SUBJECT: Use of Camino ICP Monitor in Multiplace Hyperbaric Chamber

Issue Date: 3/5/2020



MEMO:

This MEMO is in reference to **Multiplace Hyperbaric Chambers only** who have the option of using the Camino ICP monitor <u>inside</u> their chamber.

This MEMO does not apply to Monoplace Hyperbaric Chambers.

This MEMO provides <u>recommendations only</u> for placing the Camino ICP monitor inside a multiplace hyperbaric chamber.

ICP monitoring is required for all HOBIT Trial subjects. Ventricular ICP monitoring with an EVD system is the preferred method. However, there are times when a ventriculostomy is not possible and an intraparenchymal ICP monitor is an acceptable alternative.

The Camino monitor is an intraparenchymal monitor that has two optional monitoring cables, i.e., the CAMCABL or the newer Flex Cable.

Duke University, in Durham North Carolina, has tested the Camino ICP monitor with both cables up to 3 ATA. During this testing the monitor operated without problems and pressure readings from both cable types were accurate throughout all atmospheric pressures.

<u>However</u>, there are safety issues and code requirements to consider when placing this monitor inside a multiplace chamber.

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PURPOSE

The purpose of this memo is to review any known safety issues and code requirements found in Chapter 14 of the NFPA-99, <u>2018</u> edition.

The cautions and recommendations in this memo are provided only to assist HOBIT sites in their own evaluation of how to safely place and use the Camino monitor inside their multiplace hyperbaric chamber. The list of cautions should not be considered complete. Each site is responsible for their own evaluation, safety guidelines, policies and procedures regarding the safe use of the Camino monitor inside their multiplace their multiplace hyperbaries.

DESCRIPTION OF CAMINO FEATURES RELATED TO HYPERBARIC USE:

The Camino monitor (Fig. 1) is an intraparenchymal monitor that has two optional monitoring cables, i.e., the CAMCABL (Fig. 7) or the newer Flex Cable (Fig.8). It provides continuous monitoring of intracranial pressure (ICP) and intracranial temperature (ICT). It is powered from an AC/DC power adapter (Fig. 5) <u>or</u> from a rechargeable 14.4 VDC lithium ion battery (Fig.4). It uses an LCD touch screen interface (Fig.1) for setting alarms parameters and evaluating patient data. Monitor weight is 11 pounds. Operational temperature range is 59 F – 104 F.

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CAUTION (1):

The specifications state that the monitor is "Not suitable for using in the presence of flammable anesthetics mixture with air, oxygen, or nitrous oxide." (User's Manual Page 93.)

RECOMMENDATION (1):

Multiplace chamber atmospheres are normally maintained, per NFPA-99, at oxygen concentrations of 23.5% or less. However, it is well known and documented (Ref. 2018 NFPA-99, A.14.2.10.4.2) that there can be isolated pockets of oxygen that can be well above 23.5% increasing the risk of fire. Because of this, we recommend that the Camino monitor be purged with air or with an inert gas such as nitrogen. This can be accomplished using a clear plastic bag filled with air or an inert gas and maintaining a slight pressure on the bag with a constant flow of gas of approximately 3-5 lpm. This will provide a separation from possible high oxygen concentrations and provide additional cooling for the unit.

<u>Guidelines for "Gas Purging</u>" can be found in the 2018 NFPA-99, Chapter 14.2.9.3.18 and in the 2018 NFPA-99 Annex-A (A.14.2.9.3.18) and Annex B (B.14.5). Annex-B provides a fuller explanation with detailed guidelines for gas purging in a multiplace chamber.

CAUTION (2):

NFPA-99 2018 Chapter 14.2.9.3.17.6 (3) addresses the use of "Cord-Connected Devices" and requirements for <u>power on/off switches</u>. It states: "The plug of cord-connected devices shall not be used to interrupt power to the device."

RECOMMENDATION (2):

Only use the monitor's built in power <u>On/Off</u> switch (fig. 1) to <u>Turn On</u> or interrupt the device. Ensure that the DC power connection (fig. 6) is locked or secured in place to prevent it from being inadvertently disconnected.

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CAUTION (3):

Use of the Camino AC/DC power adapter in the chamber.

RECOMMENDATION (3):

We are recommending that the Camino AC/DC power adapter (Fig. 5) be placed <u>outside</u> of the chamber with only the DC power line (Fig. 5) passing through the chamber hull to the inside and connecting to the Camino monitor (Fig. 6).

We <u>do not</u> recommend placing the power adapter <u>inside</u> the chamber. There are other cautions to consider when placing a power adapter inside the chamber.

CAUTION (4):

Electrical power rating. The 2018 NFPA-99, Chapter 14.2.9.3.17.6 (2) describes the use of "inert-gas" for purging cord-connected devices. Inert-gas purging is required when a devices electrical rating exceeds 120 V and 2 A. The Camino's electrical power rating does <u>not</u> exceed 120 V or 2 A so that inert-gas purging is not required.

RECOMMENDATION (4):

<u>Although inert-gas purging is not required for the electrical rating</u>, in reference to CAUTION (1), we are recommending that the Camino monitor be purged as described in RECOMMENDATION (1) with either air or an inert-gas.

<u>Guidelines for "Gas Purging</u>" can be found in the 2018 NFPA-99, Chapter 14.2.9.3.18 and in the 2018 NFPA-99 Annex-A (A.14.2.9.3.18) and Annex B (B.14.5). Annex-B provides a fuller explanation with detailed guidelines for gas purging in a multiplace chamber.

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CAUTION (5):

Internal cooling fan.

RECOMMENDATION (5):

Recommend using an air or inert-gas purge bag to isolate the unit from high oxygen concentrations and to increase cooling. See <u>Recommendations (1 & 4)</u>. Keep the device's vent openings unblocked (Fig. 2 & 3).

Please refer to the **CAMINO USER'S MANUAL** in reference to "<u>Responding to Monitor</u> <u>Overheating Alarm</u>" and "<u>Responding to Cooling Fan Failure Alarm</u>", Chapter 5 pages 53-54.

CAUTION (6):

The User's Manual states:

"Once the Integra Camino Fiber Optic Catheter has been zeroed to the Integra Camino ICP Monitor, do not transfer this zeroed catheter to any other monitor. Transferring a zeroed catheter to a different monitor may result in inaccurate ICP measurements."

"Once the Integra Camino Flex Catheter has been initialized (autozeroed) by the Integra Camino ICP Monitor, do not replace the Integra Camino Flex Extension Cable being used for patient measurement. Replacing the Flex Extension Cable with another cable after the Flex Catheter has already been initialized may result in inaccurate ICP measurements."

"Once the Integra Camino Flex Catheter has been initialized (i.e. autozeroed) by the Integra Camino ICP Monitor, do not transfer this initialized catheter to any other monitor. Transferring an initialized catheter to a different monitor may result in inaccurate ICP measurements."

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RECOMMENDATION (6):

The Camino monitor being used at the subject's ICU bedside should be the same monitor placed inside the multiplace hyperbaric chamber with the subject.

CAUTION (7):

- NFPA-99 14.2.9.3.17.5 gives code requirements for battery operated devices. The following is stated:
- "Batteries or battery-operated equipment shall not undergo charging while located in the chamber." Subsection (4).
- "Batteries shall not be changed on in-chamber equipment while the chamber is in use." Subsection (5).
- "The equipment electrical rating shall not exceed 12 V and 48 W." Subsection (6).

Battery charging and the electrical rating of the Camino battery both exceed these requirements.

RECOMMENDATION (7):

The Camino's 14.4 VDC lithium battery <u>does exceed</u> this code requirement. <u>Always</u> <u>remove the battery</u> (Fig. 4 & 11) from the Camino device and provide power to the Camino using the <u>manufacturer supplied AC/DC power adapter (Fig. 5)</u>. The Camino will operate with the battery removed. Do not operate the Camino Monitor on battery power.

Please refer to the User's Manual for instructions on battery removal and replacement.

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CAUTION (8):

The LCD touch screen (fig. 1) is backlit with LED's. The maximum LED backlight voltage is 34.2 V and the typical Wattage is 3.4 W.

NFPA-99 14.2.9.3.17.5 (6) states a limit for "<u>Battery-Operated Devices</u>" at 12 V for DC current and 48 W for total power.

NFPA-99 14.2.9.3.17.6, which applies to devices powered via a cord connected to an external power source, does not specify the same limits (12 V and 48 W).

RECOMMENDATION (8):

The Camino is <u>not</u> to be "Battery-Operated" during the HBO treatment. Although the LCD touch screen internal circuitry does exceed the NFPA code requirement of 12 VDC for <u>battery powered</u> devices, the total power of the LCD screen at 3.4 W is well below the total power requirement of 48 W. The use of an air or inert-gas purging system provides an additional layer of safety for using this device inside the chamber. Again, we recommend the use of an air or inert-gas purge bag as noted in RECOMMENDATIONS (1) and (4).



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CHECKLIST:

We strongly recommend putting items such as the Camino device on your <u>pre-dive</u> <u>checklist</u> with check-off points to ensure that each safety step is followed every time the device is placed inside your chamber.

TESTING:

Testing and preventative maintenance information can be found in Chapter 9 starting on page 75 of the USER MANUAL.

Please contact me with any questions or concerns.

Thank you,

Bill Gossett

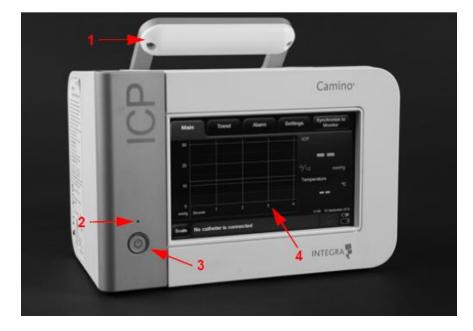
Principal Project Manager Director of Hyperbaric Operations - HOBIT Trial Direct: 612-873-3961 | Cell: 612-868-1254 <u>bill.gossett@hcmed.org</u> | <u>hcmc.org</u>



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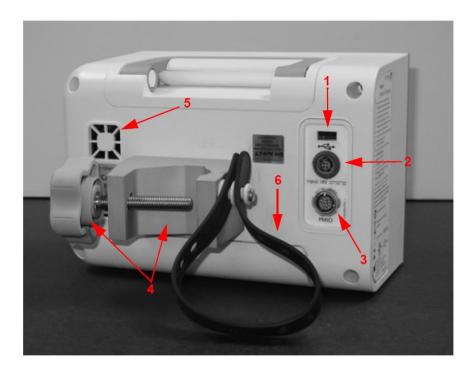
The front panel contains:

Number	ltem	Description
1	Handle	Handle used for carrying the monitor.
2	Power Status	Green LED button that indicates the monitor is being powered by the AC power adapter. Note that this button does not illuminate if the monitor is being powered by the battery.
3	Power Button	Turns the monitor on and off. This button is illuminated when the power is on.
4	Touch Screen	Provides software tools for viewing data and controlling parameters for monitoring the patient's ICP and ICT levels.

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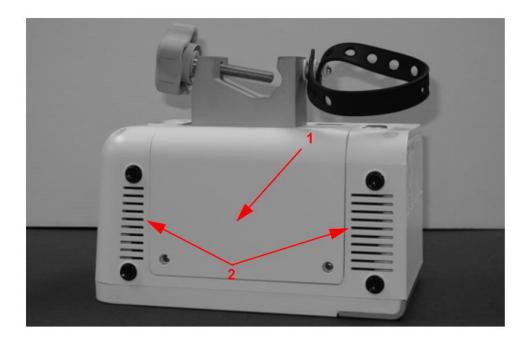
Backside View - Number Item Description

- 1. USB Port Connection port for extracting trend data via USB transfer or digital streaming.
- 2. AC Power Adapter Port Connection port for the AC power cord.
- 3. PMIO Port Connection port for PMIO cable. This cable is used to connect the Integra Camino ICP Monitor to a patient bedside monitor.
- 4. Pole Clamp Clamping system for securing monitor to an equipment pole.
- 5. Air Vent Grated opening that allows air being circulated by the internal cooling fan to leave the monitor.
- 6. Cable Strap Rubber strap used to secure AC power adapter during transport.

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Bottom Panel View

- 1. Battery Door Cover Removable cover for accessing/replacing the 14.4V lithium ion battery.
- 2. Air Vent Grated opening that allows air being circulated by the internal cooling fan to leave the monitor.

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14.4 VDC Lithium Ion Battery

Fig. 4



AC Power Adapter

18 VDC, 1.67 A, 30 W

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Fig. 5

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CAMCABL



Connector end of AC power adapter

Fig. 7

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Flex Cable





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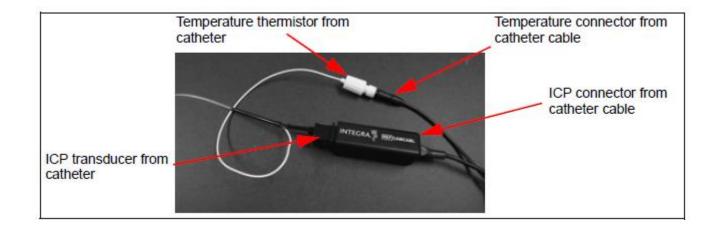




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Refer to the User's Manual for instructions on removing and installing the battery.



Fig. 11