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April 21, 2020

Dear Valued Customer,

Use of Terumo Cardiovascular's CDI® Blood Parameter Monitoring Systems in Extracorporeal Membrane Oxygenation Therapy

Background

In accordance with the FDA's Enforcement Policy for Extracorporeal Membrane Oxygenation and Cardiopulmonary Bypass Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency, Guidance for Industry and Food and Drug Administration Staff, which was issued on April 6, 2020, Terumo Cardiovascular is providing you an update regarding our CDI Blood Parameter Monitoring Systems (see Appendix A for list of applicable devices).

Using CDI Blood Parameter Monitoring Systems for Extracorporeal Membrane Oxygenation (ECMO) Therapy

CDI Blood Parameter Monitoring Systems include the use of disposable Shunt Sensors and H/S Cuvettes which are currently indicated for up to six (6) hours of continuous use in support of cardiopulmonary bypass (CPB) surgery. While Terumo Cardiovascular does not have FDA approval or clearance for continuous usage of the device for longer than six hours, the above-referenced FDA Guidance designates many blood-gas monitors, including CDI Systems, as technologically capable of being used for ECMO therapy.

In order to support the emergency use of CDI Systems for ECMO therapy, Terumo Cardiovascular is providing some relevant performance and durability information, an overview of key risks, and a summary of signs indicating that a device change out is necessary.

Performance and Durability

Prior to use, refer to the corresponding Operator's Manual for all relevant use information and instructions. Provided below are the relevant product performance and durability data excerpts from the currently approved and cleared Operator's Manuals which may be helpful when considering usage of CDI Systems in ECMO therapy.

System Operating Ranges:

	CDI System 550	CDI System 500
pH	6.80 to 7.80 pH units	6.80 to 7.80 pH units
PCO_2	10 to 80 mmHg (1.3 to 10.7 kPa)	10 to 80 mmHg (1.3 to 10.7 kPa)
PO_2	20 to 500 mmHg (2.7 to 66.7 kPa)	20 to 500 mmHg (2.7 to 66.7 kPa)
K^+	3.0 to 8.0 mmol/L	3.0 to 8.0 mmol/L
HCT	15% to 45%	17% to 38%
SO_2	60% to 100%	60% to 100%
Hgb	5.0 to 15.0 g/dL	5.6 to 12.6 g/dL
DO_2	10 to 2000 mL/min	N/A
VO_2	10 to 400 mL/min	10 to 400 mL/min
BE	-25 to 25 mEq/L	-25 to 25 mEq/L
HCO^-_3	0 - 50 mEq/L	0 - 50 mEq/L
Temperature	15° to 40°C	15° to 40°C

System Accuracy Limits:

	CDI System 550	CDI System 500
pH Sensor (pH units)	Mean: 0.007 Std Dev: 0.014	Mean: -0.018 Std Dev: 0.023
PCO_2 Sensor (mmHg)	Mean: 0.0 Std Dev: 2.9	Mean: -0.2 Std Dev: 2.2
PO_2 Sensor - Arterial (>80 mmHg)	Mean: -0.5 Std Dev: 5.5	Mean: 6.1 Std Dev: 17.6
PO_2 Sensor - Venous (<80 mmHg)	Mean: -0.4 Std Dev: 0.8	Mean: 1.3 Std Dev: 2.3
SO_2 Oxygen Saturation Value (%)	Mean: -0.5 Std Dev: 1.6	Mean: -0.4 Std Dev: 1.6
Temperature	N/A	Mean: -0.07 Std Dev: 0.22
Hgb Total Hemoglobin Value (g/dL)	Mean: -0.17 Std Dev: 0.54	Mean: -0.09 Std Dev: 0.38
K^+ Potassium Sensor (mmol/L)	Mean: 0.05 Std Dev: 0.18	Mean: -0.06 Std Dev: 0.19
HCT Hematocrit Value (%)	Mean: -0.5 Std Dev: 1.7	Mean: -0.4 Std Dev: 1.2

The Shunt Sensor requires a minimum flow of 35 mL/min. To perform accurately, the H/S Cuvette requires the blood flow rates shown in the following table:

H/S Cuvette Size	Min Flow	Max Flow
1/2"	1.0 LPM	7.0 LPM
3/8"	0.5 LPM	4.0 LPM
1/4"	0.2 LPM	1.5 LPM

When used in accordance with Operator's Manual instructions, CDI Systems will operate within the defined performance specifications for up to six hours of use.

Risks Associated with Using a CDI Blood Parameter Monitoring System in ECMO Therapy

The use of CDI Blood Parameter Monitoring Systems in ECMO Therapy for longer than the six-hour indication for use period may result in an increased likelihood of parameter inaccuracy due to degradation of the disposable Shunt Sensors and H/S Cuvettes. Parameter inaccuracy may result in a need to change out either the disposables or the full system to ensure continued monitor accuracy for the duration of ECMO therapy.

Potential risks associated with parameter inaccuracy include severe or significant injury due to inappropriate user response, and negligible blood loss due to additional lab sampling.

Potential risks associated with system or disposable change out, which are well known to clinicians utilizing these devices, are associated with the replacement process of an underperforming blood parameter monitor or improper initial system and circuit setup. Replacement of disposables is not generally recommended during CPB surgery but may be necessary to support extended use during ECMO therapy. As such, device change out instructions have been included to mitigate potential issues.

Additional risks are associated with the potential difference in environmental conditions during ECMO therapy as compared to CPB surgery. These conditions and potential risks include:

- Differences in ambient conditions (temperature, humidity, pressure) leading to potential parameter inaccuracy.
- Transportation of CDI Systems while they are in use, leading to:
    - Potential parameter inaccuracy or blood loss due to compromised disposable connection.
    - Loss of backup battery power due to extended time off AC power.
- CDI Systems may be subject to electromagnetic interference from non-CPB standard device interactions leading to potential parameter inaccuracy.
- Sporadic user interaction with device leading to missed alarms.

In order to ensure proper system performance, users should review existing Operator's Manual content related to the comparison of CDI System's displayed values to laboratory measurement or point of care blood gas analyzer (BGA), in vivo recalibration, battery backup, and alarm information.

It is recommended that only the single sterile cuvettes (models 6912, 6913, 6914) be utilized during ECMO cases. Refer to Appendix A for full list of applicable devices.

Signs Indicating a Device Change Out May Be Needed

General guidance for monitoring and maintaining CDI System parameter accuracy can be found in the Operator's Manual. In certain circumstances potentially related to use in ECMO therapy the user should monitor performance closely, including potentially increased frequency of laboratory/BGA measurement and in vivo recalibration. These circumstances may include:

- Extended duration of use (>six hours)
- Changes in environment, including temperature (patient or ambient)
- Addition of new equipment into the patient care environment
- Changes in the patient's blood or metabolic state
- Introduction of new medications

When the disposables have exceeded six hours of use, or comparisons with the laboratory/BGA measurement indicate the performance of the CDI System has been compromised, it is recommended to replace the disposables. Compromised accuracy performance may be indicated by parameter values changing while the patient is metabolically stable or changes in values in comparison to laboratory/BGA measurements.

Disposable Change Out Instructions

When the disposables have exceeded six hours of use, or signs indicate a device change out is needed, replace disposables using one of the following methods:

Option 1 - Replace the Shunt Sensor with a new, gas calibrated one.

1. End the current case
2. Disconnect the probes from the disposables replacing the probes on the CDI System monitor
3. Cycle power on the monitor
4. Perform full start up and calibration with a new Shunt Sensor (per the instructions in the Operator's Manual)
5. After calibration is completed, replace disposables in the ECMO circuit
6. Perform in vivo calibration once conditions have stabilized after replacing disposables

If logistics prevent the following of Option 1:

Option 2 - Replace disposables while leaving monitor in Operate mode.

1. For best performance, replace the Shunt Sensors (s) with sensor(s) from the same manufacturing lot
   Caution: Replacement with sensor(s) from a different manufacturing lot will likely result in more significantly affected parameter performance
2. Perform in vivo calibration once conditions have stabilized after replacing disposables

3. Increase the frequency of periodic in vivo recalibration and comparison to laboratory/BGA measurement until stability of reading is confirmed

Note: This specific set of instructions is not contained within the Operator's Manuals and has not been cleared by the FDA. However, disposable change out instructions represent a re-ordering of existing instructions and content contained within the current device labeling.

If you have questions, please contact:

Terumo Cardiovascular Customer Service at **800.521.2818.**
Customer Service Hours: Monday – Friday 8 a.m. – 6 p.m. ET

Terumo Cardiovascular Technical Support at **800.441.3220**
24-hour hot line

APPENDIX A

Applicable CDI Blood Parameter Monitoring Systems:

CDI 550
REF: 550AHCT, 550AVHCT

CDI 500
REF: 500A, 500AHCT, 500AV, 500AVHCT

Terumo CDI Shunt Sensor
REF: CDI510H

Terumo CDI H/S Cuvette
REF: 6914, 6913, 6912

Applicable CDI System Accessories:

Catalog Number	Description
540	Calibrator, for use with CDI Systems
CDI506	Gas A, calibration gas for use with the CDI Model 540 Calibrator
CDI507	Gas B, calibration gas for use with the CDI Model 540 Calibrator
7310	Printer paper for use with CDI Systems
CDI517	Monitor Pole Clamp, Long, Calibrator Mount, for use with CDI Systems Monitor (7”)
CDI518	Monitor Pole Clamp, Short, for use with CDI Systems Monitor (4.5”)
CDI519	Cable-head Bracket for use with CDI Systems