase of acidemia risk between different bins of the ACD Index

Note that when the ACD Index is below its minimum value, i.e. ACD < 1, or above its maximum value, i.e. ACD > 99, there is still a residual risk for acidemia (i.e. pHa < 7.25), or pHa ≥ 7.25 in the latter case. The following approach is used to quantify this limitation

- The risk for acidemia is evaluated given ACD Index < 1
- The risk for pHa ≥ 7.25 is evaluated given the ACD Index > 99
- The relative risk between these risks and the total risks (prevalence) in the study population is quantified with its 95% confidence interval

Table 22 describes the minimum relative risk for acidemia, which is 0.13 and 0.10 for the minimum and full data sets respectively. Note that these numbers can be interpreted as a patient with a minimum value of the ACD Index and a full set of observations is **10 times less likely** to have acidemia than their peers. The table also describes the maximum relative risk for pHa ≥ 7.25, which is 0.0 and 0.43 for both the minimum and full data sets respectively. Note that these numbers can be interpreted as a patient with a maximum value of the ACD Index and a full set of observations is **2.3 times less likely** to have pHa ≥ 7.25 mmol/L than their peers.

Data Set	Minimum relative risk	95% Confidence Interval	Maximum relative risk	95% Confidence Interval
Minimum	0.13	[0.07-0.23]	0.0	[0.0-1.23]
Full	0.10	[0.06-0.15]	0.43	[0.29-0.64]

22 The minimum and naximum relative risk for patients in the validation data set for the ACD Index

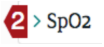
10.4 ACD Index Limitations

Healthcare professionals should consider the following limitations when employing the ACD Index for evaluation of indicated patients:

- The ACD Index cannot be used to diagnose or treat a disease or condition.
- The ACD Index is a trend monitor and as such has been validated and intended to be interpreted in the context of its entire range not versus a specific threshold.
- The ACD Index accuracy depends on the intensity of patient monitoring. The more measurements that are collected as inputs to T3, the more accurate the ACD Index will be. See the table in the Measurements section for all the data types considered by the algorithm.
- The ACD Index will not be displayed if the following minimum measurements are not available:
  - Heart rate from ECG or pulse, respiration rate, tidal volume, end-tidal-CO2, the fraction of inspired oxygen, and mean airway pressure at a minimum of once every 60 seconds
  - SpO2 from pulse oximetry at a minimum of once every 10 minutes
  - Blood Pressure (mean/diastolic/systolic) at a minimum of once every 60 minutes
  - Venous or arterial blood gas acquired every 24 hours
- The ACD Index has not been validated for patients weighing less than two kilograms.
- When the ACD Index is at its minimum value and not trending there is still a residual risk for acidemia.
- When the ACD Index is at its maximum value and not trending there is still a residual risk for pHa ≥ 7.25
- The ACD Index uses the patient's date of birth to compute the patient's age and continuously update certain parameters of the physiology model.
- The ACD Index requires initialization time to calibrate to a particular patient once data starts streaming. The ACD Index will not be displayed during the initial calibration period of five minutes. If the patient's heart rate is subsequently lost for one hour, the algorithm will wait for at least the minimum set of measurements to be restored and will re-enter a calibration period prior to reporting a new value. No ACD Index will be displayed while the index is calibrating.

11 Appendix

11.1 List of Graphical Icons in the User Interface

Description	Icon
Location Badge (appears on Measures Dashboard)	
Target icon (no targets)	
Target icon (with targets)	
Add Event (appears on the toolbar)	
Encounter – entry into the unit (appears on Time Navigation)	
Encounter – exit out of the unit (appears on Time Navigation)	
Event (appears on Time Navigation)	
Calculate Statistics (appears on the toolbar)	
Day Mode (appears on the toolbar)	
Night Mode (appears on the toolbar)	
Lock (appears on the toolbar)	

23 Application icons and graphics

The table (see Table 23) displays icons and graphics for the application's features.

11.2 List of Common Measures

Abbreviation	Name	Units
ABPd	Arterial blood pressure (diastolic)	mmHg
ABPm	Arterial blood pressure (mean)	mmHg
ABPs	Arterial blood pressure (systolic)	mmHg
ARTd	Arterial blood pressure (diastolic)	mmHg
AR	Arterial blood pressure (mean)	mmHg
ARTs	Arterial blood pressure (systolic)	mmHg
CPP	Cerebral perfusion pressure	mmHg
CVPd	Central venous pressure (diastolic)	mmHg
CVPm	Central venous pressure (mean)	mmHg
CVPs	Central venous pressure (systolic)	mmHg
dSpO2	Difference between two SpO2 values (like Left - Right)	%
etCO2	End tidal carbon dioxide concentration	mmHg
FiO2	Fraction of inspired oxygen	%
HR	Heart rate	bpm
ICPm	Intracranial pressure (mean)	mmHg
LAPd	Left atrial pressure (diastolic)	mmHg
LAPm	Left atrial pressure (mean)	mmHg
LAPs	Left atrial pressure (systolic)	mmHg
MV	Minute volume	L/min

Abbreviation	Name	Units
PAPd	Pulmonary arterial pressure (diastolic)	mmHg
PAPm	Pulmonary arterial pressure (mean)	mmHg
PAPs	Pulmonary arterial pressure (systolic)	mmHg
PB	Barometric pressure	mmHg
Peep	Positive-end expiratory pressure	cmH2O
Ppeak	Peak airway pressure	cmH2O
Pulse	Pulse	bpm
RAPd	Right atrial pressure (diastolic)	mmHg
RAPm	Right atrial pressure (mean)	mmHg
RAPs	Right atrial pressure (systolic)	mmHg
RR	Impedance respiratory rate	rpm
SpMV	Spontaneous minute volume	L/min
SpO2	Peripheral oxygen saturation	%
SpO2 l	Arterial oxygen saturation (left)	%
SpO2 r	Arterial oxygen saturation (right)	%
SpRR	Spontaneous respiration rate	rpm
Tcore	Core (body) temperature	°C
Temp	Temperature	°C
Tesoph	Tesoph esophageal temperature	°C
Trect	Rectal temperature	°C
TV	Tidal volume	mL

Abbreviation	Name	Units
UAPd	Umbilical arterial pressure (diastolic)	mmHg
UAPm	Umbilical arterial pressure (mean)	mmHg
UAPs	Umbilical arterial pressure (systolic)	mmHg
UVPd	Umbilical venous pressure (diastolic)	mmHg
UVPm	Umbilical venous pressure (mean)	mmHg
UVPs	Umbilical venous pressure (systolic)	mmHg

24 Common measures

The table (see Table 24) lists common measures displayed in T3.

11.3 List of Common Laboratory Results

Name
Arterial blood gases
Venous blood gases
Hemoglobin
Hematocrit
Lactic acid

25 Common laboratory results

The table (see Table 25) lists common laboratory results displayed in T3.

11.4 List of Clinical Calculations

Abbreviation	Name	Units	Formula
PW	Pulse width	mmHg	ABPs – ABPd
CPP_LAP	Cerebral perfusion pressure	mmHg	ABPm – LAPm
CPP_RAP	Cerebral perfusion pressure	mmHg	ABPm – RAPm
CPP_CVP	Cerebral perfusion pressure	mmHg	ABPm – CVPm
CorPP_r	Coronary perfusion pressure	mmHg	ABPd – RAPm
CorPP_l	Coronary perfusion pressure	mmHg	ABPd – LAPm
CorPP_c	Coronary perfusion pressure	mmHg	ABPd – CVPm
RPP	Rate pressure product (myocardial oxygen demand indicator)	1000 mmHg*bpm	ABPs * HR / 1000
P/F	P/F Ratio	n/a	PaO2 / FiO2
S/F	S/F Ratio	n/a	SpO2 / FiO2
OI	Oxygenation Index	n/a	(FiO2 * Mean Airway Pressure * 100) / PaO2
OSI	Oxygen Saturation Index	n/a	(Mean Airway Pressure * FiO2 * 100) / SpO2

26 Clinical calculations and their formulas

The table (see Table 26) contains clinical calculations and their formulas included in T3.

12 Glossary

Term	Description
Central-Graphs Area	The configurable plotting area in the center of the patient view.
Census Overview screen	Initial page upon logging into the application that displays all current patients in the unit. The Current Census tab shows patients that currently occupy a bed space, while the Archived Census tab shows patients that have been in the ICU in the past two months.
Clinical calculation	A measure derived by computation from one or more other measures. See *List of Clinical Calculations* for more information.
Data resolutions	Four different resolutions of data are available: 5-seconds, 1-minute, 5-minutes, and 30-minutes. T3 selects the most appropriate resolution to display based on how far the user zooms in or out.
Global features	Actions performed on the Patient View screen that display to all other users of the patient e.g. Targets and Events.
Central graphs	Five central graphs are available for users to analyze physiometric trends. Each graph can hold up to four measures.
Individual User mode	The mode of T3 for situations where a user logs in to T3 and uses the application for a defined period of time.
Legend Label	The label of the currently plotted measure on a graph, located to the left of the graph in the Central-Graphs Area.
Measures Dashboard	The list of all available measures presented on the right-hand side in the Central-Graphs Area.
Measure group	A collection of measures and laboratory results that are graphed together as a unit. Because the constituent labs and measures are predefined, T3 is able to add visual elements such as shading to emphasize data relationships.
Measure statistics	A table displaying the average, standard deviation, maximum, minimum, and data gap percentage calculated for measures displayed in the Central-Graphs Area for the selected time range.
Measure synonyms	The logic that recognizes parameters that measure the same physiologic condition and determines at each point in time which one of several synonymous measures have the highest priority.
Night time display	A configurable feature where the T3 Patient View is displayed with a dark background, at night, and a light background during the day.

Term	Description
Patient History	A table that displays details (time, user, action) for all global actions done on the patient.
Persistent Display	The mode of T3 for situations where T3 is meant to constantly display data for a specific bedspace.
Time navigation bar	A navigation tool that allows users to condense or extend the amount of data displayed in the Central-Graphs Area.
User arrangement	Actions, performed on the Patient View, that are saved only for the current user for the current patient (e.g. Central-Graphs Area arrangement and placement and y-axis control).
Y-axis control	The ability for users to change the Y-axis for each graph by clicking on the Y-axis range of a graph and selecting the Y-axis range.

13 FAQ Section

13.1 Contact Us

13.1.1 *How can I contact Etiometry?*

Etiometry's support staff is always ready to help with any questions you may have.

13.1.2 *Want to Talk?*

You can reach us by phone at (857) 366-9333.

13.1.3 *Want to send us an email?*

Contact us through email at support@etiometry.com

13.1.4 *Want to learn more about Etiometry, Inc?*

For more general information, check out our website, www.etiometry.com.

13.2 Serious Incident

13.2.1 Serious Incident denotes any direct or relevant indirect link between the use of this software and the death of a patient, a serious public health threat, or the temporary/permanent loss or deterioration of a patient's state of health or wellbeing.

13.2.2 if any serious incident has occurred in relation to the software, it should be reported to the Etiometry and the competent authority of the Member State in which the user is established

- Report to the Etiometry by phone at US +1 (857) 366-9333
- Report to the Etiometry by email at support@etiometry.com
- Report to the competent authority of the Member State: List of national competent authorities in the EEA

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