Operation Manual
MGU-810 series
Multigas Unit

CE 0086

FUKUDA DENSHI CO.,LTD.
3-39-4 Hongo, Bunkyo-ku, Tokyo, Japan
Phone:+81-3-5684-1455 Fax:+81-3-3814-1222

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CE 0086

This device bears the CE label in accordance with the provisions of Medical Device Directive 93/42/EEC.

This device bears the CE label in accordance with the provisions of RoHS Directive 2011/65/EU.

EC REP Fukuda Denshi UK
Unit 7, Genesis Business Park, Albert Drive, Woking, Surrey GU21 5RW, United Kingdom

Thank you for purchasing our product.
Read the "Safety Precaution" thoroughly before use to ensure correct and safe use of the product.
Please also refer to the operation manual of the DS-8500 System Patient Monitor, which the MGU-810 is connected to.

Safety Precautions

Make sure to follow the precautions indicated below, as these are important messages related to safety. The followings are descriptions and graphic symbols of the safety and precaution messages used in this manual.

⚠DANGER	Failure to follow this message may cause immediate threat of death or serious injury.
⚠WARNING	Failure to follow this message may result in death or serious injury.
⚠CAUTION	Failure to follow this message may cause injury or failure to the equipment.
NOTE	A note is not related to product safety, but provides information about the correct use and operating procedures to prevent incorrect operation and malfunction of the equipment.

⚠DANGER

- Never connect the MGU-810 to other than the specified patient monitor. Danger such as electric shock may result to the patient and operator.
- Never operate the MGU-810 in the presence of flammable anesthetics, high concentration of oxygen, or inside hyperbaric chamber. Also, do not operate the equipment in an environment in which there is a risk of explosion.

  Explosion or fire may result.

⚠WARNING

- Do not use the MGU-810 is under an environment not fulfilling the specified condition. If is used, not only that the module cannot deliver its maximum performance, the module may be damaged and safety cannot be ensured.
- Do not use the MGU-810 in magnetic resonance imaging (MRI) environments.
- Connection of the MGU-810 exhaust outlet to the hospital's waste gas scavenging system is strongly recommended to prevent exposure of hospital personnel to the patient's respiratory sample.

⚠CAUTION (For USA)

Federal Law restricts this device to sale by or on the order of a physician.

⚠CAUTION

Precautions for Safe Operation of Medical Electrical Equipment
Read the following precautions thoroughly to correctly operate the equipment.

- Users should have a thorough knowledge of the operation before using this equipment.
- Pay attention to the following when installing and storing the equipment.
  - Do not install or store in an area where the equipment will be subject to splashing water.
  - Do not install or store in an area where the environmental conditions, such as atmospheric pressure, temperature, humidity, ventilation, sunlight, dust, sodium, sulfur, will adversely affect the equipment.
  - Place the equipment on a stable surface where there is no inclination, vibration, or shock (including during transportation).
  - Do not install or store in an area where chemicals are stored or gasses are evolved.
- Before operating the equipment, verify the following items.
  - Check the cable connection and polarity to ensure proper operation of the equipment.
  - Make sure the power system has adequate earth ground.
  - Ensure that all cables are firmly and safely connected.
  - Pay special attention when the equipment is used in conjunction with other equipment as it may cause erroneous judgment and danger.
- During operation of the equipment, verify the following items.
  - Always observe the equipment and patient to ensure safe operation of the equipment.
  - If any abnormality is found on the equipment or patient, take appropriate measures such as ceasing operation of the equipment in the safest way for the patient.
  - Do not allow the patient to come in contact with the equipment.
- After using the equipment, verify the following items.
  - When unplugging the cables, do not apply excessive force by pulling on the cable. Pull from the connector part of the cable.
  - Clean the accessories and cables, and keep them together in one place.
  - Keep the equipment clean to ensure proper operation for the next use.
- If the equipment is damaged and in need of repair, user should not attempt service. Label the equipment "OUT OF ORDER" and contact Fukuda Denshi.
- Do not remodel the equipment.
- Maintenance Check
  - Make sure to periodically check the equipment, accessories and cables.
  - Before reusing the equipment that has been left unused for a while, make sure that the equipment works normally and safely.
- Regarding the DS-8500 System Patient Monitor, which the MGU-810 is connected to;
  - Use only the accessories specified for the system. Otherwise, proper function of the system cannot be executed.
  - For quality improvement, specifications are subject to change without prior notice.
  - The system is intended to be used for only one patient.
  - The installation of the system should be performed by our service representative or a person who is well acquainted with the system.
  - If it is not used for a long period, make sure to turn OFF the power of the main unit.

For additional warnings, cautions or contraindications when using the DS-8500 system with the MGU-810, refer to the DS-8500 operation manual.

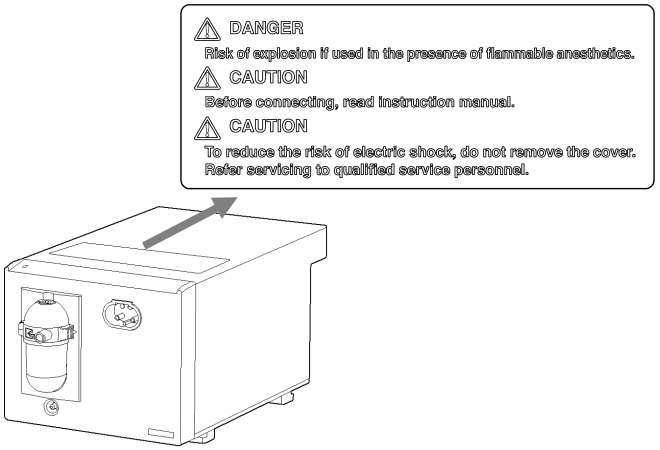
Warning Label

Make sure to read the warning label attached to the equipment and comply with the requirements while operating the equipment.

⚠CAUTION

- Do not damage or erase the warning label attached to the equipment.
- The warning label contains important descriptions for handling and operating the equipment properly and safely. A damaged label may compromise safe operation.

MGU-811P



Graphic Symbols

The following are the symbols and their meaning indicated on the equipment.

Symbol	Description
	Caution; refer to accompanying documents Indicates the need to refer to related accompanying documents before operation.
	Type BF Applied Part with Defibrillation-Proof Indicates the degree of protection against electric shock which is Type BF Applied Part with defibrillation-proof.
	GAS Output Indicates the position where it exhausts the sampling gas.
	Year of Manufacture Indicates the manufactured year.
	WEEE (Waste Electrical and Electronics Equipment) Indicates a separate collection for electrical and electronic equipment.

General Description

The MGU-810 series is a sidestream gas measuring unit. The following model types are available according to the different measurement parameters.

Model Type	CO_2/N_2O	Agent GAS Measurement	O_2 Measurement	Spirometry
MGU-811P	Yes	Yes	Yes*	Yes
MGU-812	Yes	Yes	No	Yes
MGU-813	Yes	No	No	Yes

* with the Servomex Paramagnetic Oxygen Sensor

This equipment is used for the specified patient monitor. The contents to be displayed differ depending on the connected patient monitor, thus refer to the patient monitor's operation manual, the DS-8500 System.

Features

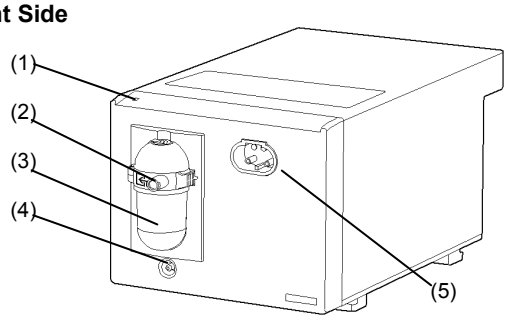
- Automatically detects the type of anesthetic gas for monitoring.
- With the sidestream method, the patient connection part is smaller, lighter and quieter.
- CO_2, N_2O, five anesthetic agents (Halothane, Isoflurane, Sevoflurane, Enflurane, and Desflurane), and O_2 concentration can be measured.
- Model types with/without the Agent GAS measurement and/or O_2 measurement is available.
- O_2 measurement uses a paramagnetic method.
- Spirometry with the flow sensor allows measuring the Airway Pressure, Tidal Volume, Airway Flow, Minute Volume, Airway Compliance, Airway Resistance, and I:E ratio.

Name of Parts and Their Functions

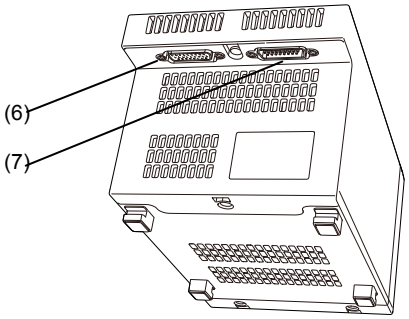
⚠WARNING

Do not connect a unit or cable not authorized by Fukuda Denshi to any I/O connector. If done so by mistake, the equipment cannot deliver its maximum performance and the connected units may be damaged, resulting in a safety hazard.

Front Side



Rear Side



(1) Power Supply Indicator
Indicates the power status.
Green : Power is supplied to the MGU-810.
Light Off : When the power of the DS-8500 System, which is connected to the MGU-810, is OFF, or the power supply indicator on the display unit is orange (in standby mode).

(2) Inlet
Connects the gas sampling line of the SPRIT™ Flow Sensor.

(3) DRYLINE™ Water Trap (with container)
Removes water inside the sampling tube connected to the patient. Empty the water trap container when it is half full. When connecting to a new patient, clean it with the specified disinfect solution (refer to the "Cleaning" below). When removing the water trap, press the side buttons.

(4) Exhaust Outlet
Connects gas exhaust system and exhausts sampling gas.

(5) Flow Sensor Connector
Connects the pressure line of the SPRIT™ Flow Sensor.

(6) External Equipment Connector 2
Connects the HR-800 Recorder Unit via the unit connection cable.

(7) External Equipment Connector 1
Connects to the DS-8500 System via the unit connection cable.

Connection Procedures

For more detail about how to connect a respiration circuit and the calibration procedure, refer to the operation manual of the patient monitor, the DS-8500 System.

The following connection cables are available depending on the installation.

Model Type	Length
CJO-09SS0.3	0.3m
CJO-09SS1.5	1.5m
CJO-09SS5	5m

⚠WARNING

Use only the cables specified by Fukuda Denshi.
Not only the MGU-810 cannot deliver its maximum performance but may also result in increase in emission or decrease in immunity.

⚠CAUTION

- Make sure that the power of the DSC-8500 Main Unit is turned OFF when connecting/disconnecting the connection cable.
- When connecting with the unit connection cable, make sure to secure the connector with screws.

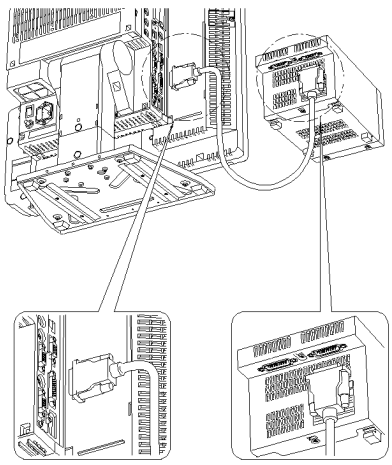
⚠CAUTION

Precautions about the Operating Environment

- The following environmental conditions should be observed when operating the equipment.
  Ambient Temperature: 10 to 35°C
  Relative Humidity :30 to 85% (non-condensing)
- The power is supplied from the patient monitor. Read the patient monitor's operation manual and then connect the connection cable properly.
- Pay attention when installing or storing the equipment. Do not install or store in the following locations.
  - where chemicals are stored or gas may evolved
  - where the equipment will be subject to splashing water or humidity from a nebulizer or vapolizer
  - where the equipment will be subject to direct sunlight
  - unstable place with inclination, vibration, or shock

How to Connect the DSC-8500 series Main Unit and the MGU-810

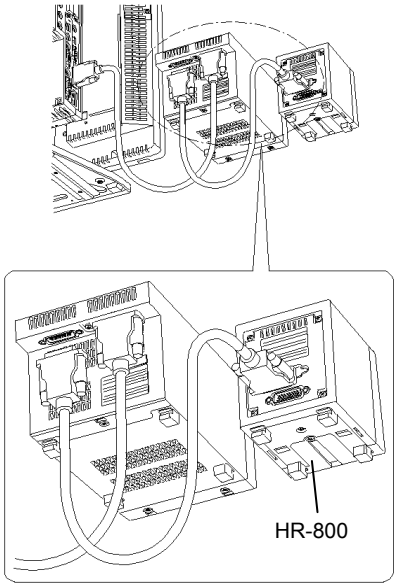
1 Connect the main unit (DSC-8500 series) and MGU-810 using the unit connection cable (CJO-09SSxx).



How to Connect the DSC-8500 series Main Unit with the MGU-810 and HR-800

1 Connect the DSC-8500 series Main Unit and the MGU-810 with the unit connection cable (CJO-09SSxx).

2 Connect the MGU-810 and the HR-800 with the unit connection cable (CJO-09SSxx).



Settings on the Patient Monitor

To use the MGU-810, the setting, such as "External Device Connection Setup under Initial Settings", on the DS-8500 System is required.
For more details, refer to the operation manual of the patient monitor, the DS-8500 System.

Measurement Accuracy

In order to perform accurate measurement, follow the precautions below.

⚠CAUTION

- Before measurement, make sure to warm up the unit for more than 10 minutes.
- Make sure to secure the connection between this unit and the sampling line, or the airway adaptor so that the gas will not leak.

Accuracy Check of Gas Measurement

In order to maintain the measurement accuracy, make sure to perform the accuracy check of gas measurement once a year. When performing the accuracy check, follow the precautions below.

⚠CAUTION

- Before the accuracy check, make sure to warm up the unit for more than 10 minutes.
- Make sure to use the specified calibration gas which is within the expiration date. The measurement accuracy will decrease if a low pressure gas is used.

Manual Zero Calibration

On the patient monitor, a zero calibration for the multigas measurement is periodically performed, but it can also be performed manually when necessary.

For the measurement range and accuracy of each parameter, refer to the "Specification" section below.

Troubleshooting

For troubleshooting, refer to the operation manual of the patient monitor, the DS-8500 System.

Maintenance

Maintenance Check

To ensure safety reliability and high performance of the MGU-810 series, make sure to perform a daily check according to the Daily Check List on the operation manual of the DS-8500 System.

For the details, refer to the operation manual of the patient monitor, the DS-8500 System.

⚠WARNING

Be aware that Fukuda Denshi is not liable of any accidents arising from lack of daily check.

Periodic Replacement

To ensure safety reliability, function, and performance of this equipment, the following components must be replaced periodically. When replacing, contact our service representative.

DRYLINE™ Water Trap	Periodic Replacement Period: 1 month
DRYLINE™ Receptacle	Periodic Replacement Period: 1 year

Cleaning

Cleaning the Housing

1 Wipe the housing using tightly squeezed cloth that is soaked with a neutral liquid detergent or water.
2 Clean using a cloth dampened with alcohol.
3 Wipe the housing using a smooth cloth and then dry it completely.

⚠CAUTION

- Clean the equipment frequently so stains can be removed easily.
- To prevent injury, it is recommended to wear gloves when cleaning the equipment.
- Do not open the housing.
- Do not allow liquids or cleaning solution to enter the equipment or connectors.
- Do not use organic solvents, thinner, toluene or benzene to avoid damaging the resin case.
- Do not polish the housing with abrasive or chemical cleaner.
- When sterilizing the entire room using a spray solution, pay close attention not to have liquids get into the equipment or connectors.
- Use only neutral detergent to clean the housing. The surface resin coating may be damaged, resulting in discoloration, scratches, and other problems.
  Do not use chemical cloth, scrub brush, abrasive, polishing powder, hot water, volatile solvent and chemicals (cleanser, thinner, benzine, benzol, and synthetic detergent for house and furniture), or sharp-edged tools.

Cleaning the Water Trap

⚠CAUTION

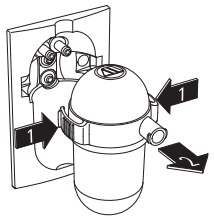
- Do not use other cleaning methods.
- Do not clean or wash the filter housing of the water trap.
- Never allow alcohol to enter the filter housing.
- Never force air through the water trap.

When connecting to a new patient, empty the water trap container and it shall be hand washed and disinfected. Suitable disinfectants are:

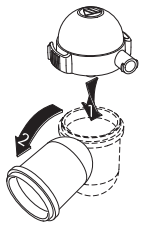
- Ethanol 70%, Methanol 70% or Isopropanol 70%
- Glutaraldehyde (e.g. Cidex™)
- Chlorhexidine/ethanol (e.g. Hibitane™)
- Hypochlorite solution (e.g. Clorox™)

If disinfectants and/or detergents are used, make sure that the container is thoroughly rinsed with water. Dry the container before use.

1 To remove the water trap from its receptacle, press the lugs on the sides of the trap and pull out.



2 To empty the water trap, twist the container relative to the filter housing.

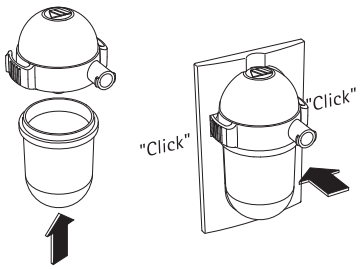


⚠WARNING

The contents of the water trap should be handled as a potential infection hazard.

3 Empty the container and clean it with specified disinfect solution.

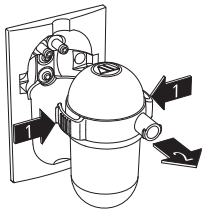
4 Re-install the water trap.



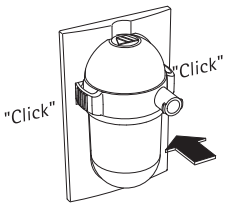
Replacing the Water Trap

The water trap on the MGU-810 collects fluids from the sampling tube connected to the patient.
Replace the water trap once a month, or when the “Replace Water Trap” message appears on the patient monitor screen.

1 To remove the water trap from its receptacle, press the lugs on the sides of the trap and pull out



2 Install the new water trap to the MGU-810.



Specification

Size

125(W) x 109(H) x 200(D) mm (not including the protrusion)

Weight

MGU-811P : 2.2kg (not including the accessory)
MGU-812 : 1.8kg (not including the accessory)
MGU-813 : 1.8kg (not including the accessory)

Environmental Conditions

Operation Temperature : 10 to 35°C
Operation Humidity : 30 to 85 % (non-condensing)
(Inside airway: 0 to 100%, condensing)
Transport/Storage Temperature : -10 to 60°C
Transport/Storage Humidity : 10 to 95% (at 40°C) (non-condensing)
Storage Ambient Pressure : 700 to 1060hPa

Safety

General Standard (with DS-8500 System):
EN 60601-1: 1990+A1: 1993+A2: 1995
IEC 60601-1: 1988+A1: 1991＋A2: 1995
(Medical electrical equipment - Part 1: General requirements for safety)
EN 60601-1-1: 2001
IEC 60601-1-1: 2000
(Medical electrical equipment – Part 1-1:General requirements for safety– Collateral standard: Safety requirements for medical electrical systems)
EMC Standard (with DS-8500 System):
EN 60601-1-2: 2007
IEC 60601-1-2: 2007
(Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility Requirements and tests)
Type of protection against electric shock:
Class I Equipment (with DS-8500 System)
Degree of protection against electric shock:
Type BF Applied Part
Protection against defibrillation discharge:
Provided
Operation Mode:
Continuous Operating Equipment
Degree of protection against ingress of water:
IPX0 (no protection)
Protection against ignition of flammable gas:
Not provided

Power Supply

Voltage : DC 18V
(Supplied from the DSC-8500 series Main Unit.)

Usable Life

6 years : According to self-certification
Refer to the above “Maintenance Periodic Replacement” for parts requiring periodic replacement.

Sampling Flow and Accuracy

Flow Range : 70 to 200mL/min
Accuracy : ±10mL/min or ±10%, whichever is greater

System Response Time

< 4 sec.
(Includes sampling delay and response time when using the sampling line shorter than 2.5m.)

Warm-Up Time

ISO Accuracy : 45 sec.
Full Accuracy : 10 min.

Auto Zeroing Interval

ISO Accuracy : 30 sec.
Full Accuracy : 4 hours

Measurement Method

CO_2, N_2O, Agents:
Sidestream, Non-dispersive infra-red (NDIR) technology
O_2: Paramagnetic oxygen technology (MGU-811P only)

CO_2

Measurement Range : 0 to 10.0vol%
(0 to 76mmHg, 0 to 10kPa)
Measurement Rise Time: 250ms
Accuracy
0 to 1% of Volume : ±0.1% of Reading*
1 to 5% of Volume : ±0.2% of Reading*
5 to 7% of Volume : ±0.3% of Reading*
7 to 10% of Volume : ±0.5% of Reading*
>10% of Volume : Unspecified
Interference from other gases
O_2 : 0.1% of Reading
N_2O : 0.1% of Reading
Any agent : 0.3% of Reading
Threshold : 0.1vol% (0.3% during ISO accuracy mode)
(0.0% is displayed if value is < 0.1 %.)

Respiration Rate

Resp. Detection : >1.0vol% change in CO_2 level
Measurement Range : 0, 2 to 100Bpm
Accuracy : ±1Bpm @ < 60Bpm
Unspecified @ >60 Bpm

O_2（MGU-811P only）

Measurement Range : 0 to 100vol%
Measurement Rise Time : 500ms (@200mL/min)
: 600ms (@120mL/min)
Accuracy
0 to 25% of Volume : ±1% of Reading*
25 to 80% of Volume : ±2% of Reading*
80 to 100% of Volume : ±3% of Reading*
Interference from other gases
CO_2 : 0.2% of Reading
N_2O : 0.2% of Reading
Any Agent : 1.0% of Reading

N_2O

Measurement Range : 0 to 100vol%
Measurement Rise Time : 250ms
Accuracy
0 to 20% of Volume : ±2% of Reading*
20 to 100% of Volume : ±3% of Reading*
Interference from other gases
CO_2 : 0% of Reading
O_2 : 0% of Reading
Any agent : 0% of Reading
Threshold : 3vol% (3% during ISO accuracy mode)
(0.0% is displayed if value is < 3%.)

Anesthetic agents

Measurement Range
Halothane, Enflurane, and Isoflurane : 0 to 5vol%
Sevoflurane : 0 to 8vol%
Desflurane : 0 to 18vol%
Measurement Rise Time :
Halothane, Isoflurane, Sevoflurane, and Desflurane : 300ms
Enflurane : 350ms
Accuracy
Halothane, enflurane, and isoflurane
0 to 1% of Volume : ±0.15% of Reading*
1 to 5% of Volume : ±0.2% of Reading*
>5% of Volume : Unspecified
Sevoflurane
0 to 1% of Volume : ±0.15% of Reading*
1 to 5% of Volume : ±0.2% of Reading*
5 to 8% of Volume : ±0.4% of Reading*
>8% of Volume : Unspecified
Desflurane
0 to 1% of Volume : ±0.15% of Reading*
1 to 5% of Volume : ±0.2% of Reading*
5 to 10% of Volume : ±0.4% of Reading*
10 to 15% of Volume : ±0.6% of Reading*
15 to 18% of Volume : ±1.0% of Reading*
>18% of Volume : Unspecified
Interference from other gases
CO_2 : 0% of Reading
N_2O : 0.1% of Reading
O_2 : 0.1% of Reading
2nd agent : 0.2% of Reading (Typical)
Threshold: Primary agent ID# 0.15% (0.4% during ISO accuracy mode)
Secondary agent ID# 0.3% (0.5% during ISO accuracy mode) or 5% $_{REL}$ (10% $_{REL}$ for Isoflurane) of primary agent if primary agent >10%
For HAL, add 0.1% $_{ABS}$ to threshold values.

*Specification reflects International Standards Organization accuracy conditions:
- Add ±0.3% $_{ABS}$ to inaccuracy for CO_2
- Add ±0.8% $_{REL}$ to inaccuracy of all Agents
- N_2O inaccuracy is ±(8% $_{REL}$ +2% $_{ABS}$)
- O_2 no addition

Spirometry

AWP [cmH_2O]
Measurement Range : -20 to 100 cmH_2O (Adult, Pediatric*)
Accuracy : ±1 cmH_2O (Adult, Pediatric*)
AWF (both direct.) [L/min]
Measurement Range : 1.5 to 100 L/min (Adult), 0.25 to 25 L/min (Pediatric*)
Tidal Volume (insp. and exp.) [mL]
Measurement Range : 150 to 2000 mL (Adult), 15 to 300 mL (Pediatric*)
Accuracy : ±6% or 30 mL, whichever is greater (Adult), ±6% or 4 mL, whichever is greater (Pediatric*)
Minute Volume (insp. and exp.) [L/min]
Measurement Range : 2 to 20 L/min (Adult), 0.5 to 5 L/min (Pediatric*)
Compliance [mL/cmH_2O]
Measurement Range : 4 to 100 m/cmH_2O (Adult), 1 to 100 m/cmH_2O (Pediatric*)
Airway Resistance [cmH_2O/L/s]
Measurement Range : 0 to 40 cmH_2O/L/s (Adult, Pediatric*)
Peak, Plateau, PEEP, and Mean Pressure [cmH_2O]
Measurement Range : -20 to 100 cmH_2O (Adult, Pediatric*)
I:E Ratio
Measurement Range : 1:4.5 to 2:1 (Adult, Pediatric*)

Conditions of use for Stated Accuracy
Respiration Rate : 4 to 35 Bpm (Adult), 4 to 50 Bpm (Pediatric*)
I:E Ratio : 1:4.5 to 2:1 (Adult, Pediatric*)
Intubation Tube : 5.5 to 10 mm (Adult), 3 to 6 mm (Pediatric*)
*Including neonate.

Accessories

⚠CAUTION
- Use only the accessories specified for this device. Otherwise, proper function cannot be executed.
- Do not reuse a disposable product.

Accessories

The standard accessory of this equipment is as follows:

Item	Qty.
Operation Manual (this manual)	1

Optional Accessories

The following products are available as optional accessories. Purchase them as required.

⚠WARNING
- Use only specified sampling devices, such as Water Trap, Flow Sensor, and Receptacle, manufactured by "ARTEMA Medical AB". Refer to the following sampling device list. These accessories may be purchased from Fukuda Denshi or any authorized "ARTEMA Medical AB" distributor.
- The flow sensor is intended for single patient use only, and must not be reused in order to avoid cross infection.
- For additional warnings, cautions or contraindications when using the following sample device with the MGU-810, refer to each sampling device's operation manual.

Sampling Devices (ARTEMA® Model)

Item	Model Type	Description
DRYLINE™ Water Trap, Adult	60-13100-00	Non-sterile
DRYLINE™ Water Trap, Neonate	60-13200-00	Non-sterile
SPRIT™ Flow Sensor, Adult	60-16100-00	Single use only
SPRIT™ Flow Sensor, Pediatric	60-16200-00	Single use only

Other

Item	Model Type	Description
Exhaust Line	655-FD	

Electromagnetic Compatibility

The performance of this device under electromagnetic environment complies with EN 60601-1-2 (2007)/IEC 60601-1-2 (2007) (When using with the DS-8500 System).
For the precautions for safe operation under electromagnetic influence and EMC guidance, refer to the operation manual of the DS-8500 System.