MADM™

ANESTHESIA DELIVERY MODULE

OPERATOR'S MANUAL

Caution: Federal law restricts this device to sale by or on the order of a physician.

THORNHILL MEDICAL

Inspiring Innovation

Part Number: 124764 Rev. K

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1. Notices

Contact Information

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Patents Notice

MADM™ is covered by one or more US and international patents and patents pending.

Copyright and Trademark Notices

Technical Support

For technical support, please contact Thornhill Research Inc. directly.

MADM™ Intended Use

MADM™ is intended to deliver volatile anesthetic to a patient when placed in either circle or open anesthetic circuits. It vaporizes isoflurane and sevoflurane and delivers the vaporized anesthetic agent into the inspiratory limb of the breathing circuit.

MADM™ is also intended to monitor respiratory rate, CO_2, and the anesthetic gases isoflurane and sevoflurane. It is intended to be connected to a patient breathing circuit for monitoring of patients to whom it is delivering volatile anesthetic gases.

MADM™ is not indicated for use with a carrier gas containing nitrous oxide.

MADM™ Intended Environments

MADM™ is intended to be operated in hospitals. MADM™ is not intended to be used during patient transport.

MADM™ Intended Use Population

The intended patient population is adults who weigh 40 kg (88 lbs) or more.

Contraindications

MADM™ is subject to any contraindication to inhaled anesthetics.

MADM™ Intended Users

MADM™ is intended to be used by:

- Trained physicians
- Anesthesiologists

MADM™ Duration of Use

MADM™ is intended to be used for the duration of anesthetic delivery.

Restriction Notice

US Federal law restricts this device to sale by or on the order of a licensed medical practitioner.

Declaration of Conformity Notice

MADM™ is declared to conform to the Medical Device Directive of the European community (re: Medical Device Directive 93/42/EEC). This is indicated by the CE Mark shown below.

CE
2797

MADM™ also conforms to the following Technical Standards:

IEC 60601-1
IEC 60601-1-2
IEC 60601-1-8
ISO 80601-2-13
ISO 80601-2-55

For more information on these standards, see *Standards Compliance* on *page 41*.

Hazardous Materials Notice

MADM™ may contain phthalates. Any device or article displaying this symbol contains the phthalate di (2-ethylhexyl) phthalate (DEHP). Phthalates are classified as carcinogenic, mutagenic or toxic to reproduction.

In addition, patient-applied breathing tubes, face masks, etc., that are used with MADM™ (but which are not shipped with the device nor supplied by Thornhill Research Inc.) may also contain the phthalate DEHP or be made from plastic PVC which produces dioxin, a known carcinogen when incinerated. In order to reduce the potential risk from phthalates, long term exposure should be avoided in the treatment of children and pregnant or nursing women.

In addition, latex may be present in some products, or they may be composed of latex. It has been found that latex can cause allergic reaction.

MADM™ users are advised to be aware of these issues and avoid using accessories that contain hazardous materials. All accessories containing hazardous materials are required to be labeled as such.

Disposal Instructions

MADM™ and its components are not suitable for regular trash disposal. Follow local guidelines for proper disposal of medical devices.

Any accumulated fluids should be disposed of as biological waste according to local guidelines.

Calibration gas and exhausted anesthetic should be scavenged with an anesthetic scavenger compliant with IEC 60601-2-13.

Serious Incident Reporting Notice

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

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2. Classification, Symbols, Cautions and Warnings

MADM™ is classified as portable, internally powered (battery mode), Class I ME Equipment (via PSU).

MADM™ is a medical device intended for use only by or under the order of a physician.

Personnel operating this equipment are responsible for reading and thoroughly understanding all product documentation provided. Service of this instrument is restricted to trained personnel only.

Statements throughout the product documentation have special significance as explained in the following table.

Icon & Type	Explanation
 ***NOTE:***	*Notes are used to call attention to statements pertaining to more efficient or convenient operation or service of the equipment.*
 **CAUTION!**	**A CAUTION INDICATES THAT THERE IS A POSSIBILITY OF DAMAGE TO THE PRODUCT OR OTHER EQUIPMENT ATTACHED TO IT.**
 **WARNING!**	**A WARNING MEANS THAT THERE IS A POSSIBILITY OF PERSONAL INJURY TO THE OPERATOR OR PATIENT.**

Table 1: Manual Icons

Product Labels Symbols

SYMBOL	DESCRIPTION
	Caution. Read accompanying documentation.
	Follow instructions for use.
	Do not reuse (single use only).
	No latex used in the manufacture of this product.
	Defibrillation-proof Type BF applied part

SYMBOL	DESCRIPTION
CE 2797	**"Conformité Européen" Mark** – The CE mark indicates that a notified body has conducted a conformity assessment on the product under the relevant EU directives.
EC REP	Authorized Representative in the European Community
C US 244588	Canadian Standards Association (CSA) certification mark. Indicates product has been tested under a formal process and that it meets the safety and/or performance requirements of applicable standards.
Rx ONLY	Device restricted to sale by or on the order of a licensed medical practitioner.
PHT DEHP	Device may contain the phthalate di (2-ethylhexyl) phthalate (DEHP).
IPX1	Degree of ingress protection
	Manufacturer
	Date of manufacture
REF	Reference or Model Number
SN	Serial Number
NON STERILE	Non sterile; material cannot be guaranteed to be free of contamination.

Table 2: Product Label Symbols and Descriptions

Warnings

	**WARNING! IN CASE OF ANESTHETIC WORKSTATION FAILURE, THE LACK OF IMMEDIATE ACCESS TO APPROPRIATE ALTERNATIVE MEANS OF VENTILATION CAN RESULT IN PATIENT INJURY.**
	**WARNING! TO AVOID RISK OF ELECTRIC SHOCK, MADM™ MUST ONLY BE CONNECTED TO A SUPPLY MAINS WITH PROTECTIVE EARTH.**
	**WARNING! MADM™ SHOULD NOT BE POSITIONED SO AS TO MAKE IT DIFFICULT TO DISCONNECT IT FROM THE POWER SUPPLY.**
	**WARNING! A BIOPHYSICAL MONITORING DEVICE SHOULD ALWAYS BE USED TO MEASURE AND MONITOR A PATIENT'S VITAL SIGNS WHEN USING THE MADM™ SYSTEM.**
	**WARNING! REUSE OF ANY SINGLE-USE COMPONENT MAY INTRODUCE A RISK OF CROSS-INFECTION AND ADVERSELY AFFECT DEVICE PERFORMANCE.**
	**WARNING! THE OPERATOR SHOULD DISCONNECT THE ANESTHETIC DELIVERY SYSTEM FROM THE PATIENT BREATHING CIRCUIT IF THE MINUTE VENTILATION IS SIGNIFICANTLY DIFFERENT THAN EXPECTED.**
	**WARNING! THE MADM™ SYSTEM SHOULD NOT BE USED IF THERE IS SIGNIFICANT DISCREPANCY BETWEEN THE ANESTHETIC DIAL SETTING AND THE DISPLAY OF THAT ANESTHETIC CONCENTRATION ON THE GUI SCREEN.**
	**WARNING! SKIPPING THE MADM™ STARTUP SELF-CHECK RUNS THE RISK OF OVER OR UNDER DELIVERING ANESTHETIC.**
	**WARNING! ALWAYS HAVE A BACKUP METHOD OF DELIVERING ANESTHETIC TO THE PATIENT AVAILABLE IN CASE OF DEVICE FAILURE.**
	**WARNING! REFER TO AND FOLLOW ALL WARNINGS AND CAUTIONS ON THE LABELING OF THE INTENDED VOLATILE AGENT.**
	**WARNING! MADM™ DELIVERS INHALATIONAL ANESTHETICS INCLUDING ISOFLURANE AND SEVOFLURANE WHICH CAN BE LEAKED INTO THE OPERATING ROOM ENVIRONMENT DURING PATIENT CIRCUIT DISCONNECTIONS OR OTHER EVENTS. TO MINIMIZE POTENTIAL UNINTENTIONAL EXPOSURE, ANESTHETIC SHOULD ONLY BE DELIVERED IN A WELL VENTILATED AREA.**
	**WARNING! MADM™ IS NOT INTENDED TO BE USED IN THE PRESENCE OF FLAMMABLE ANESTHETICS.**
	**WARNING! NO MODIFICATION OF THE EQUIPMENT IS ALLOWED.**
	**WARNING! SOUND PRESSURE LEVELS OF AUDITORY ALARM SIGNAL THAT ARE LESS THAN AMBIENT LEVELS CAN IMPEDE OPERATOR RECOGNITION OF ALARM CONDITIONS.**
	**WARNING! IF THE PATIENT INFORMATION DISPLAY AREA INDICATES THAT A SENSOR OR SENSORS ARE OUT OF CALIBRATION, DO NOT ADJUST THE ANESTHETIC DIAL SETTING IN AN ATTEMPT TO COMPENSATE.**

	**WARNING! MADM™CONTAINS NO USER SERVICEABLE PARTS. DISSASSEMBLY OR SERVICING BY AN UNQUALIFIED PERSON WILL VOID THE WARRANTY AND MAY CAUSE THE DEVICE TO MALFUNCTION AND SERIOUSLY HARM THE PATIENT OR OPERATOR.**
	**WARNING! USE OF ACCESSORIES NOT SUPPLIED WITH MADM™, OR NOT SPECIFICALLY LISTED IN THIS DOCUMENT, MAY ADVERSELY AFFECT DEVICE PERFORMANCE AND HARM THE PATIENT OR OPERATOR.**
	**WARNING! OPERATION OF MADM™ OUTSIDE SPECIFIED TEMPERATURE RANGE MAY RESULT IN UNDERDELIVERY OF ANESTHETIC TO THE PATIENT.**
	**WARNING! DO NOT USE OR CHARGE A DAMAGED BATTERY.**
	**WARNING! MADM™ IS NOT INDICATED FOR USE WITH A CARRIER GAS CONTAINING NITROUS OXIDE.**
	**WARNING! ALTHOUGH MADM CONTINUES TO DELIVER ANESTHETIC DURING A SCREEN FAILURE, THE OPERATOR SHOULD SWITCH TO AN ALTERNATIVE MEANS OF ANESTHETIZING THE PATIENT AS SOON AS POSSIBLE.**
	**WARNING! DO NOT ADJUST THE MADM™ CONTROL DIAL BASED ON DISPLAYED INSPIRED OR END TIDAL VALUES.**
	**WARNING! REMOVAL OF THE PATIENT OR INLET SENSOR FROM THE CIRCUIT TO REPLACE THE ADAPTER WILL RESULT IN MADM™ DISCONTINUING THE DELIVERY OF ANESTHETIC. THIS SHOULD ONLY BE DONE AT THE POINT IN THE OPERATION WHERE ANESTHETIC DELIVERY CAN BE DISCONTINUED FOR 30 SECONDS OR MORE.**
	**WARNING! DO NOT SET THE TARGET ANESTHETIC CONCENTRATION ABOVE WHAT IS DESIRED FOR AN INSPIRATORY CONCENTRATION AT THAT TIME. THE TARGET CONCENTRATION SHOULD BE ADJUSTED PERIODICALLY TO REFLECT THE DIFFERENT STAGES OF SURGICAL STIMULATION.**
	**WARNING! DO NOT USE THE MADM™ WITH METERED DOSE INHALERS OR NEBULIZED MEDICATIONS AS THIS MAY AFFECT THE LIGHT TRANSMISSION OF THE AIRWAY ADAPTOR WINDOWS AND THE PERFORMANCE OF THE ANESTHETIC GAS SENSORS.**

Cautions

	**CAUTION! US FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A LICENSED MEDICAL PRACTITIONER.**
	**CAUTION! CONNECT ONLY THE RECOMMENDED ANESTHESIA AND CO_2 MONITORING SENSOR TO THE ANESTHESIA AND CO_2 MONITORING SENSOR PORT.**
	**CAUTION! USE ONLY THE POWER SUPPLY AND BATTERY BASE SUPPLIED WITH THE SYSTEM AND LABELED FOR USE WITH MADM™.**
	**CAUTION! DURING DISCONNECTION OF THE MALE ADAPTER FROM THE CANISTER, AND THE BOTTLE ADAPTER FROM THE BOTTLE, SMALL AMOUNTS OF ANESTHETIC AGENT WILL ESCAPE INTO THE ENVIRONMENT.**

	**CAUTION! OPERATION OF MADM™ OUTSIDE OF SPECIFIED LIMITS MAY CAUSE INACCURATE DELIVERY.**
	**CAUTION! MADM™ IS TO BE USED ONLY WITH AN ANESTHETIC GAS SCAVENGING TRANSFER AND RECEIVING SYSTEM THAT COMPLIES WITH ISO/IEC 80601-2-13.**
	**CAUTION! MADM™ IS TO BE USED ONLY WITH ANESTHETIC BREATHING CIRCUITS THAT COMPLY WITH ISO/IEC 80601-2-13.**
	**CAUTION! MADM™ IS TO BE USED ONLY WITH ANESTHETIC WORKSTATIONS OR COMPONENTS THEREOF THAT COMPLY WITH ISO/IEC 80601-2-13.**
	**CAUTION! MADM™ IS NOT MRI COMPATIBLE, AND USE NEAR STRONG MAGNETIC FIELDS MAY INTRODUCE A SIGNIFICANT HAZARD.**
	**CAUTION! MADM™ IS TO BE USED ONLY WITH ANESTHETIC VENTILATORS THAT COMPLY WITH ISO/IEC 80601-2-13.**
	**CAUTION! REUSE OF SINGLE-USE COMPONENTS INCLUDING BOTH THE INLET SENSOR AND AIRWAY ADAPTERS MAY RESULT IN INACCURATE ANESTHETIC DELIVERY OR FAILURE TO DETECT DANGEROUS ANESTHETIC DELIVERY LEVELS.**

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3. Acronyms / Abbreviations

Acronym / Abbreviation	Term
BPM or B/M	Breaths Per Minute
FCA	Fractional Concentration in Circuit of Anesthetic
FETA	Fractional End Tidal Anesthetic
FIA	Fractional Inspiratory Anesthetic
g & kg	Gram & Kilogram
GUI	Graphical User Interface
ISO	Isoflurane
L, mL & µL	Liter, Milliliter & Microliter
lb	Pound
LCD	Liquid Crystal Display
LED	Light Emitting Diode
LPM	Liters Per Minute
MAC	Minimum Alveolar Concentration
MADM™	Mobile Anesthetic Delivery Module
min	Minute
mmHg	Millimeters of Mercury
PET CO2	Partial Pressure End Tidal of CO2
PI CO2	Partial Pressure Inspired of CO2
RR	Respiratory Rate
s & ms	Second & Millisecond
SEVO	Sevoflurane
VE	Minute Ventilation

Table 3: Acronyms and Abbreviations

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4. The MADM™ System

System Description

The MADM™ system consists of a *Control and Display Unit*, an *Anesthesia and CO_2 Monitoring Sensor*, and a *Medical Grade Power Supply*.

Control and Display Unit

The *Control and Display Unit* consists of a user interface, an information display screen, an anesthetic reservoir, a precision pump and heater, and flow and gas sensors.

Anesthesia and CO_2 Monitoring Sensor

The *Anesthesia and CO_2 Monitoring Sensor* is located on the inspiratory tube near the patient's mouth. It measures the content of the patient's inhaled and exhaled gas in order to allow it to be displayed on the screen. The anesthesia and CO_2 monitoring sensor is connected to the side of MADM™.

Medical Grade Power Supply

A single medical-grade power supply (Elpac Power System™, model # MWA065024A) powers the system.

CAUTION! CONNECT ONLY THE RECOMMENDED ANESTHESIA AND CO_2 MONITORING SENSOR TO THE ANESTHESIA AND CO_2 MONITORING SENSOR PORT.

Standard System Contents

The MADM™ system is ordered as PN 124198 and is provided with the following standard system contents.

RE-ORDER P/N	DESCRIPTION	QUANTITY
N/A	MADM™ Control and Display Unit	1
127503	Anesthetic Canister – Sevoflurane	1
127502	Anesthetic Canister – Isoflurane	1
127507	Sevoflurane Refilling Adapter	1
127506	Isoflurane Refilling Adapter	1
129440	Abbvie Sevoflurane Filler Adapter	1
127508	Tubing, 22mm x 36"	1
125913	Patient (Mouth) Anesthesia and CO_2 Monitoring Sensor	1
127509	Airway Adapter (for anesthetic gas sensors)	2
127505	Power Supply	1
127504	Hospital Grade Power Cable	1
124764	Operator's Manual	1
127462	Transport Case with Foam	1
127706	Mounting Bracket and Clamp	1 bracket, 1 clamp

Table 4: MADM™ Standard System Components

Device Description

The main components of MADM™ are shown below. The *Anesthesia and CO_2 Monitoring Sensor* and the *Power Supply* are considered accessories to the *Control and Display Unit.*

Control and Display Unit

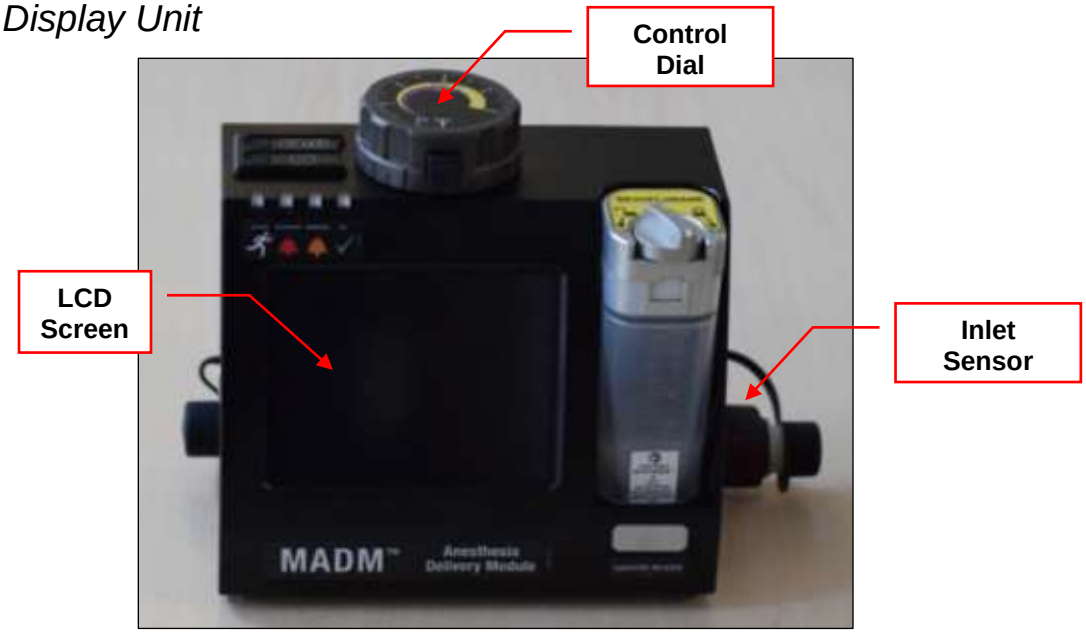


Figure 1: MADM™ Control and Display Unit

The *Control and Display Unit* is operated by turning the control dial *counter-clockwise* until the desired concentration of inspired anesthetic is reached. The button on the dial must be pressed in and held before the dial will move from a parked/stopped position. The same procedure must be followed when putting the dial into the parked/stopped position.

INLET SENSOR

The *Inlet Sensor* is used to measure the composition of all inflow gases to MADM™. The *Inlet Sensor* is automatically compensated for changes in barometric pressure within its specified operating altitude range (see page 41).

***NOTE**: If the error message "Inlet Sensor: Unspec Acc" (Unspecified Accuracy) is displayed, the minute ventilation (VE) may not be within stated accuracy specifications.*

LCD Screen

Information from several categories is displayed in various areas of the LCD screen. For more information, see the section *User Interface Controls and Functions* beginning on *page 24*.

Anesthesia and CO_2 Monitoring Sensor

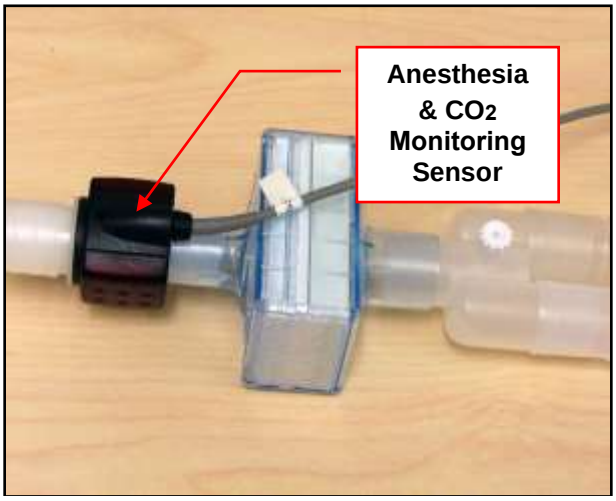


Figure 2: Anesthesia and CO_2 Monitoring Sensor

The *Anesthesia and CO_2 Monitoring Sensor* (a.k.a. *Patient Sensor*) is attached to the patient filter which is connected ahead of the patient circuit at the Y-piece. The sensor is used to measure inspiratory and expiratory anesthetic and carbon dioxide concentrations. These values are displayed on the LCD screen on the front of the MADM™ *Control and Display Unit*.

In addition, the screen shows the precise target inspired concentration, battery level, and details of any alarm/warning conditions. Also displayed are respiratory rate and minute ventilation. The *Anesthesia and CO_2 Monitoring Sensor* is automatically compensated for changes in barometric pressure within its specified operating altitude range (see page 41).

***NOTE**: If the error message "Patient Sensor: Unspec Acc" (Unspecified Accuracy) is displayed, the following readings may not be within stated accuracy specifications: FIA and FETA ISO, FIA and FETA SEVO, $PICO_2$ and $PETCO_2$.*

Power Supply

The Elpac Power System™ (model # MWA065024A), a single medical-grade power supply, powers the system.

WARNING! MADM™ SHOULD NOT BE POSITIONED SO AS TO MAKE IT DIFFICULT TO DISCONNECT IT FROM THE POWER SUPPLY.

The system also contains an embedded battery to provide uninterrupted function in the event of a temporary power loss. It is recommended that the battery be used only in this situation. MADM™ can run on battery power for a minimum of 30 minutes at ambient temperature (18°C to 25°C or 65°F to 77°F).

A separate battery base is optionally provided which includes a hot-swappable battery capable of powering MADM™ for at least 2 hours of normal use. For more information see, *The MADM™ Battery Base and Battery* beginning on *page 49.*

Functional Description

MADM™ measures the flow and anesthetic concentration of the gas entering the system on the inspiratory limb of the ventilator circuit via its internal flow sensor and inlet gas sensor and adjusts its internal liquid anesthetic delivery pump to control the anesthetic vaporization rate and consequently the concentration of anesthetic in the gas exiting the system and delivered for patient inhalation.

Precautions

Do not set the target anesthetic concentration above what is desired for an inspiratory concentration AT THAT TIME. The target concentration should be adjusted periodically to reflect the different stages of surgical stimulation.

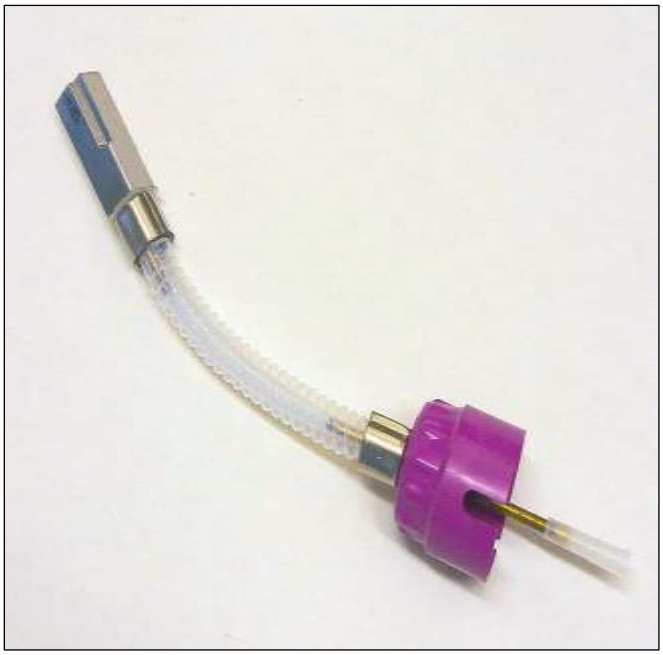
Unlike a traditional vaporizer, when adjustments to the MADM™ vaporizer are made, concentrations change very quickly and do not require over-pressuring to wash out the circuit. As a result, the dial on the MADM™ only needs to be set to the target inspired anesthetic concentration.

MADM™ Accessories

The following table lists the accessories used with the MADM™ unit.

PICTURE	RE-ORDER P/N	DESCRIPTION
	127503	Anesthetic Canister – Sevoflurane **Manufacturer:** Thornhill Research Inc.
	127502	Anesthetic Canister – Isoflurane **Manufacturer:** Thornhill Research Inc.

PICTURE	RE-ORDER P/N	DESCRIPTION
	127507	Sevoflurane Refilling Adapter **Manufacturer:** VAPOFIL (PN 8907-S)
	129440	AbbVie Sevoflurane Filler Adapter **Manufacturer:** Thornhill Research Inc.

PICTURE	RE-ORDER P/N	DESCRIPTION
	127506	Isoflurane Refilling Adapter **Manufacturer:** VAPOFIL (PN 8907-F)
	127508	Tubing, 22mm x 36" (Package of 10) **Manufacturer:** GlobalMed Inc. (PN C22B036IN8837G)

PICTURE	RE-ORDER P/N	DESCRIPTION
	125913	Anesthesia and CO_2 Monitoring Sensor **Manufacturer:** Masimo Corporation (PN 200601)
	127509	Airway Adapter (for anesthetic gas sensors) (Package of 10) **Manufacturer:** Masimo Corporation (PN 106220)

PICTURE	RE-ORDER P/N	DESCRIPTION
	127505	Power Supply **Manufacturer:** Elpac Power Systems (PN MWA065024A)
	127504	Hospital Grade Power Cable **Manufacturer:** Qualtek (PN 233009-06)
	124764	Operator's Manual **Manufacturer:** Thornhill Research Inc.

PICTURE	RE-ORDER P/N	DESCRIPTION
	127462	Transport Case with Foam **Manufacturer:** Thornhill Research Inc.
	127705	External Battery Charger/Base (Optional Accessory) **Manufacturer:** Thornhill Research Inc. **Note:** No longer available for purchase. See MADM™ Product Catalogue for full ordering information.
	127704	External Battery (Optional Accessory) **Manufacturer:** Bren-Tronics (PN BT-70757BV)

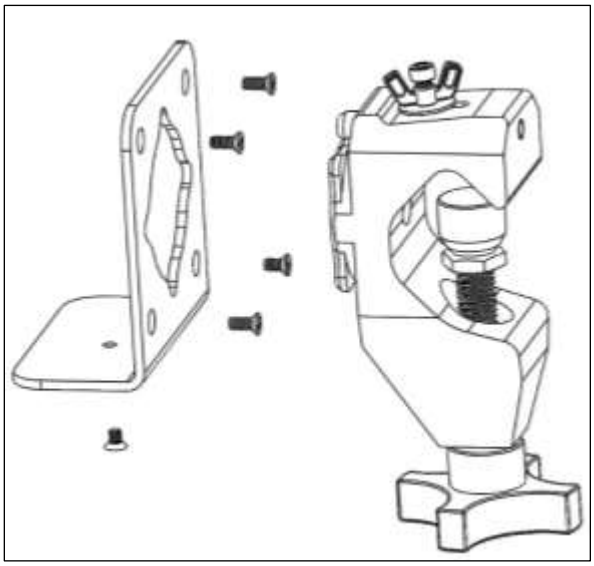
PICTURE	RE-ORDER P/N	DESCRIPTION
	127706	Clamp (Contains Mounting Bracket, Clamp and Hardware) **Manufacturer:** Thornhill Research Inc.
	127847	Waste Gas Tubing, 30mm x 30ft (with 22mm Adapter) **Manufacturer:** Thornhill Research Inc.

Table 5: MADM™ Accessories

Transporting MADM™

Observe the following when transporting MADM™:

1. All tubing should be detached from MADM™.
2. Anesthetic canisters should be ejected and drained.
3. Any other removable components should be detached.
4. MADM™ should be securely packed in its transport case.

5. User Interface Controls and Functions

Startup Screen

When MADM™ is first started, the *Startup* screen is presented. Initially it is shown in warm-up mode. The Patient (Mouth) Anesthesia and CO_2 Monitoring Sensor must be connected, and the Control Dial must be in the off position. The warm-up process can take up to two minutes. After warm-up is complete, a Self-Check of the system's Algorithm and Safety processors can be completed.

Figure 3: Startup Screen – Warm-up Mode

NOTE: *To skip the Self-Check and use previously stored zero points, press the [X] key on the top left of MADM™.*

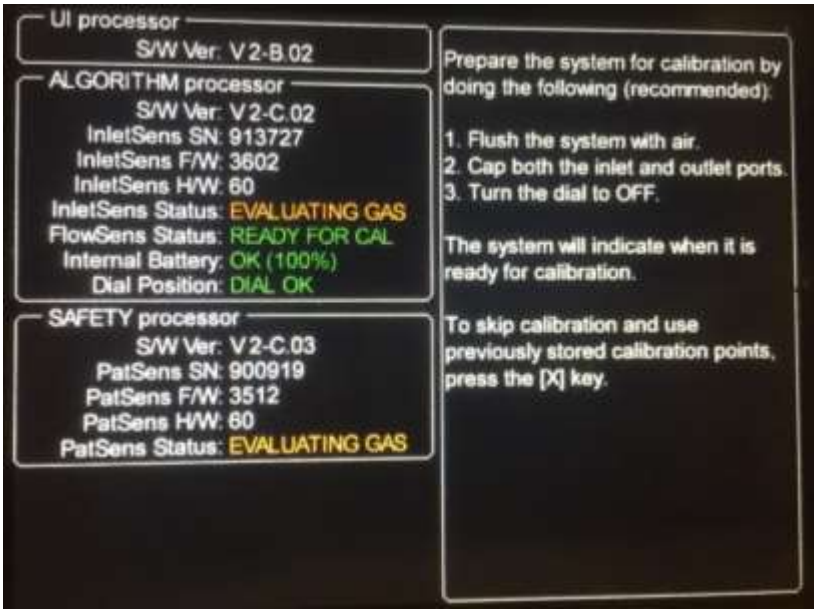


Figure 4: Startup Screen - Preparing for Self-Check

Once warm-up is complete, the *Startup* screen will be presented as shown below and the Self-Check can be completed.

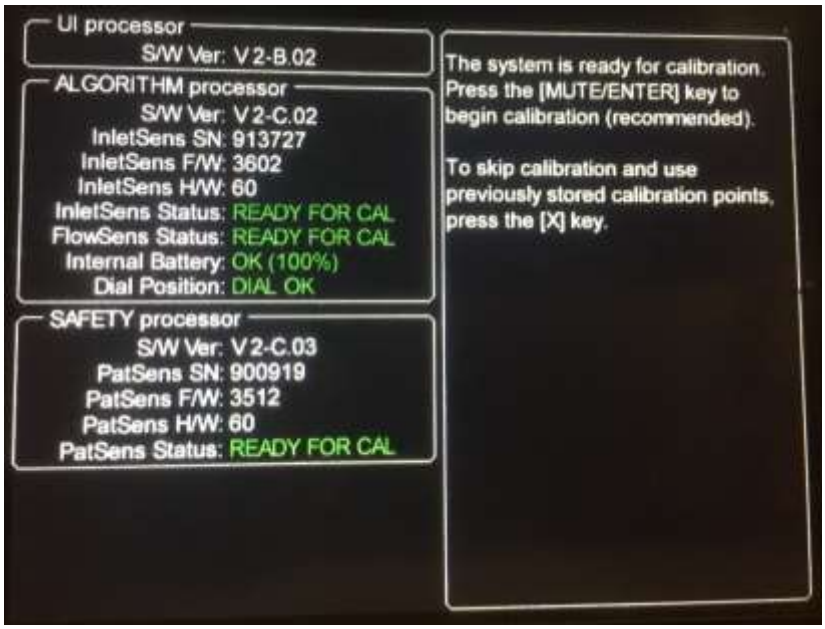


Figure 5: Startup Screen – Ready for Self-Check

This *Startup* screen indicates the status of the device's three internal processors. The user need only be concerned with two of these processors, the *Algorithm* processor and the *Safety* processor, which are used for the Self-Check. The *Algorithm* processor zeroes two internal sensors, one for concentration of anesthetic (isoflurane and sevoflurane) and the other for amount of flow. The *Safety* processor zeroes the sensor at the patient's mouth, which measures concentration of both anesthetic and CO_2.

As directed by the screen, before performing the Self-Check the user should flush all traces of anesthetic from MADM™ with fresh gas if it has been used recently and cap the inlet and outlet ports to zero the flow.

***NOTE*:** *Flushing of MADM™ should be done with air.*

***NOTE*:** *If the MADM™ continually states "EVALUATING GAS" on the Startup screen for the InletSens Status, flush the system by running fresh air through it. If the MADM™ continually states "EVALUATING GAS" on the Startup screen for the PatSens Status, flush the patient sensor by running fresh air through it. The MADM™ can also be power cycled in this situation.*

***NOTE*:** *If the MADM™ continually states "FLOW DETECTED" on the Startup screen for the FlowSens Status, ensure that the inlet and outlet ports are occluded with their protective caps. The MADM™ can also be power cycled in this situation.*

To complete the Self-Check (zeroing of the sensors), press the [MUTE/ENTER] key (the key on top of the device and closest to the back, or farthest from the user, when the user is facing the device). This key is used both to initiate the Self-Check of the sensors and mute the alarms.

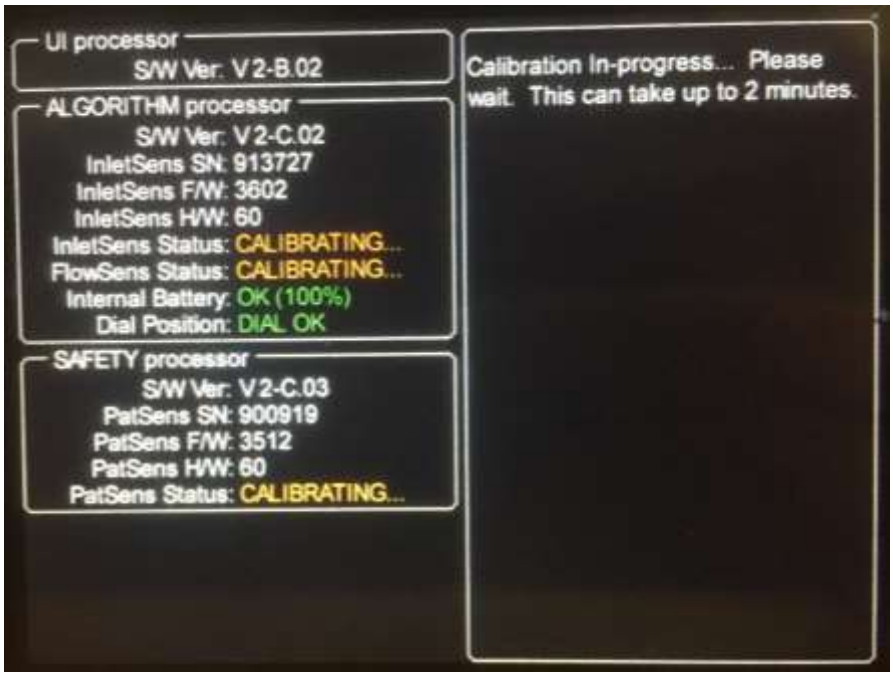


Figure 6: Startup Screen – Calibrating

NOTE: *To skip the Self-Check and use previously stored zero points, press the [X] key on the top left of MADM™.*

WARNING! SKIPPING A MADM™ SELF-CHECK RUNS THE RISK OF OVER OR UNDER DELIVERING ANESTHETIC.

Once the Self-Check is complete, the *Startup* screen acknowledges the fact (see screen following) and proceeds automatically to the *Patient Weight-Entry* screen where the patient's weight is confirmed prior to anesthetic delivery.

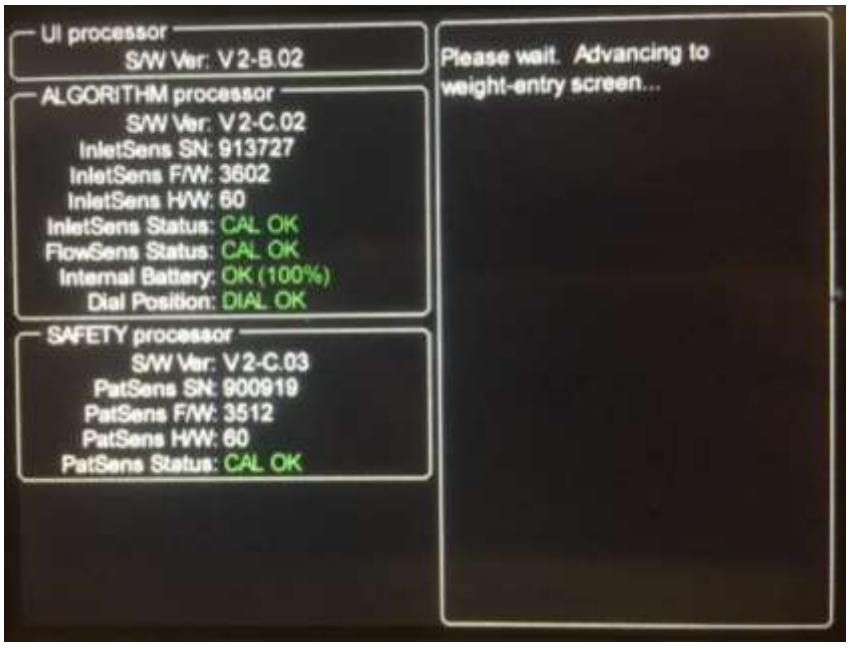


Figure 7: Startup Screen – Finished Self-Check

Patient Weight-Entry Screen

After the Self-Check is complete (or skipped), the *Patient Weight-Entry* screen is presented.

Figure 8: Patient Weight-Entry Screen

Push in the large square button on the dial on top of MADM™ and turn the dial to select one of two weight ranges, either 40-60 kg (88-132 lbs) or > 60 kg (> 132 lbs).

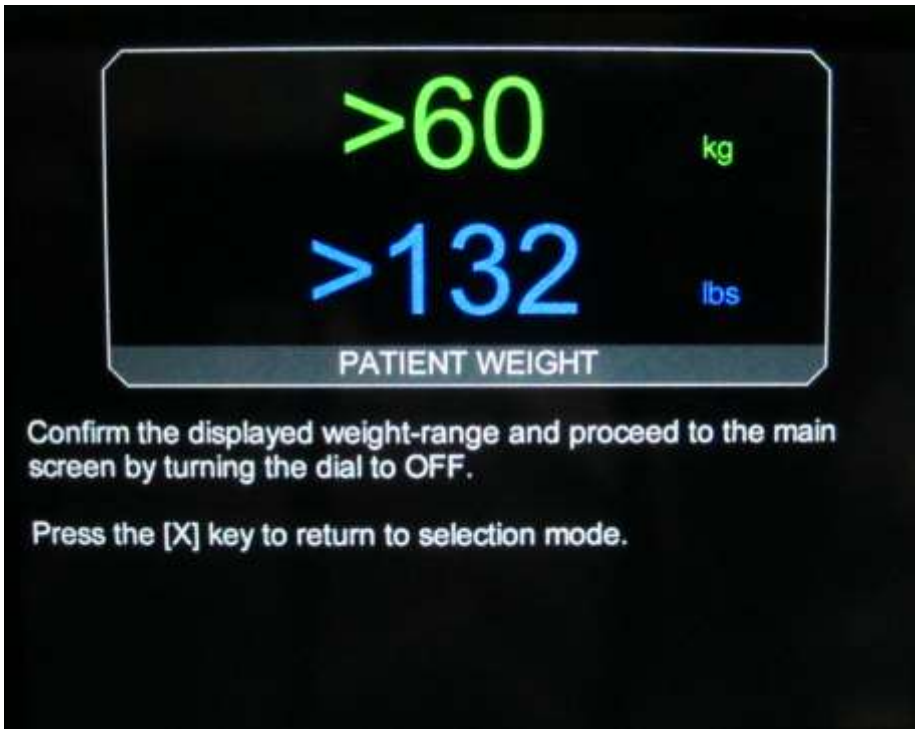


Figure 9: Patient Weight-Entry Screen Showing Values

Once a weight-range is selected, the user needs to confirm it. To do this, press the [Mute/Enter] key, then return the dial to the OFF position, again pushing in the large square button.

NOTE: *For full details on using the Patient Weight-Entry screen, see Setting the Patient Weight Value on page 72.*

NOTE: *Once the patient weight has been confirmed on the Patient Weight-Entry screen, it cannot be changed. If the incorrect weight is selected on the Patient Weight-Entry screen, the MADM™ must be powered off and then on again to re-initialize the device.*

At this point, the *Patient Weight-Entry* screen briefly indicates the selection has been confirmed and automatically proceeds to the Main or Information screen.

Figure 10: Patient Weight-Entry Screen Showing Values

Information Screen

Once the patient weight has been entered and committed, the *Main* or *Information* screen is presented.

Figure 11: Information Screen – Showing Five Errors

NOTE: *Red circles shown on the screen above are for identification purposes in this manual only and DO NOT appear on the* MADM™ *screen.*

In the screen above five errors are shown, listed in order of severity, in the top right quadrant:

- A HIGH priority alarm ("Canister Not Detected") is shown at the top of the list indicating that a canister is not present in MADM™. The 3 beside it is location specific and is also shown (circled in red) beside the empty canister icon with a question mark to indicate the location of the error.
- Secondly, a MEDIUM priority alarm ("Patient Sensor: Circuit Disconnect") is shown. The 4 is again location specific and is shown (circled in red) beside the head representation to indicate the location of the error.
- The third, LOW priority error ("Operating On Internal Power"), generates a LOW priority alarm. The 2 is location specific and is shown (circled in red) at the top left of the screen where the power status is displayed.
- The fourth error ("Patient Sensor: Cal Skipped") is another LOW alarm. The 5 is location specific and placed at the patient sensor (circled in red) on the onscreen diagram.
- The fifth error, Inlet/Flow Sensors: Cal Skipped is another LOW alarm. The 7 is location specific and placed at the inlet port of MADM™ (circled in red) on the onscreen diagram.

NOTE: *If additional errors are detected, the screen will be updated to show the additional errors and alarms and to identify the locations of the errors (see Table 6: Location of Alarm Descriptors for more information on locations).*

NOTE: *If multiple errors occur in the same location, only the color and symbol representing the highest priority alarm will be shown in the location.*

Location of Alarm Descriptors

Descriptor Number	Location
1	Battery
2	External DC Power
3	Anesthetic Canister
4	Patient
5	Patient Sensor
6	MADM™ Unit
7	Inlet Sensor
8	Ventilator/Breathing Circuit
9	FIA ISO
10	FIA SEVO
11	FETA ISO
12	FETA SEVO
13	FETA MAC
14	FIA Set

Table 6: Location of Alarm Descriptors

Information Screen Icons

The following table explains the icons and text shown (or that could be shown) from the top left to the middle of the Info screen.

Icon /Text	Explanation
	Battery Level Status
	Power Status – Wall power is connected to the Elpac Power System™ and power system is supplying DC power to MADM™.
	Power Status – Wall power is disconnected (Error). MADM™ is operating on internal power.
	Anesthetic Canister Level (SEVO)
	Anesthetic Canister Level (ISO)

Icon /Text	Explanation
	Type of Anesthetic (yellow and SEVO = sevoflurane; purple and ISO = isoflurane)
	Alarm Status The icon at left indicates that the audio of all alarms has been *temporarily* muted (dashed X) for a period of two (2) minutes.

Table 7: Info Screen Icons – Top Left

NOTE: *Alarms are muted by pressing the [MUTE/ENTER] key (the key on top of the device and closest to the back, or farthest from the user when facing the device). One press will mute the alarm(s) for two minutes (and display a dashed X through the bell).*

NOTE: *The exception to the above is the Purge Limit Exceeded Fault alarm, which is reset by turning the device OFF and then ON again.*

Device Status Area

The area in the top right quadrant of the screen provides information about the status of MADM™.

Figure 12: Device Status Area

In the Figure above, MADM™ is showing four alarms / errors (and that no anesthetic is being delivered).These are accompanied by numbers that indicate what area of the system is experiencing the problem and which correspond to picture areas on the screen where the numbers are replicated.

The four alarms / errors are also color- and symbol-coded to indicate the severity of the alarm / error. The following table explains the alarm color and symbol coding.

Symbol	Description	Alarm Level
	Red Circle	High
	Solid Amber Square	Medium
	Empty Amber Square	Low

Table 8: Alarm Symbols & Color Coding

Other messages that could be displayed in the same place are shown in the following table.

Message	Explanation
<not available>	Indeterminate state. Communication has been lost with Algorithm processor.
Stopped	MADM™ is ready to be used.
Stopping	MADM™ is preparing to stop.
Priming	Anesthetic is being introduced into the system to be supplied to the patient.
Standby	The system has been supplied with anesthetic and is ready to begin delivering it to the patient.

Message	Explanation
Delivering	MADM™ is supplying anesthetic to the patient. The pumps delivering air and anesthetic are ON. If isoflurane is being delivered, the heater used to evaporate the anesthetic is targeted to 65°C. If sevoflurane is being delivered, the heater used to evaporate the anesthetic is targeted to 75°C. (***NOTE:*** *A counter showing minutes and seconds is also displayed beneath this message.*)
Purging	The system is purging itself. When the anesthetic type is being changed (from ISO to SEVO, or vice versa), the system automatically purges any remaining liquid anesthetic from its internal vaporization pathway.
Error	MADM™ is in a high priority alarm state and no anesthetic is being delivered to the patient.

Table 9: Device Status Messages

Patient Information Display Area

The remainder of the screen is primarily given over to the display of patient information taken from the patient sensor near the patient's mouth.

Figure 13: Patient Information Display Area – System Delivering

WARNING! IF THE PATIENT INFORMATION DISPLAY AREA INDICATES THAT A SENSOR OR SENSORS ARE OUT OF CALIBRATION, DO NOT ADJUST THE ANESTHETIC DIAL SETTING.

The following table explains the various display areas.

Display Area	Info Displayed
FIA SET	**Fractional Inspiratory Anesthetic Setting** – The concentration of anesthetic that the user is setting to be delivered to the patient. A maximum limit of **3.5%** is set for isoflurane and **5.0%** for sevoflurane.
FIA	**Fractional Inspiratory Anesthetic** – The concentration of inspired anesthetic being delivered to the patient measured by the patient sensor near the mouth. ISO values are shown in purple. SEVO values are shown in yellow. Measured as a percentage.
FETA	**Fractional End Tidal Anesthetic** – The concentration of expired anesthetic being vented by the patient at the end of a breath out and measured by the patient sensor near the mouth.
RR	**Respiratory Rate** – Measured in B/M (breaths per minute)
PI CO2	**Partial Pressure Inspired of CO2** – The amount of CO_2 inhaled by the patient and measured in mmHg. Measured by the patient sensor near the mouth.
PET CO2	**Partial Pressure End Tidal of CO2** – The concentration of expired CO_2 being vented by the patient at the end of a breath out and measured by the patient sensor near the mouth.
VE	**Minute Ventilation** – Total volume of gas supplied to the patient in one minute (measured in liters per minute).
FCA	**Fractional Concentration in Circuit of Anesthetic** – The average concentration of anesthetic seen at the gas inlet.
MAC	**Minimum Alveolar Concentration –** The concentration of the vapor in the lungs that is needed to prevent movement (motor response) in 50% of subjects in response to surgical (pain) stimulus.

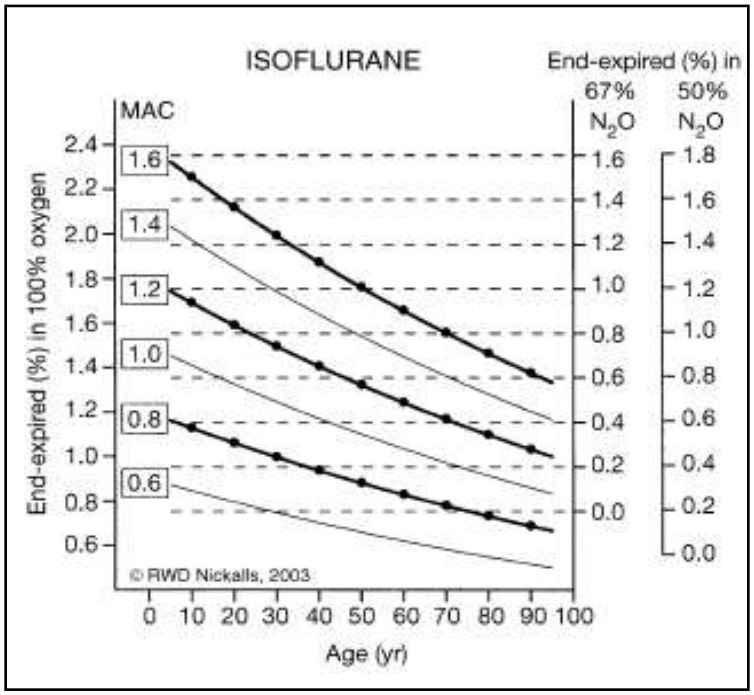
Table 10: Patient Info Display

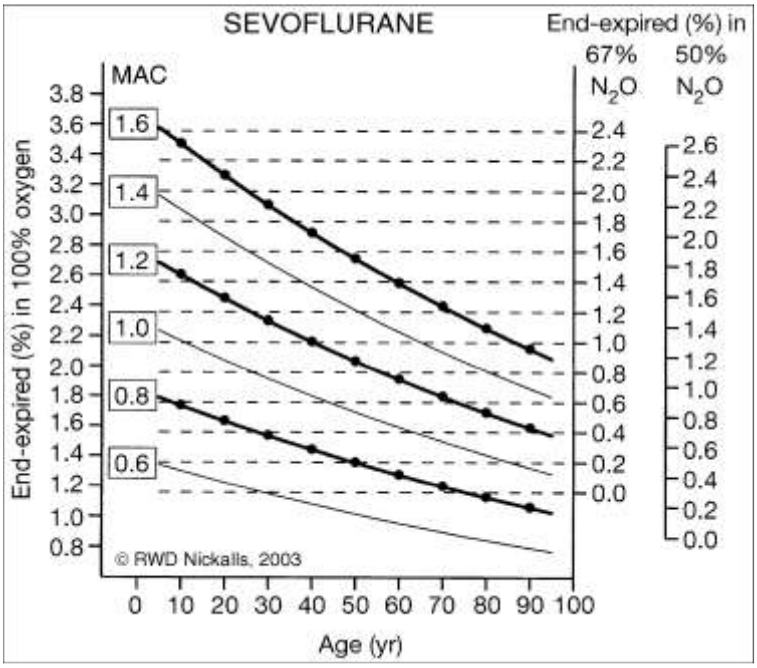
MAC Calculation and Display

MAC is defined as the concentration of the vapor in the lungs that is needed to prevent movement (motor response) in 50% of subjects in response to surgical (pain) stimulus.

Dependence of MAC on Age and Agent Type

The dependence of MAC on age and agent type is shown below.*





*MAC dependence on age and N_2O% for males reproduced from *British Journal of Anaesthesia 91 (2): 170±4 (2003).*

Value of MAC

The value of MAC is the combined effect of all anesthetic agents in the system. The effect varies with the physiology of the patient and the altitude. The MAC value displayed on MADM™ is adjusted for altitude and is calculated only on isoflurane and sevoflurane in the system. If halothane, enflurane, desflurane, or N_2O are detected, the MAC value cannot be computed. Below is the basic equation for MAC for a 40 year-old adult patient at sea level.

$$MAC = \frac{Iso_{ET\%}}{1.15\%} + \frac{Sevo_{ET\%}}{2.05\%}$$ [Source: ISO 80601-2-55:2011(E)]

Uncompensated, the MAC value will vary at altitude. Since the effect of anesthetic agents is dependent on partial pressure, and not volume percent, the above expression can alternatively be expressed as:

$$MAC = \frac{Iso_{ET\%}}{1.15\%} \cdot \frac{101.325}{101.325} + \frac{Sevo_{ET\%}}{2.05\%} \cdot \frac{101.325}{101.325},$$
$$= \frac{Iso_{pp}}{1.165} + \frac{Sevo_{pp}}{2.077}$$

… where the pp subscript denotes partial pressure of the anesthetic agent.

So, the altitude-adjust MAC based on the volume percent readings is governed by the following equation:

$$MAC = \left(\frac{Iso_{ET\%}}{1.165} + \frac{Sevo_{ET\%}}{2.077} \right) \cdot P_{baro}$$, where P_{baro} is the barometric pressure.

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6. MADM™ Specifications

Model Number

The documentation in this manual is for MADM™ model number 124641.

Physical Specifications

Property	Specification
Unit Weight	3.22kg (7.1 lbs), with empty anesthetic canister installed
Width	29.0 centimeters (11.4 inches)
Height	20.5 centimeters (8.1 inches)
Depth	13.6 centimeters (5.36 inches)
Exterior Housing Material	ABS plastic
Volume at Maximum Fill Level	100 mL maximum
Effect of Tilting up to 25 degrees	None

Table 11: Physical Specifications

MADM™ Electrical Specifications

Property	Specification
Input Voltage	24 VDC
Input Current	3.0 A

Table 12: Electrical Specifications

Power Supply Electrical Specifications

Property	Specification
Input Voltage	100–240 VAC Nominal
Input Frequency	50/60 Hz
Input Current	<1.5 A rms
Inrush Current	<37 A at 230 VAC cold start
Zero Load Power Consumption	<0.5 W
Earth Leakage Current (Typical)	<100 µA (nominal)
Patient Leakage Current	<50 µA
Output Voltage	24.0 V
Output Current	3.0 A

Table 13: Power Supply Electrical Specifications

Performance Specifications

Property	Specification
Time from startup to monitoring	1m 20s
Delivered Vapor Accuracy	+30%/-20% of dial setting or +7.5%/-5% of maximum agent setting, whichever is greater
Time from start-up to anesthetic delivery	2m 10s
Detection Threshold for a single halogenated agent	0.15%. When concentration has passed the threshold, concentrations will be reported even below the threshold.
Detection Threshold for multiple halogenated agents in a gas mixture	0.2%. When concentration has passed the threshold, concentrations will be reported even below the threshold.
High Priority Alarm Sound Pressure Level (at one meter)	47.2 dB
High Priority Alarm A-Weighted Background Sound Level	26.8 dB
Medium Priority Alarm Sound Pressure Level (at one meter)	46.3 dB
Medium Priority Alarm A-Weighted Background Sound Level	26.8 dB
Delivery Range	0-3.5% (ISO), 0-5% (SEVO)
Electrical Source Displayed	Yes
Time from standby to 1.0 MAC	<30 s
CO2 Range and Accuracy	0-15 vol% ± (0.3 vol% + 2% of reading)
N2O Range and Accuracy	Alarm only
HAL Range and Accuracy	Alarm only
ISO Range and Accuracy	0-8 vol% ± 0.15 vol% + 5% of reading
ENF Range and Accuracy	Alarm only
SEV Range and Accuracy	0-10 vol% ± 0.15 vol% + 5% of reading
DES Range and Accuracy	Alarm only
Total system Response Time	<2 s

Table 14: Performance Specifications

O_2 Effect on Gas Readings

The table below shows the typical effect if using SetO2 value 50 vol% (default for MADM™).

O_2 Concentration in Gas Mix	Effect on Gas Reading (% Relative)	Displayed Value if True Concentration is 5.0 vol% CO_2
21 vol%	2.76	4.9
50 vol%	0.00	5.0
70 vol%	-1.91	5.1
95 vol%	-4.29	5.2

Table 15: O_2 Effect on Gas Readings

Compatible Ventilator Specifications

MADM™ has been validated to meets its specifications when used with open circuit ventilators such as the Impact Eagle (K931473) and circle system ventilators such as the Narkomed 2B (K86447) for the ventilation conditions shown below.

Property	Specification
Peak Flow	60 LPM
Maximum Minute Ventilation at Max ISO Setting (3.5%)	15 LPM
Maximum Minute Ventilation at Max SEVO Setting (5%)	10 LPM
Ventilator Respiratory Rate (Anesthetic Delivery & Monitoring)	6-40 BPM
Ventilator Respiratory Rate (Patient Monitoring Only)	0-99 BPM
Range of IE ratio for which end-tidal gas readings remain accurate	1:1 to 1:3

Table 16: Compatible Ventilator Specifications

About Performance Graphs and Tables

All data is acquired at an input flow rate of 10 LPM and 100% oxygen unless otherwise stated.

Effects of Output at Varied Altitudes and Sub Atmospheric Pressure.

The MADM™ vaporizer is calibrated in percent v/v, and the calibration is not affected by ambient pressure changes within the operating range specified.

Effects of Ambient Temperature

MADM™ is not significantly affected by temperature variations and meets its operating accuracy specifications, within the operating range specified.

Effects of Back Pressure and Resistance

MADM™ is not significantly affected by back pressure or airway resistance and meets its operating accuracy specifications across the ranges experienced in a ventilator breathing circuit (up to 50 cmH_2O).

Effects of Carrier Gas Composition

MADM™ is not significantly affected by changes in carrier gas composition for carrier gas comprising 10–100% oxygen (opened or circle system) and 0–80% nitrous (in a circle system) and meets its operating accuracy specifications.

Effects of Ventilator Characteristics

MADM™ meets its operating accuracy when inserted into a manual resuscitating bag circuit, a flow-through circuit and a circle circuit ventilator. MADM™ has been tested with respiratory rates from 0 to 40 BPM, IE ratios from 2:1 to 1:3, and Tidal Volumes up to 1 L. MADM™ is capable of achieving maximum target concentrations of ISO only at fresh gas flows up to 15 LPM and at 10 LPM for SEVO.

Environmental Specifications

Variable	Storage Condition	Operating Condition
Altitude	NA	0–10,000 ft
Temperature	–20°C to 50°C (–4°F to 122°F)	10°C to 40°C (50°F to 104°F)
Relative Humidity	15% to 95% (non-condensing).	15% to 95% (non-condensing).

Table 17: Device Environmental Specifications

CAUTION! OPERATION OF MADM™ OUTSIDE OF SPECIFIED LIMITS MAY CAUSE INACCURATE RESULTS.

Standards Compliance

MADM™ complies with the standards listed below.

STANDARD #	DESCRIPTION
IEC 60601-1	Medical Electrical Equipment (Ed 3.1, 2012), General Requirements for basic safety and essential performance.
IEC 60601-1-2	Medical Electrical Equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests (Ed 4.1, 2020)
IEC 60601-1-8	Medical Electrical Equipment – Part 1-8: General requirements for safety – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems (Ed 2.1 2012)
ISO 80601-2-13	Medical Electrical Equipment – Part 2: Particular Requirements for the safety and essential performance of anesthetic systems (Ed. 1.0, 2015)
ISO 80601-2-55	Medical Electrical Equipment – Particular requirements for the basic safety and essential performance of respiratory gas monitors (Ed. 1.0, 2011)

Table 18: Standards Compliance

EMC (Electromagnetic Compatibility) Statements

Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF emissions CISPR 11	Group 1	MADM™ uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	MADM™ is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: **WARNING:** MADM™ is intended for use by healthcare professionals only. MADM™ may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating MADM™ or shielding the location.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 19: EMC Immunity Tests

MADM™ is intended for use in the electromagnetic environment specified below. The customer or the user of MADM™ should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 Kv contact ±8 Kv air	±6 Kv contact ±8 Kv air with documented necessary	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 Kv for power supply lines ±1 Kv for input/output lines	±2 Kv for power supply lines ±1 Kv for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 610004-5	±1 Kv line(s) to line(s) ±2 Kv line(s) to earth	±1 Kv line(s) to line(s) ±2 Kv line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70 % UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	<5% UT (>95% dip in UT) for 0,5 cycle 40 % UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles No anomalies <5% UT (>95% dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. End user shall ensure charged batteries are installed in the equipment.
Power frequency (50 Hz) magnetic field IEC 61000-48	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Table 20: EMC Immunity Tests

7. MADM™ Components and Connections

Figure 14: Front Controls

Front Controls	
Label	**Control**
A	Anesthetic Canister Release Button

Figure 15: Top Controls

Top Controls	
Label	**Connection**
A	[MUTE/ENTER] Key
B	[X] Key
C	Anesthesia Control Dial
D	Anesthesia Control Dial Release / Lock Button
E	LED Status Indicators

Figure 16: Left Side Connections

Left Side Connections	
Label	**Connection**
A	Gas Outlet
B	Patient Anesthetic and CO_2 Sensor Connection

Figure 17: Right Side Connections

Right Side Connections	
Label	**Connection**
A	Gas Inlet (Inlet Sensor)

Figure 18: Rear Controls and Connections

Rear Controls and Connections	
Label	**Connection**
A	On / Off Switch
B	Power Connection
C	Clamp Connection Point

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8. The MADM™ Battery Base and Battery

Overview

The MADM™ battery base, with its various parts labeled, is shown in the two Figures below.

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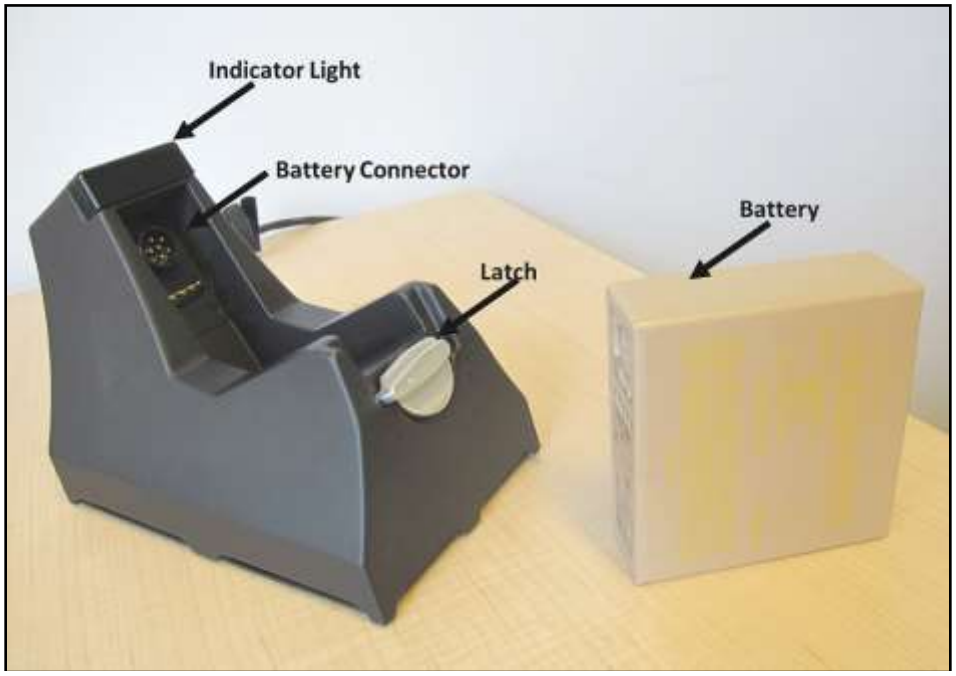

Figure 19: MADM™ Battery Base & Battery

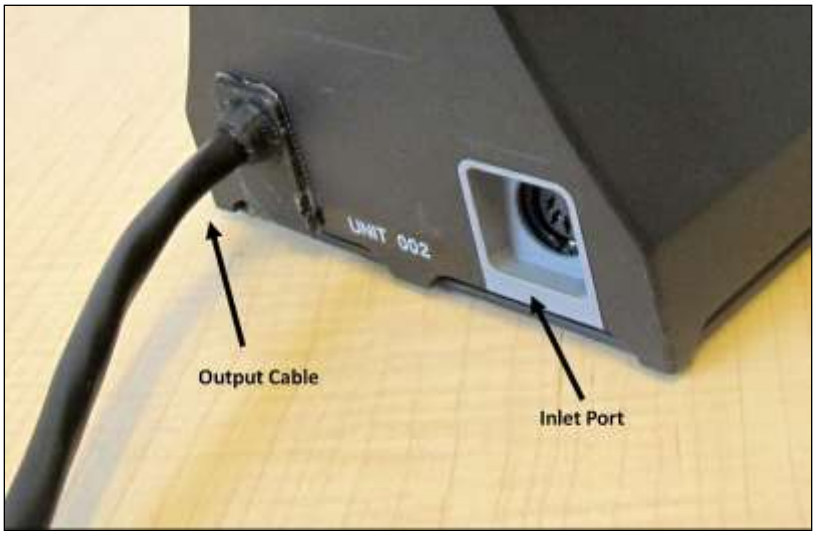

Figure 20: MADM™ Battery Base Rear View

Using the Battery Base

To use the MADM™ Battery Base:

1. Insert a battery pack into the battery base and align the battery connector on the battery base to the Connector on the battery.

NOTE: *Use only the Bren-Tronics BB-2557/U (BT-70757BV) battery with the MADM™ Battery Base.*

2. Rotate the latch to lock the battery pack in place.
3. Attach the MADM™ power supply to the inlet port of the Battery Base.
4. Connect the output cable of the Battery Base to MADM™.
5. Monitor the Indicator Light to confirm the charging and discharging status as per the table below.

Note: The Battery Base will not charge the external battery while connected to the MADM™ unit.

Battery Base LED State	Explanation
Green LED Blinking	Battery is Charging
Green LED Solid	Battery is Charged
Yellow LED Blinking	Battery is Discharging
Yellow LED Solid	Battery Charge Level is Low
Orange LED Solid	Error Detected (Replace Battery): • Battery temperature too high • Unsupported battery detected

Table 21: Battery Charging Status Indicators

Battery and Battery Base Maintenance

The MADM™ Battery Base can only be serviced by qualified service personnel. However, batteries should be regularly inspected for physical damage such as cracks, holes and leaks. If any of these are discovered the battery should not be used. It should be replaced, and the damaged battery discarded in accordance with local disposal regulations. Batteries should be recharged at least once per year and stored in a fully charged state.

WARNING! DO NOT USE OR CHARGE A DAMAGED BATTERY.

The external surface of the Battery Base can be cleaned using standard cleaning agents, including hospital-grade cleaning products but excluding oxidizing agents. It is recommended that the external surfaces be wiped down with isopropyl alcohol after each use.

The Battery Base can be wiped clean with one of the following:

- Isopropyl Alcohol
- Chlorine Compounds*****
    - Maximum Concentration: 1:10

*****_These compounds are diluted by volume in water._

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9. The MADM™ Clamp

Overview

The MADM™ clamp is intended to securely mount the MADM™ device in an upright position to a stationary horizontal or vertical pole. The clamp is attached to the device by way of a pre-installed mounting bracket as shown below.

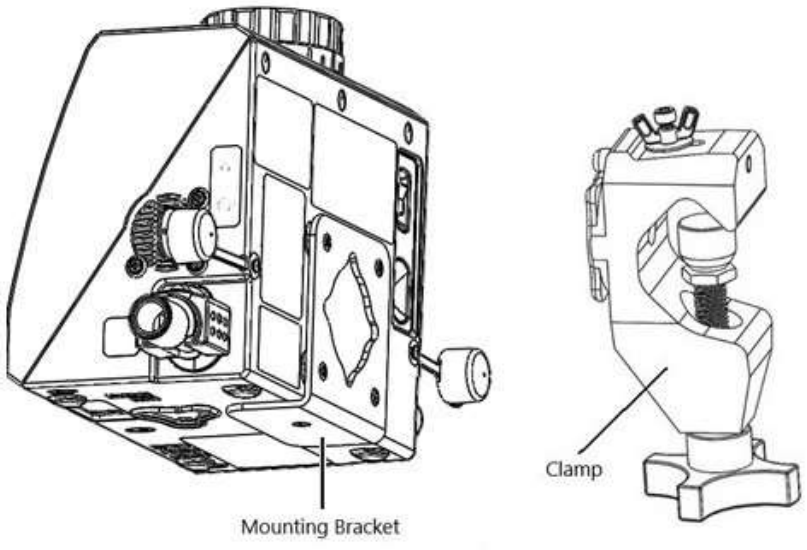

Figure 21: MADM™ Clamp and Mounting Bracket

Using the Clamp

1. The mating surface of the clamp component is aligned at any 45-degree position relative to the device and inserted through the mounting bracket.

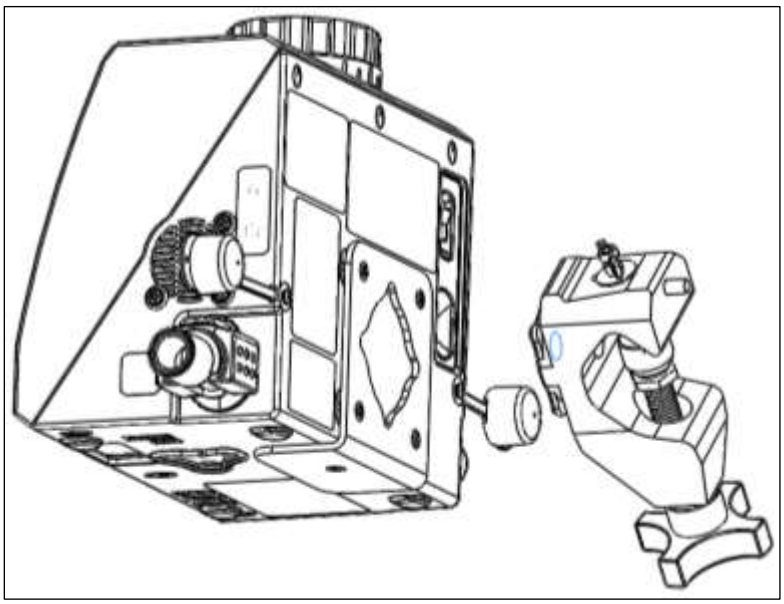

Figure 22: Clamp Alignment at 45-Degrees

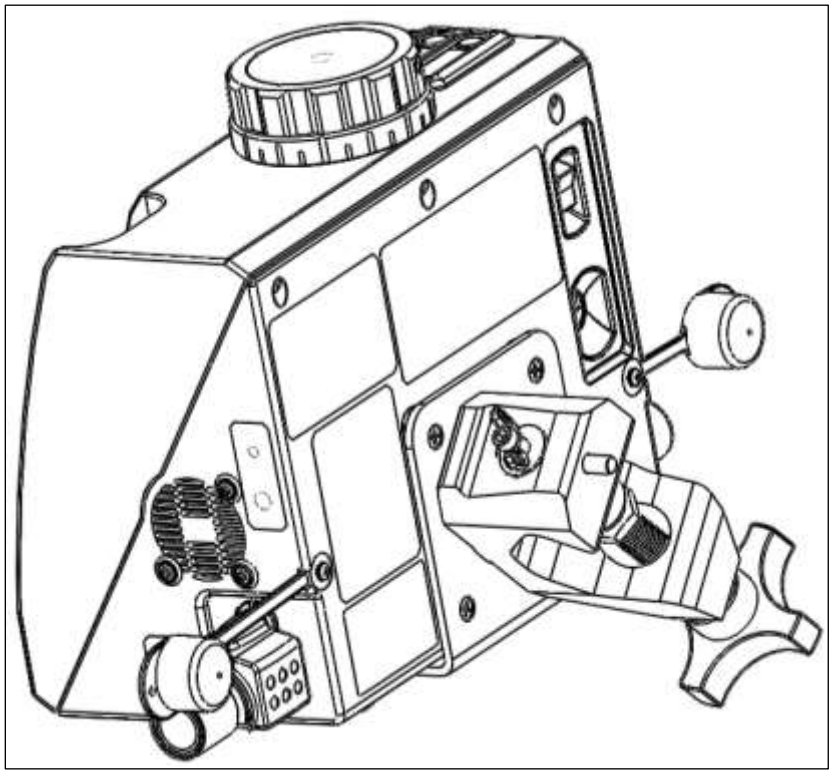

Figure 23: Clamp Mating to Mounting Bracket at 45-Degrees

2. Loosen the wing-nut on the clamp, and pull the wing-nut outwards, away from the MADM™ device.

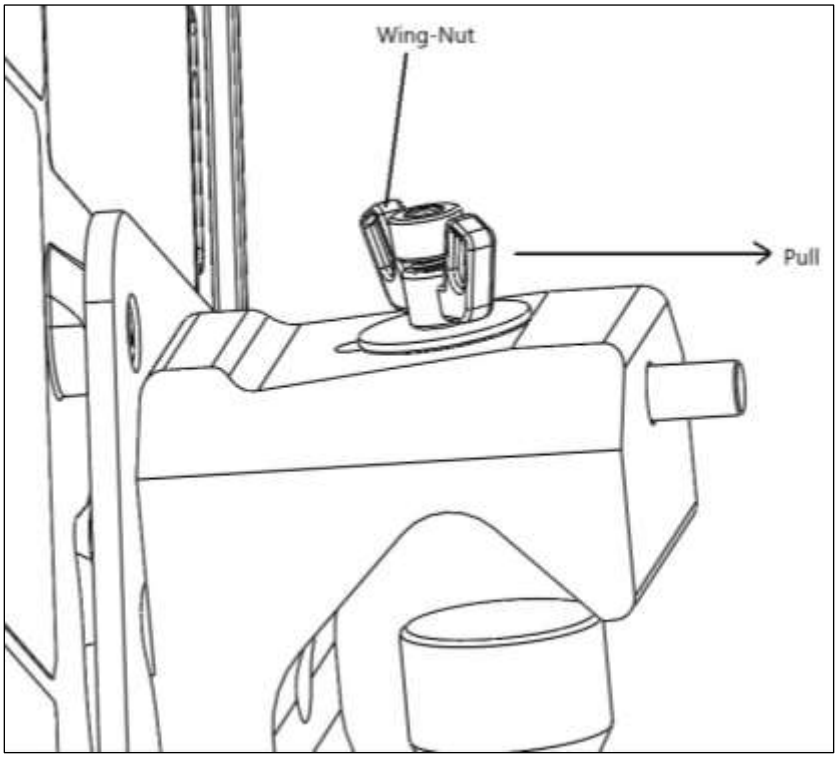

Figure 24: Loosen and Pull Wing-Nut

3. Rotate the clamp to any 90-degree position relative to the device and the clamp will lock into place. Once locked in the desired position, hand-tighten the wing-nut. The device can now be clamped to a stationary pole as desired.

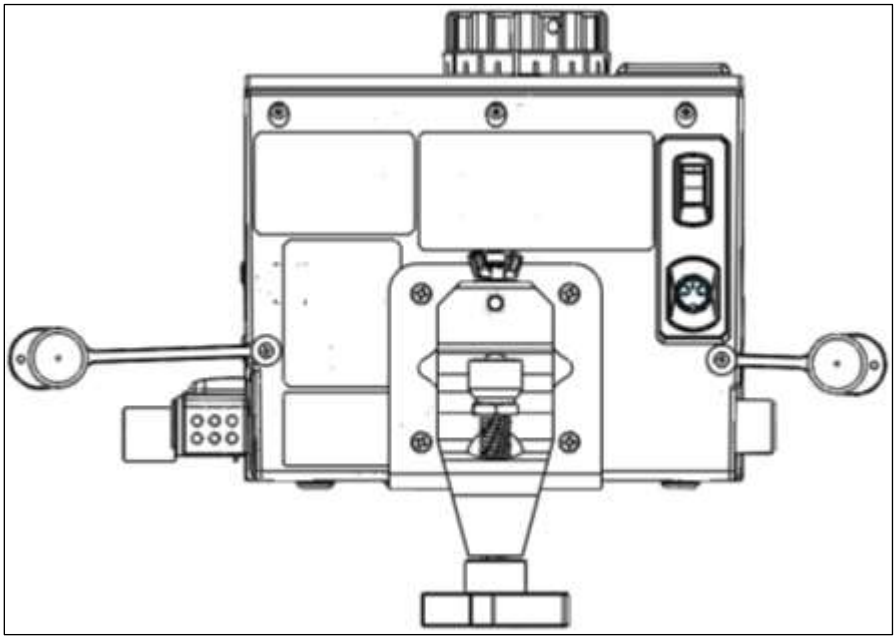

Figure 25: Clamp Locked at 90-Degrees

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10. Setup, Filling and Draining Instructions

Setup Overview

MADM™ can be used in two different configurations:

1. Open circuit with ventilator
2. Closed circuit (circle circuit) with ventilator

The first configuration exhausts the exhaled gas. The second configuration recirculates the exhaled gas and, consequently, less anesthetic is used.

Anesthetic from MADM™ is delivered to the patient via an endotracheal tube inserted into the patient's airway via the mouth.

NOTE: *The Startup Self-Check should be completed before using MADM™. For further information, see Startup Self-Check on page 71.*

NOTE: *MADM™ has been designed to attach to 22 mm ID (inside diameter) airway tubing.*

Open Circuit with Ventilator

Assembly Diagram

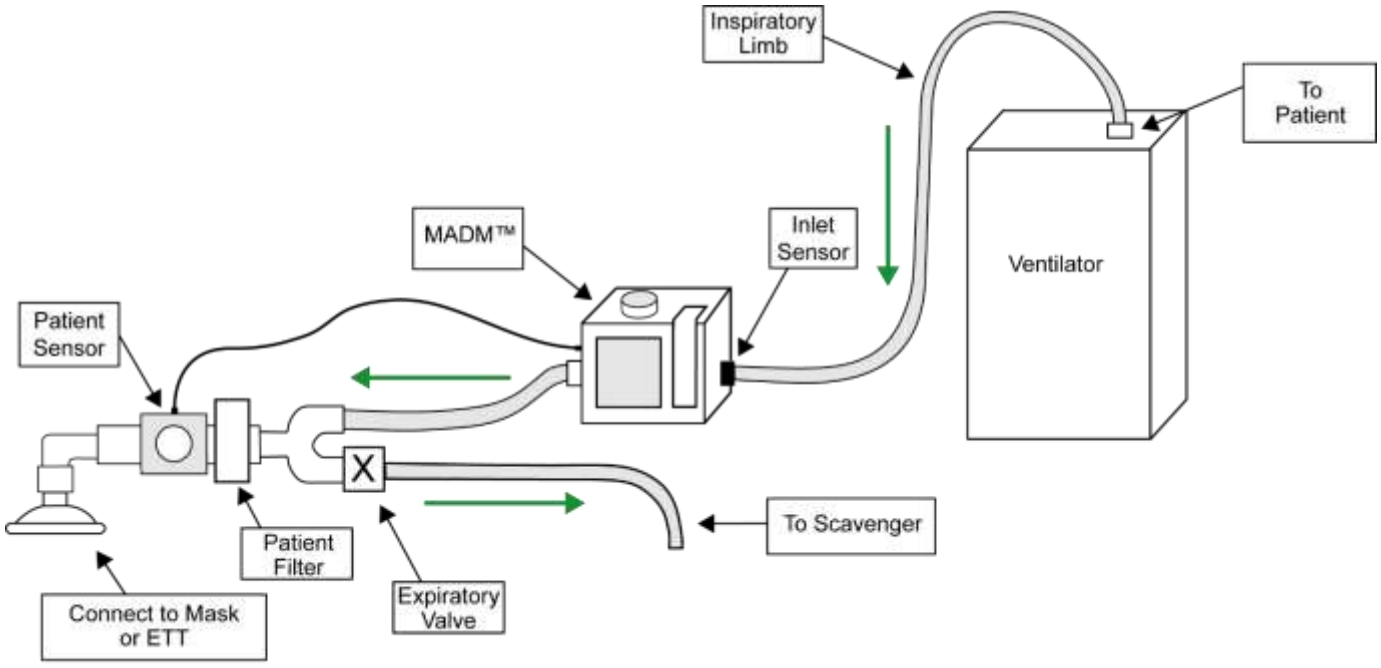


Figure 26: Open Circuit with Ventilator Assembly Diagram

NOTE: *Green arrows in diagram above indicate direction of air flow.*

Steps

3. Attach the fitting with the *patient sensor* to the input / supply end of the tracheal tube connected to the patient.
4. Attach the opposite end of the patient-sensor fitting to one end of the *patient filter*.
5. Attach the other end of the patient filter to the patient port of the *"Y" fitting / exhalation valve*, which is part of the ventilator breathing circuit supplied with the ventilator.
6. Attach the open end of the ventilator breathing circuit inspiratory limb connection tube to the *outlet port* on the left side of MADM™.
7. Attach the ventilator outlet to the *inlet port* on the right side of MADM™ using the patient tubing supplied with the MADM™.
8. Attach the open end of the expiratory limb connection tube to either an activated charcoal *adsorption filter* or a *wall connection* used for the removal of waste anesthetic gases.

Closed Circuit with Ventilator

Assembly Diagram

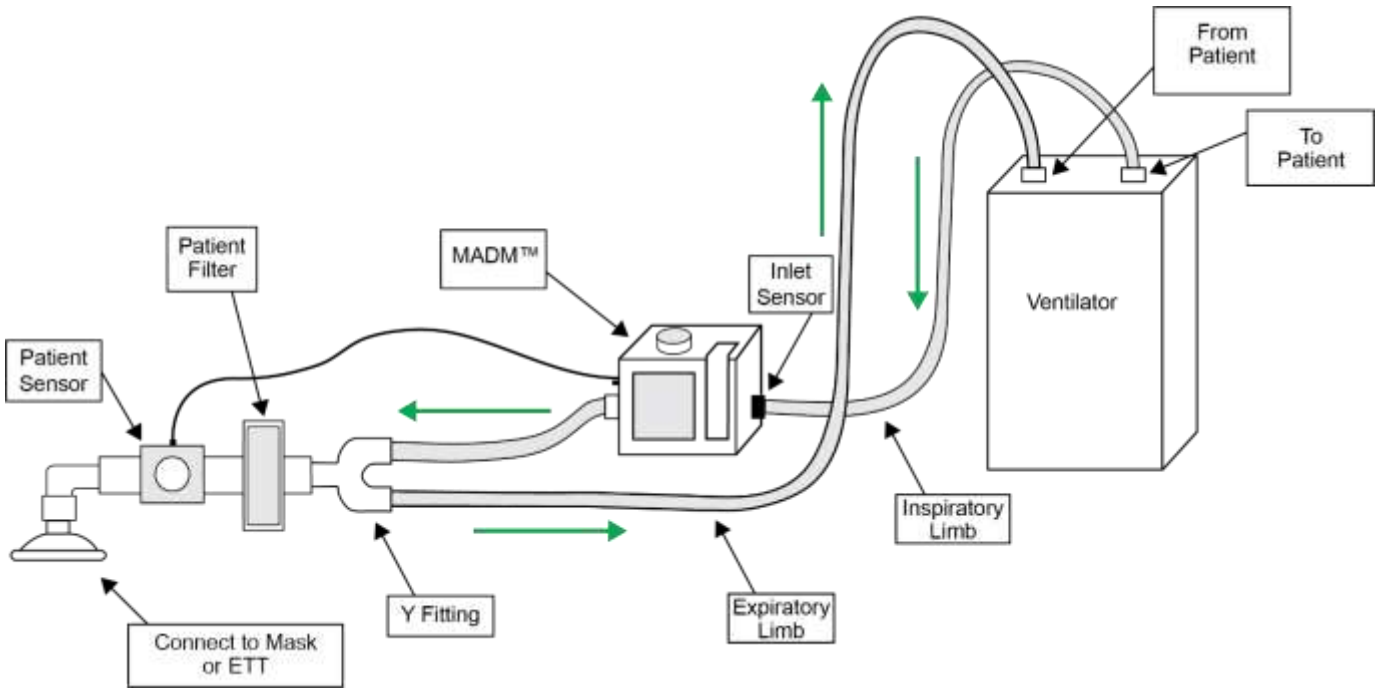


Figure 27: Closed Circuit with Ventilator Assembly Diagram

NOTE: *Green arrows in diagram above indicate direction of air flow.*

Follow the previous steps for an *Open Circuit with Ventilator*. When you reach *Step 6*, attach the output end of the expiratory limb connection tube to the input for the expiratory limb connection on the ventilator (rather than to an activated charcoal *adsorption filter* or a *wall connection*).

Anesthetic Canister Filling Instructions

NOTE: *The maximum capacity of the anesthetic canister is 100 mL.*

NOTE: *The anesthetic canisters should only be filled with anesthetic for immediate delivery by MADM™. Anesthetic should not be stored in the anesthetic canisters, and unused anesthetic should be drained from the canisters after they are ejected from MADM™.*

NOTE: *MADM™ canisters should only be filled with agent-specific filling systems which comply with ISO 5360.*

NOTE: *The anesthetic canisters can be filled or refilled while installed in MADM™ including during anesthetic delivery.*

To fill or refill the anesthetic canister that is part of MADM™, follow the instructions below:

1. Locate the *refill door* on the front of the canister near the top.

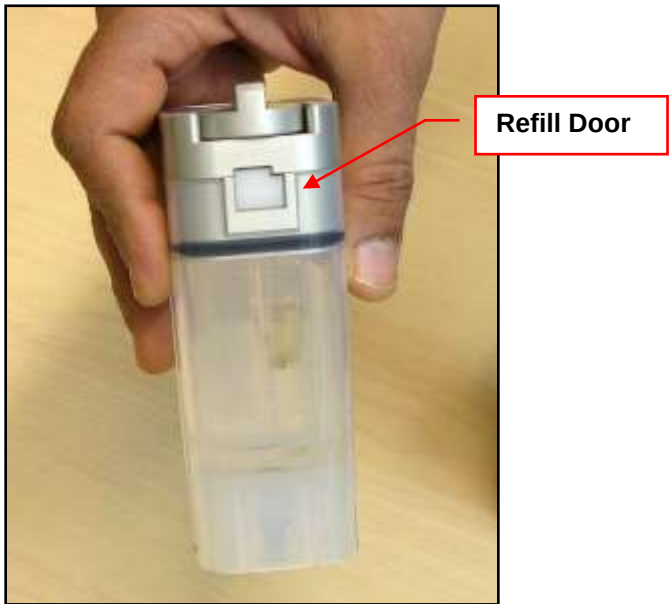


Figure 28: Refill Door

2. Turn the knob above the door *counterclockwise* to release the pressure on the door so that it can be pushed open.
3. Attach the refill gooseneck connector to the anesthesia bottle by fitting the interlocking matching connectors together and screwing down the circular collar on the gooseneck.

NOTE: *Matching interlocking collars are present on both the gooseneck and the anesthesia bottle. The collars are also colour-coded: purple for isoflurane and yellow for sevoflurane.*

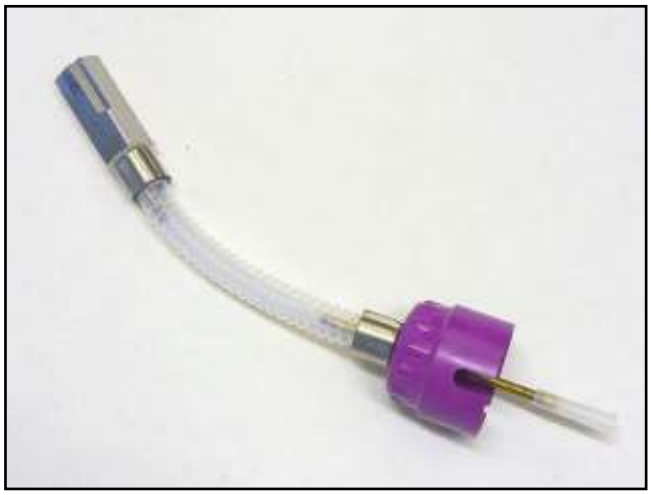


Figure 29: Refill Gooseneck Connector

Figure 30: Anesthesia Bottle with Collar

Figure 31: Bottle with Gooseneck Attached

4. Insert the rectangular fitting on the end of the gooseneck into the door of the canister and secure it there by turning the knob above clockwise until the rectangular fitting feels firmly clamped.

Figure 32: Gooseneck Fitted to Canister

5. Raise the bottle above the canister input and allow the anesthetic to flow into canister until the desired amount is reached.
6. Lower the bottle and allow the residual anesthetic in the gooseneck to flow back into the bottle.
7. Turn the screw on the top of the canister counterclockwise to loosen the door, withdraw the gooseneck fitting, then turn the screw on top of the canister clockwise until it locks.
8. Reinsert the canister vertically from the top of MADM™ into its slot. Be sure to align the indentations on the side of the canister with their matching extrusions on either side of the slot.
9. When the canister is correctly seated, press it down firmly until it snaps into place.

CAUTION! DURING DISCONNECTION OF THE MALE ADAPTER FROM THE VAPORIZER, AND THE BOTTLE ADAPTER FROM THE BOTTLE, SMALL AMOUNTS OF ANESTHETIC AGENT WILL ESCAPE TO THE ENVIRONMENT.

NOTE: *If you are trying to determine the liquid level remaining in the canister, it is easier to see the level clearly when MADM™ is turned on.*

Anesthetic Canister Draining Instructions

Anesthetic should not be left in the MADM™ canister once a procedure is completed. It should be drained from the canister and returned to the anesthesia bottle.

Figure 33: Residual Anesthetic Should Be Drained

To drain the anesthetic canister that is part of MADM™, follow the instructions below:

1. Attach the end of the gooseneck connector to the anesthesia bottle by fitting the interlocking matching connectors together and screwing down the circular collar on the gooseneck.

Figure 34: Bottle with Gooseneck Attached

2. Remove the canister from MADM™ by pressing the *release button* below it and lifting the canister out.
3. Locate the *refill door* on the front of the canister near the top.
4. Turn the knob above the door *counterclockwise* to release the pressure on the door so that it can be pushed open.

Figure 35: Turn Knob Counterclockwise to Release

5. Insert the rectangular fitting on the end of the gooseneck into the door of the canister and secure it there by turning the knob above it clockwise until the rectangular fitting feels firmly clamped.

Figure 36: Insert the Rectangular Fitting

Figure 37: Turn Knob Clockwise to Secure

6. Raise the canister above the bottle input and allow the anesthetic to flow into the bottle until the canister is empty.

Figure 38: Raise Canister Above Bottle

7. Lower the canister and allow any remaining anesthetic in the gooseneck to flow back into the bottle.
8. Turn the screw on the top of the canister counterclockwise to loosen the door, withdraw the gooseneck fitting, then turn the screw on top of the canister clockwise until it locks.
9. Remove the gooseneck connector from the anesthesia bottle by unscrewing the circular collar on the gooseneck and separating the interlocking matching connectors of the gooseneck and the bottle.
10. Tightly recap the anesthesia bottle.

MADM™ AbbVie Sevoflurane Anesthetic Filler Adapter

Intended Use

The MADM™ AbbVie Anesthetic Filler Adapter is used for the transfer of Sevoflurane (SEVO) anesthetic agent from a bottle to the MADM™ Sevo Canister.

Figure 39: MADM™ AbbVie Sevoflurane Anesthetic Filler Adaptor

Warnings

- Do not use the adaptor for any other anesthetic agent
- Inspect the adaptor for damage or wear before each use. Do not use the adaptor if it is damaged.
- Ensure that all liquid anesthetic has evaporated from inside the adaptor prior to returning it to storage.

Filling Instructions

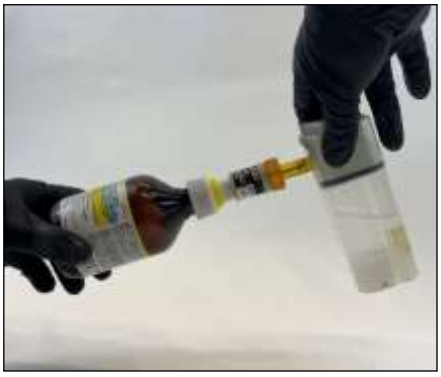
1. Remove the adaptor from its packaging and remove the cap from the SEVO bottle.

2. Align the adaptor slots to the bottle fitting and push the adaptor onto the fitting until it is fully seated. Rotate the locking collar on the adaptor clockwise to tighten.

3. Unlock the refill-door on the front of the MADM™ SEVO canister.

4. With the bottle upright, align the SEVO Canister refill door with the adaptor and insert it, then rotate the refill-door knob clockwise until the adaptor is firmly clamped.


5. Raise the bottle above the canister input and squeeze the bottle once to allow the anesthetic to flow into the canister until the desired amount is reached. Lower the bottle and allow any residual anesthetic to flow back into the bottle.

6. Turn the knob on the top of the canister counterclockwise to release the adaptor and remove it. Lock the refill door.


7. Remove the adaptor from the SEVO bottle and ensure that it is dried completely before returning it to storage.

Draining Instructions

1. Remove the adaptor from its packaging and remove the cap from the SEVO bottle.

2. Align the adaptor slots to the bottle fitting and push the adaptor onto the fitting until it is fully seated. Rotate the locking collar on the adaptor clockwise to tighten.

3. Unlock the refill-door on the front of the MADM™ SEVO canister.

4. With the canister upright, align the adaptor with the SEVO Canister refill door and insert it, then rotate the refill-door knob clockwise until the adaptor is firmly clamped.

5. Raise the canister above the bottle input and squeeze the bottle once to allow the anesthetic to flow back into the bottle until the canister is empty.

6. With the bottle upright, turn the knob on the top of the canister counterclockwise to release the adaptor and remove it from the canister. Lock the refill door.

7. Remove the adaptor from the SEVO bottle by rotating the locking collar counterclockwise. Recap the SEVO bottle.

8. Ensure that the adaptor has dried completely before returning it to storage.

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11. Using MADM™

Startup Self-Check

Before MADM™ is used, the Startup Self-Check should be completed. Specifically, the Self-Check zeroes its two internal sensors (for flow and anesthetic concentration) and its external patient sensor (for anesthetic concentration and CO_2). Therefore, the patient sensor must be connected to the device when the Self-Check is being performed.

NOTE: *If MADM™ has been recently used prior to Self-Check, any residual anesthetic remaining in the device must be flushed out. Flushing should be done by running fresh air through the MADM™.*

NOTE: *If the internal battery status indicates "NOT FUNCTIONING", it may take up to 24 hours for the internal battery to charge when connected to wall power.*

NOTE: *The alarm "Unsupported Agent Detected" may appear beside the MAC value if MADM™ has not been thoroughly flushed out with fresh air after a previous use. If this alarm appears, MADM™ should be flushed with air and the Self-Check should be repeated.*

NOTE: *The alarm "Unsupported Agent Detected" may also appear if the adapter has been replaced in the patient sensor even though MADM™ has been thoroughly flushed out. In this case, pressing and holding the [MUTE / ENTER] key for five (5) seconds at the Startup screen will force the Self-Check to be initiated.*

NOTE: *The Operator should be within arm's reach of MADM™ throughout the procedure and be able to view the display without obstruction.*

Steps

1. Connect the patient (mouth) anesthetic sensor to the control unit by fitting its cable connector into the pin connection on the left side of MADM™. Rotate the control dial to the off position.
2. Place protective caps over the input and output ports on the right and left sides of MADM™.
3. Turn on MADM™ using the toggle switch on the back in the top left corner.
4. Wait for MADM™ to warm up. During warm up, the alarm LEDs cycle through a sequence of green, amber, and red repeatedly. All three alarm LEDs (red, amber and green) display as solid when the device has finished warming up and is ready for zeroing. If the device continues in a state of "evaluating gas", the gas sensors are detecting residual anesthetic. Remove the end caps and flush with fresh gas, then continue.
5. When you are prompted on screen, press the [MUTE / ENTER] key (the key farthest from the user on the top of MADM™).
6. As the Self-Check is being done, the red and green LEDs on top of the control unit will toggle. The yellow LED will remain solidly lit.
7. The green LED will blink slowly after the Self-Check has been completed (or if it is skipped).

NOTE: *If the Self-Check does not complete successfully the reason may be that there is residual anesthetic in the system, or that the patient sensor is not connected. Address these issues and try again.*

Setting the Patient Weight Value

1. After the MADM™ Startup Self-Check has been completed successfully, select the patient's weight range on the *Weight* screen by turning the *Concentration Knob* to the desired selection. The table below displays the MADM™ weight ranges and the configuration parameters associated with each setting.

Weight Range (kg)	Window Time (ms)	Initial Maximum Pump Rate (µL/min)
40 to 60	8342	1200
> 60	5561	3000

Table 22: MADM Weight Ranges & Config Parameters

2. Confirm the selection first by pressing the [MUTE/ENTER] key on the top left of MADM™ and then, second, by turning the *Concentration Knob* to OFF.
3. The green LED stops flashing and the alarm system takes control of the alarm LEDs and indicates the alarm level of the system.
4. The anesthetic canister can now be installed in MADM™ and the patient sensor inserted into the circuit.

Effect of Setting the Weight Value

The delay between when MADM™ adjusts its anesthetic delivery rate and when it reaches the patient sensor depends on minute ventilation and can be as long as 30 seconds for smaller patients. For smaller patients, increases in anesthetic delivery rate are limited to ensure that unsafe levels are not delivered to the patient before the patient sensor can detect them. The weight setting determines the rate at which MADM™ can increase its anesthetic delivery rate, referred to as "Window time" on the preceding table.

Impact of Setting an Incorrect Weight

Setting an incorrect low weight may slow MADM™'s responsiveness to changes in dial-settings ventilation or fresh gas flow. Setting an incorrect high weight may reduce the effectiveness of some MADM™ safety measures; however, it will not have an effect unless the device malfunctions for another reason.

If the incorrect weight is displayed on the screen, the weight can be adjusted by resetting the device. This should only be done when anesthetic delivery can be safely disrupted for more than a minute. In addition, a secondary anesthetic source should always be available.

Running MADM™

NOTE: *It is recommended that a biophysical monitoring device be used to measure and monitor a patient's vital signs while the patient is connected to MADM™.*

After the MADM™ Self-Check has been successfully completed, follow the steps below to begin using the device.

WARNING! ALWAYS HAVE A BACKUP METHOD OF DELIVERING ANESTHETIC TO THE PATIENT AVAILABLE IN CASE OF DEVICE FAILURE.

CAUTION! MADM™ IS TO BE USED WITH AN ANESTHETIC GAS SCAVENGING TRANSFER AND RECEIVING SYSTEM IN ACCORDANCE WITH ISO/IEC 80601-2-13.

Steps

1. Insert the anesthetic canister, containing liquid anesthetic, into its slot in MADM™ and press it down firmly until it snaps into place.
2. Make sure that all circuit connections (either open or closed) are in place.
3. Press in and hold the *Release / Lock Button* on the circular knob on the top of MADM™ that controls anesthetic concentration.
4. Turn the Concentration Knob *counterclockwise* to the desired percent concentration.

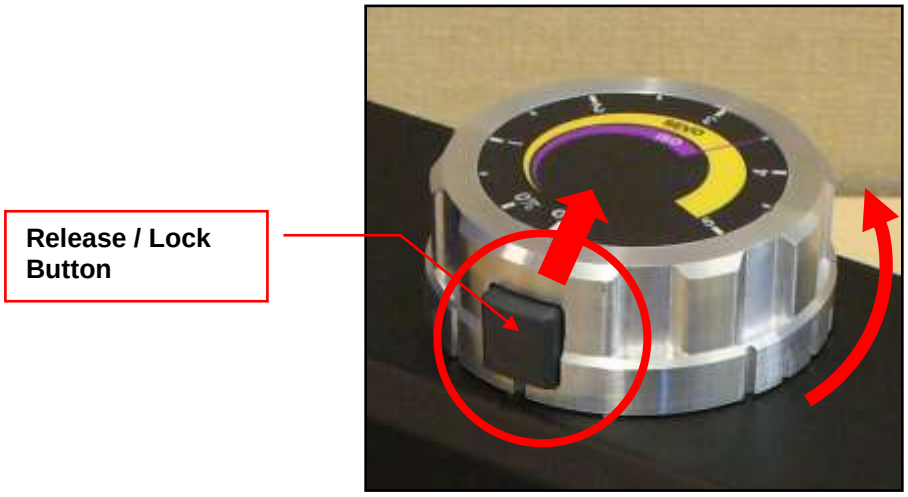

Figure 40: Concentration Knob

Running

When a full anesthetic canister is inserted into MADM™, and the device is turned on, the screen will indicate that it is in *Standby* mode; i.e., that the system has been supplied with anesthetic and is ready to begin delivering it to the patient.

When the *Concentration Knob* is set to a percentage, the screen will first display a message that the system is *Priming*; i.e., that anesthetic is being introduced into the system to be supplied to the patient.

Once *Priming* is complete, the screen will then display a message that the system is *Delivering*; i.e., that it is supplying anesthetic to the patient. A counter showing running time in minutes and seconds will also be displayed beneath this message.

Anesthetic concentration can be adjusted throughout the procedure by turning the *Concentration Knob* to the desired value. MADM™ can be set to "standby" (delivering no anesthetic but still primed and ready to deliver) by turning the knob to the area between 0% and OFF.

NOTE: *More anesthetic may be needed to increase the anesthetic dosage at higher altitudes (compared to sea level).*

Turning Off

To turn the *Concentration Knob* to the OFF position, the *Release / Lock Button* must be pressed again.

LEDs and Related Alarms

A blue LED is used to indicate that MADM™ is in an Active state. Three other LEDs indicate when the system is in one of these other states: Warming Up, Finished Warming Up, Self-Check in Progress, Self-Check Completed, Normal, Warning, and Error. The system's overall status, audio alarm, and alarm LED state are defined by the active alarm condition with the highest severity.

LED State	Explanation	Alarm Priority / Audio Tone Sequence
LEDs cycle through a sequence of GREEN, AMBER, and RED repeatedly.	The system is **warming up**.	Not applicable
GREEN, AMBER, and RED LEDs display solidly lit.	The system has **finished warming up**.	Not applicable
RED and GREEN LEDs on top of the control unit toggle. The YELLOW LED remains solidly lit.	Self-Check has been initiated and is **in progress**.	Not applicable
GREEN – Flashing (slowly)	Self-Check of the system has been **completed**. Patient weight range needs to be selected and confirmed.	Not applicable
NOTE: Once the patient weight has been selected and confirmed, the green LED stops flashing. At this point, *the MADM™ alarm system takes control of the alarm LEDs* and indicates the alarm level of the system. If there are no alarms, the green LED becomes solidly lit.		
GREEN – Solid	The system is in a **Normal** state; i.e. safe and good working order. (***NOTE:*** *No audio alarm is present.*)	Not applicable
BLUE – Solid	The system is in an **Active** state and will deliver anesthetic as needed to reach the desired inspired anesthetic setpoint (FiA SET).The system may not actually be delivering anesthetic if the recycled anesthetic percentage (FcA) is larger than the current FiA setpoint (FiA Set).	Not applicable
AMBER – Solidly lit	The system is in a **Caution** state. Operator awareness is required.	Low priority alarm / Tone sequence off
AMBER – Flashing (slowly) (blink rate = 1 Hz, 50% duty cycle)	The system is in a **MEDIUM** priority alarm state. The system delivers anesthetic and attempts to maintain target inspired concentration. (***NOTE****: A slow-pulsed audio alarm is present.*)	Medium priority alarm / Three notes of equal, medium length and ascending pitch: C–D–G (alarm can be muted for up to 120 seconds). When measured with a microphone at a distance of one (1) meter, the sound pressure level of the Medium Priority alarm is 46.3 dB. (This was measured with an A-weighted background level of 26.8 dB which included any information signal or extraneous noise.)

LED State	Explanation	Alarm Priority / Audio Tone Sequence
RED – Flashing (quickly) (blink rate = 2.5 Hz, 50% duty cycle)	The system is in a HIGH priority alarm state. It is not delivering anesthetic and will not run. (NOTE: A fast-pulsed audio alarm is present.)	High priority alarm / Three short notes of ascending pitch followed by two long notes of ascending pitch: C– D–G followed by C–D. When measured with a microphone at a distance of one (1) meter, the sound pressure level of the Medium Priority alarm is 47.2 dB. (This was measured with an A-weighted background level of 26.8 dB which included any information signal or extraneous noise.)

Replacing Inlet and Mouth Sensor Airway Adapters

When the *Patient or Inlet Sensor: Replace Adapter* message is displayed, the operator should replace the indicated adapter.

Steps

1. Ensure a replacement adapter is available.
2. Remove the adapter that needs replacement from the circuit and reconnect the circuit.
3. Replacer the adapter with a new adapter and replace in the circuit.

WARNING! REMOVAL OF THE PATIENT SENSOR OR INLET SENSOR FROM THE CIRCUIT TO REPLACE THE ADAPTER WILL RESULT IN MADM™ DISCONTINUING THE DELIVERY OF ANESTHETIC. THIS SHOULD ONLY BE DONE AT THE POINT IN THE OPERATION WHERE ANESTHETIC DELIVERY CAN BE DISCONTINUED FOR 30 SECONDS OR MORE.

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12. Alarms

Alarm Description

There are three alarm priorities: low, medium and high. In the low and medium priority alarm conditions, the system can still deliver anesthetic, but the user should take some action to resolve the low and medium alarm conditions. For high-priority alarms, delivery of anesthetic is not possible due to a physical condition or an unsafe condition for the patient. For warnings, an amber LED blinks and sound is generated in sync with the blinking. For errors, a red LED blinks and sound is generated in sync with the blinking. The buzzer complies with IEC60601-1-8 2012 2.1b requirements for multitones and loudness.

Highest Alarm Priority	LED	Audio Tone Sequence
No alarms	Green only	Off
Low	Solid Amber only	Off
Medium	Amber only (blink rate = 1 Hz, 50% duty cycle)	C-D-G (can be muted for up to 120s)
High	Red only (blink rate = 2.5 Hz, 50% duty cycle)	C-D-G – C-D (can be muted for up to 120s)

Table 23: Alarm Description

NOTE: *To mute all alarms temporarily (120 seconds), press the [MUTE/ENTER] key (the key on top of the device and closest to the back) once.*

NOTE: *There are no operator-adjustable alarms. See the table in the following section, Alarm Causes and Corrections on page 78, for all pre-set alarm limits. No change in these pre-set limits occurs after power loss.*

WARNING! SOUND PRESSURE LEVELS OF AUDITORY ALARM SIGNAL THAT ARE LESS THAN AMBIENT LEVELS CAN IMPEDE OPERATOR RECOGNITION OF ALARM CONDITIONS.

Safety Interlock

When an error condition occurs, or in the absence of a positive determination that no errors are present, MADM™ initiates a safety interlock preventing the device from delivering anesthetic. This interlock involves preventing the solenoids from opening to allow anesthetic to move from the canister to the system, disabling the heater, and prohibiting the anesthetic delivery pump from operating.

Verification of the Alarm System

The alarm system can be verified by disconnecting the Anesthetic and CO_2 sensor from MADM™ or ejecting the canister. Both of these actions will cause a high priority alarm, including an audio signal and flashing LEDs. These indicators will be active until the alarm-generating condition or conditions are resolved.

Alarm Causes and Corrections

The following table lists all error and warning alarms displayed by MADM™ and their possible cause(s) and suggests the action(s) to be taken to correct them.

***NOTE:** If an alarm or message persists after all suggested actions have been taken, return MADM™ to qualified service personnel for servicing.*

***NOTE:** If there is a discrepancy between the alarm state displayed on the screen and the alarm state as reported by the LEDs, the alarm state report displayed by the LEDs should be considered accurate, and device operation should be discontinued as soon as possible.*

Table 24: Alarm Causes and Corrections

Alarm Message	Location	Cause	Delay	Action
HIGH PRIORITY ALARMS				
1. Internal Fault 1 (*Error Code*) 6	Device 6	Unspecified internal device fault detected.	< 5s	• Power cycle the device. • Retry Self-Check.
2. Internal Fault 2 (*Error Code*)	Device 6	Unspecified internal device fault detected.	< 5s	• Power cycle the device. • Retry Self-Check.
3. Device Tilted > 30˚	Device 6	Device tilted at angle exceeding 30˚ from normal.	< 5s	• Power cycle the device. • Retry Self-Check. • Place device on a flat surface.
4. Critical SEVO% At Mouth (> 5.5%)	FIA SEVO Display 10	Concentration of SEVO at patient sensor too high.	1 breath	• Reduce device anesthetic delivery set point. • Flush patient circuit with fresh gas.
5. Critical ISO% At Mouth (> 4.0%)	FIA ISO Display 9	Concentration of ISO at patient sensor too high.	1 breath	• Reduce device anesthetic delivery set point. • Flush patient circuit with fresh gas.
6. Unsupported Agent Detected	MAC Display 13	Anesthetic agent other than SEVO and ISO detected by device.	1 breath	• Flush patient circuit with fresh gas. • Replace patient circuit.
7. Patient Sensor Fault (*Error Code*)	Patient Sensor 5	Patient sensor fault detected by device.	< 5s	• Power cycle the device. • Retry Self-Check. • Replace patient sensor.
8. Patient Sensor: Adapter Missing	Patient Sensor 5	Patient circuit adapter on patient sensor missing.	< 5s	Replace sensor adapter.
9. Patient Sensor: Unsupported Model	Patient Sensor 5	Patient sensor model not supported.	< 5s	Replace patient sensor with model approved for use MADM™.
10. Unrecognized Canister Type	Canister 3	Anesthetic gas canister not recognized by device.	< 5s	• Remove agent canister from device and reinstall. • Remove agent canister and reinstall a different canister.

Alarm Message	Location	Cause	Delay	Action
11. Airway Tubes Backwards	Ventilator 8	Ventilator connected to device backwards.	1 breath	Disconnect ventilator tubes from device and connect tubes as indicated on device or in manual.
12. Inlet Sensor Fault (*Error Code*)	Inlet Sensor 7	Inlet sensor fault detected by device.	< 5s	• Power cycle the device. • Retry Self-Check.
13. Inlet Sensor: Adapter Missing	Inlet Sensor 7	Patient circuit adapter on inlet sensor missing.	< 5s	Replace sensor adapter.
14. Inlet Sensor: Unsupported Model	Inlet Sensor 7	Inlet sensor model not supported.	< 5s	• Power cycle the device. • Retry Self-Check.
15. Inlet Sensor: Cal Failed	Inlet Sensor 7	Self-Check/Zeroing of inlet sensor failed.	< 5s	• Power cycle the device. • Retry Self-Check.
16. Patient Sensor: Cal Failed	Patient Sensor 5	Self-Check/Zeroing of patient sensor failed.	< 5s	• Power cycle the device. • Retry Self-Check. • Replace patient sensor.
17. Flow Sensor Fault	Device 6	Flow sensor fault detected by device.	< 5s	• Power cycle the device. • Retry Self-Check.
18. Patient Sensor: Disconnected	Patient Sensor 5	Patient sensor disconnected from device.	< 5s	• Fully disconnect and reconnect the patient sensor to the device. • Fully disconnect the patient sensor and reconnect a different patient sensor. • Power cycle the device.
19. Inlet Sensor: Internal Fault	Inlet Sensor 7	Inlet sensor disconnected from device.	< 5s	• Power cycle the device. • Retry Self-Check.
20. Patient Sensor: Fault – Try Re-Cal	Patient Sensor 5	Patient sensor fault detected by device.	< 5s	• Fully disconnect and reconnect the patient sensor to the device. • Power cycle the device. • Retry Self-Check. • Replace patient sensor.
21. Inlet Sensor: Fault – Try Re-Cal	Inlet Sensor 7	Inlet sensor fault detected by device.	< 5s	• Power cycle the device. • Retry Self-Check.
22. FIA exceeds FIA set (High Priority)	FIA ISO Display 9 or SEVO Display 10	Concentration of anesthetic agent at patient sensor too high (> 0.5% absolute or > 25% of target, whichever is greater).	1 breath for steady state 45s after a decrease in dial setting	• Reduce device anesthetic delivery set point. • Flush patient circuit with fresh gas.

Alarm Message	Location	Cause	Delay	Action
23. Canister Not Detected	Canister 3	Anesthetic agent canister not detected by MADM™.	< 5s	• Fully install anesthetic agent canister into MADM™. • Remove agent canister and reinstall a different canister.
24. Patient Sensor: Replace Adapter	Patient Sensor 5	Patient circuit adapter on patient sensor is dirty or broken.	< 5s	• Replace sensor adapter. • Replace patient sensor.
25. Inlet Sensor: Replace Adapter	Inlet Sensor 7	Patient circuit adapter on inlet sensor is dirty or broken.	< 5s	• Replace sensor adapter.
26. Internal Battery Level Critically Low	Battery 1	Device internal battery is insufficient to continue delivery.	< 5s	• Plug device into wall. • Return device for servicing.
27. Purge Limit Exceeded	Device 6	Internal reservoir of anesthetic has been exceeded.	< 5s	• Power cycle the device. • Retry Self-Check.
28. Illegal Delivery Detected	Device 6	Pump delivering more anesthetic than expected.	< 5s	• Turn dial to OFF.
MEDIUM PRIORITY ALARMS				
1. Agent Underdelivery	FIA ISO Display 9 or SEVO Display 10	FIA of Canister Anesthetic Agent Type is below dial setpoint by ≥ 0.2% absolute and 20% relative for at least one minute.	1 breath	• Reduce device anesthetic delivery set point. • Ensure device, including patient sensor, is set up and connected to the patient as intended for normal use. • Check patient circuit for loose connections and leaks.
2. FIA Exceeds FIA Set (Medium Priority)	FIA ISO Display 9 or SEVO Display 10	Concentration of anesthetic agent at patient sensor too high (> 0.2% absolute and 15% relative to setpoint).	1 breath	• Reduce device anesthetic delivery set point. • Flush patient circuit with fresh gas.
3. Detected Agent Mismatch for Canister	Patient Sensor 5	Anesthetic agent detected by device does not match agent canister.	1 breath	• Flush patient circuit with fresh gas. • Replace patient circuit. • Remove agent canister from device and reinstall. • Remove agent canister and reinstall a different canister.
4. Device In Expiratory Limb	Ventilator 8	Device has detected unscrubbed exhaled gas, which indicates it is placed in the expiratory limb.	45s	• Install device in inspiratory limb. • Ensure scrubber is installed in circle system.

Alarm Message	Location	Cause	Delay	Action
5. Patient Sensor: Re-Cal Reqd	Patient Sensor 5	Patient sensor requires zeroing.	< 5s	• Power cycle the device. • Retry Self-Check. • Replace patient sensor.
6. Agent Level in Canister Low	Canister 3	Anesthetic agent level in canister low.	< 5s	Refill or replace anesthetic agent canister.
7. Inlet Sensor: Re-Cal Reqd	Inlet Sensor 7	Inlet sensor requires zeroing.	< 5s	• Power cycle the device. • Retry Self-Check.
8. Maximum Delivery Rate Exceeded	Device 6	Minute ventilation measured by device exceeds upper alarm limit.	60s	• Reduce Fresh Gas flow, ventilation rate, or target anesthetic level.
9. Internal Battery Failure	Battery 1	Failure detected with device battery.	< 5s	• Power cycle the device. • Retry Self-Check.
10. Internal Battery Level Low	Battery 1	Device battery charge level is low.	< 5s	Connect wall power to power device and charge battery.
11. Patient Sensor: Unspec Acc	Patient Sensor 5	Potential inaccurate measurement from patient sensor.	< 5s	• Power cycle the device. • Move sources of radio frequency interference (e.g., mobile phones) away from Patient Sensor • Retry Self-Check. • Replace sensor adapter. • Replace patient sensor.
12. Inlet Sensor: Unspec Acc	Inlet Sensor 7	Potential inaccurate measurement from patient sensor.	< 5s	• Replace sensor adapter. • Power cycle the device. • Retry Self-Check
13. Vent Waveform Not Detected	Ventilator 8	Ventilation waveform not detected.	< 5s	• Ensure device is set up and connected to the patient as intended for normal use. • Check patient circuit for loose connections and leaks. • Ensure Ventilator is on, or patient is being ventilated through MADM™.
14. Both SEVO and ISO Detected	Patient Sensor 5	Device detects both SEVO and ISO in patient circuit in quantities above 0.15%.	1 breath	• Flush patient circuit with fresh gas. • Replace patient circuit.
15. Internal Temperature Too High	Device 6	Internal temperature is greater than 42°C	< 5s	• Move MADM™ to a cooler location.

Alarm Message	Location	Cause	Delay	Action
16. Patient Sensor: Circuit Disconnect	Patient Sensor 5	Patient breathing not detected.	20s	• Ensure device, including patient sensor, is set up and connected to the patient as intended for normal use. • Check patient circuit for loose connections and leaks. • Replace patient sensor. • Clinical intervention required.
17. Unknown Barometric Pressure	Device 6	Internal barometric pressure sensor mismatch.	< 5s	• Power cycle the device. • Retry Self-Check. • Replace patient sensor.
LOW PRIORITY ALARMS				
1. Operating On Internal Power	Plug 2	Device is not connected to wall power.	< 5s	Connect wall power to device.
2. Internal Fault, Service Soon	Device 6	Unspecified internal device fault detected.	< 5s	• Power cycle the device. • Retry Self-Check.
3. Internal Tilt Sensor Fault	Device 6	Failure detected with device tilt sensor. Device may not detect and alarm if tilted.	< 5s	• Power cycle the device. • Retry Self-Check.
4. Inlet/Flow Sensors: Cal Skipped	Inlet Sensor 7	Inlet and flow sensor Self-Check/Zeroing has been skipped by user.	< 5s	• Power cycle the device. • Retry Self-Check.
5. Patient Sensor: Cal Skipped	Patient Sensor 5	Patient sensor Self-Check/Zeroing has been skipped by user OR patient sensor has been disconnected and reconnected.	< 5s	• Connect patient sensor to device. • Power cycle the device. • Retry Self-Check.
6. Flow Sensor: Using Default Cal	Device 6	Flow sensor has not been zeroed through the Startup Self-Check.	< 5s	• Power cycle the device. • Retry Self-Check.
7. Dial Beyond Maximum Allowable	FIA Set 14	Device dial is set beyond the maximum safe concentration for the agent detected in the canister.	< 5s	Turn dial down to allowable setting.
8. N2O Detected	MAC Display 13	N2O detected in circuit.	< 5s	• Information only, N2O not included in MAX calculation. • To eliminate N2O, flush circuit.
9. Dial Setting May Be Inaccurate	FIA Set 14	Potential misalignment of dial.	< 5s	• Use displayed dial setting on GUI. • Power cycle the device. • Retry Self-Check.
10. Internal Battery Level Low	Battery 1	Device battery charge level is low.	< 5s	• Wait for battery to charge.

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13. Servicing and Maintenance

Servicing and Maintenance While Connected to the Patient

Except for replacement of inlet and airway sensor adapters, and filling the anesthetic canister, no other maintenance or servicing (including the functional test outlined below) may be performed while the device is connected to a patient.

System Inspection and Functional Test

The Startup Self-Check should be performed prior to connecting each patient. If desired, system inspection and limited functional testing can be performed as follows:

1. Visual inspection, including the agent specific filling system and canister detection. Confirm that there is no damage, tears or holes in the device or device components.
2. Disconnect wall plug and confirm device operates on internal battery power; reconnect plug and confirm device operates on wall power.
3. Connect a flow-controlled gas source (air or oxygen) to the system inlet and set to a constant flow of 2 to 5 LPM. Set target anesthetic dial to 1.5% and measure output concentration. To measure the output gas concentration, attach patient tubing to the system outlet and attach the mouth sensor to the end of the tubing.
4. After 60 seconds, confirm that MADM™ does not display any overdelivery or underdelivery alarms.

NOTE: *In the absence of patient-generated CO_2, the performance of the MADM™ must be evaluated with a constant gas flow and not with a ventilator, as described above.*

System Maintenance

MADM™ is designed for easy maintenance. Refer to the MADM™ Service Manual for periodic maintenance instructions. MADM™ can only be serviced by authorized and qualified service personnel.

If MADM™ is subjected to extremely rough handling, environmental stress, or sustains damage, it must be referred to authorized and qualified service personnel for inspection and/or repair.

Devices in long term storage should have their internal battery recharged annually.

System Cleaning

The external body of the system can be cleaned using standard cleaning agents, including standard hospital-grade cleaning products but excluding oxidizing agents. It is recommended that the external device surfaces be wiped down with isopropyl alcohol after each use.

External surfaces of MADM™ can be wiped clean with one of the following:

- Isopropyl Alcohol
- Chlorine Compounds*****
    - Maximum Concentration: 1:10

*******These compounds are diluted by volume in water.*

If the device becomes contaminated by direct exposure to exhaled gas without the protection of a patient filter (specifically when used in a closed circuit configuration), the MADM™ should be forwarded to qualified service personnel immediately. In addition, all consumable components must be replaced.

System Block Diagram

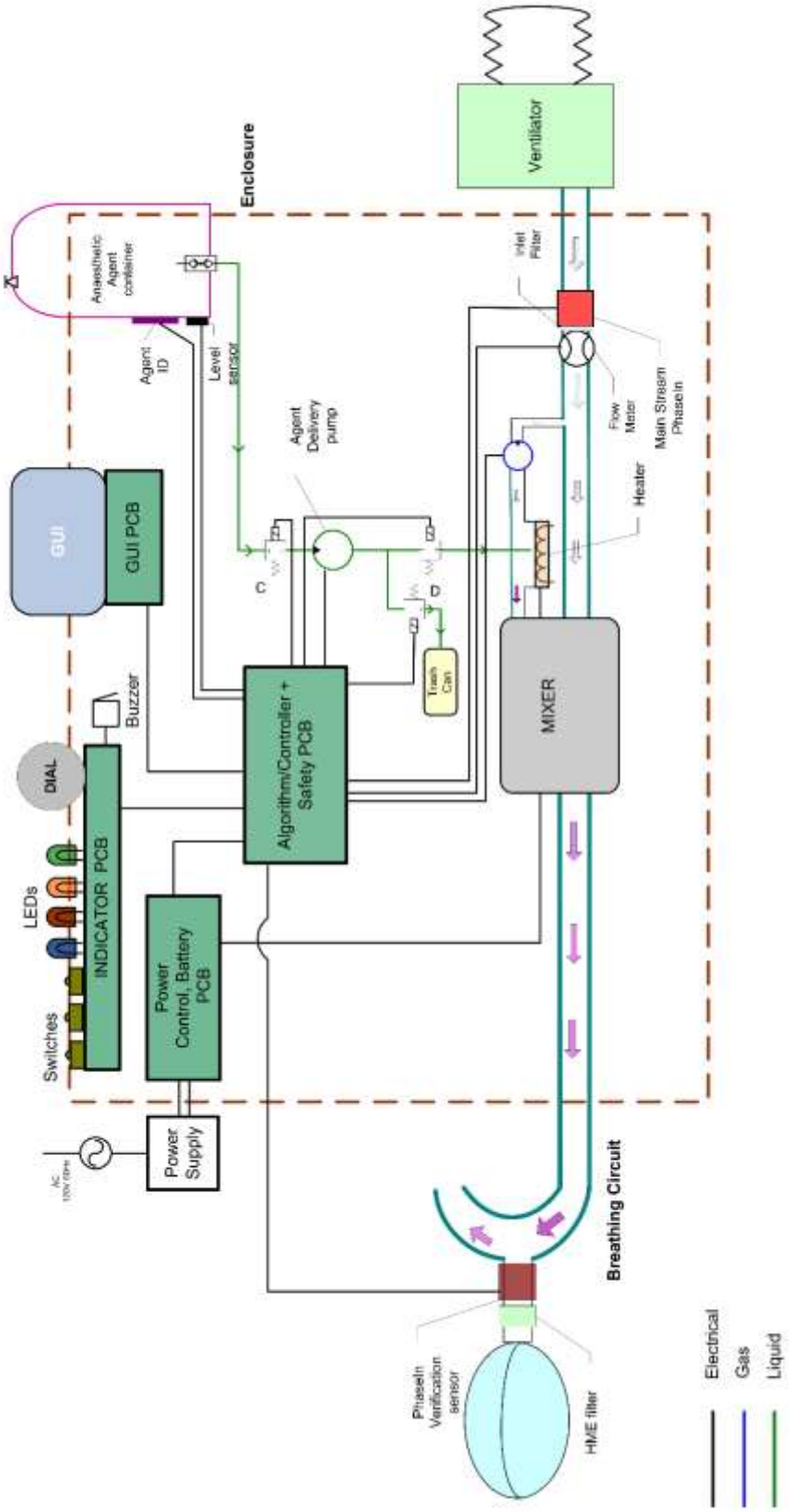

Figure 41: System Block Diagram

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