

## EVALUATION

# Anesthesia Units for General-Purpose and Low-Acuity/Ambulatory Surgery Applications, Focusing on the Mindray A5 Advantage and A7 Advantage

A Report Excerpted from the *Device Evaluation Website* | June 2021

### Also Includes Ratings and Purchasing Advice for:

Draeger Apollo  
Draeger Fabius GS Premium  
Draeger Fabius Tiro  
Draeger Perseus A500  
GE Aisys CS2  
GE Avance CS2  
GE Carestation 650  
Getinge Flow-c  
Getinge Flow-e  
Maquet FLOW-i C20



## ABOUT THIS REPRINT

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We evaluate a broad range of diagnostic and therapeutic technologies, examining safety, effectiveness, cost, human factors, and other essential elements. We rate products on a scale of one to five stars, with five stars being the highest. We assign ratings based on (1) the criteria we establish and (2) comparison with the performance of similar products on the market. Our criteria and ratings can change as a technology evolves—for example, as a once-groundbreaking feature becomes routinely available and no longer constitutes a purchasing advantage. All of our studies are intensively reviewed by engineering and clinical professionals, both within and outside the organization, before publication.

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- **Patient Safety:** empowering leaders to eliminate patient harm through the dissemination of best practices, guidance, benchmarking, and recommendations.
- **Evidence-Based Medicine:** providing clinical evidence to inform and support decisions on the effectiveness of medical technologies, procedures, genetic tests, and clinical practice guidelines.
- **Technology Decision Support:** arming hospital systems with unbiased insights, so they can optimize their supply chain.

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# EVALUATION

## Anesthesia Units for General-Purpose and Low-Acuity/ Ambulatory Surgery Applications, Focusing on the Mindray A5 Advantage and A7 Advantage

A Report Excerpted from the *Device Evaluation Website* | June 2021

This report focuses on our Evaluations of the Mindray A5 Advantage and A7 Advantage anesthesia units for general-purpose and low-acuity/ambulatory surgery applications. For perspective, it also includes our findings for the other products we evaluated: the Draeger Apollo, Draeger Fabius GS Premium, Draeger Fabius Tiro, Draeger Perseus A500, GE Aisys CS2, GE Avance CS2, GE Carestation 650, Getinge Flow-c, Getinge Flow-e, and Maquet FLOW-i C20.

A summary of our findings is presented below and on the next 10 pages. Our detailed Evaluation results begin on page 13 for the A5 Advantage and on page 25 for the A7 Advantage.

### RATINGS: ANESTHESIA UNITS FOR GENERAL-PURPOSE APPLICATIONS

| Model   | Rating  | Where Marketed | Performance | Safety    | Workflow | Patient Experience | Interoperability | Cyber-security | Maintenance | User Experience | Cost of Ownership (Estimated) over 10 Years |
|---|---|----------------|-------------|-----------|----------|--------------------|------------------|----------------|-------------|-----------------|---|
| <b>Mindray A5 Advantage</b><br>Last updated 11/2020     | ★★★★★   | Worldwide      | Excellent   | Excellent | Good     | Not evaluated      | Good             | Good           | Good        | Good            | Good; \$87,000                              |
| <b>Mindray A7 Advantage</b><br>Last updated 11/2020     | ★★★★★   | Worldwide      | Excellent   | Excellent | Good     | Not evaluated      | Good             | Good           | Good        | Good            | Good; \$100,000                             |
| <b>Draeger Apollo</b><br>Last updated 11/2020           | ★★★★★ WITH CONDITIONS<br>Rating applies only when equipped with optional auxiliary air/oxygen blender | Japan, U.S.    | Excellent   | Excellent | Good     | Not evaluated      | Good             | Good           | Good        | Good            | Good; \$105,000                             |
| <b>Draeger Fabius GS Premium</b><br>Last updated 7/2020 | ★★★★★ WITH CONDITIONS<br>Rating applies only when equipped with optional auxiliary air/oxygen blender | Worldwide      | Good        | Good      | Good     | Not evaluated      | Good             | Good           | Good        | Good            | Good; \$86,000                              |
| <b>Draeger Fabius Tiro</b><br>Last updated 7/2020       | ★★★★★ WITH CONDITIONS<br>Rating applies only when equipped with optional auxiliary air/oxygen blender | Worldwide      | Good        | Good      | Good     | Not evaluated      | Good             | Good           | Good        | Good            | Good; \$76,000                              |
| <b>Draeger Perseus A500</b><br>Last updated 11/2020     | ★★★★★ WITH CONDITIONS<br>Rating applies only when equipped with optional auxiliary air/oxygen blender | Worldwide      | Excellent   | Excellent | Good     | Not evaluated      | Good             | Good           | Good        | Good            | Good; \$119,000                             |
| <b>GE Aisys CS2</b><br>Last updated 11/2020             | ★★★★★ WITH CONDITIONS<br>Rating applies only when equipped with optional ACGO                         | Worldwide      | Excellent   | Excellent | Good     | Not evaluated      | Good             | Good           | Good        | Good            | Good; \$152,000                             |
| <b>GE Avance CS2</b><br>Last updated 11/2020            | ★★★★★ WITH CONDITIONS<br>Rating applies only when equipped with optional ACGO                         | Worldwide      | Excellent   | Excellent | Good     | Not evaluated      | Good             | Good           | Good        | Good            | Good; \$130,000                             |
| <b>GE Carestation 650</b><br>Last updated 7/2020        | ★★★★★ WITH CONDITIONS<br>Rating applies only when equipped with optional ACGO                         | Worldwide      | Excellent   | Good      | Good     | Not evaluated      | Good             | Good           | Good        | Good            | Good; \$118,000                             |
| <b>Getinge Flow-c</b><br>Last updated 3/2021            | ★★★★★ WITH CONDITIONS<br>Rating applies only when unit is equipped with optional AFGO                 | Worldwide      | Excellent   | Excellent | Good     | Not evaluated      | Good             | Good           | Good        | Not evaluated   | Good; \$113,000                             |
| <b>Getinge Flow-e</b><br>Last updated 3/2021            | ★★★★★ WITH CONDITIONS<br>Rating applies only when unit is equipped with optional AFGO                 | Worldwide      | Excellent   | Excellent | Good     | Not evaluated      | Good             | Good           | Good        | Not evaluated   | Good; \$113,000                             |
| <b>Maquet FLOW-i C20</b><br>Last updated 2/2017         | ★★★★★   | Worldwide      | Excellent   | Excellent | Fair     | Not evaluated      | Good             | Not evaluated  | Good        | Fair            | Good; \$100,000                             |

ACGO—auxiliary common gas outlet.

AFGO—auxiliary fresh gas outlet.

**RATINGS: ANESTHESIA UNITS FOR LOW-ACUITY/AMBULATORY SURGERY SETTINGS**

| Model   | Rating  | Where Marketed | Performance | Safety    | Work-flow | Patient Experience | Interoperability | Cyber-security | Maintenance | User Experience | Cost of Ownership (Estimated) over 10 Years |
|---|---|----------------|-------------|-----------|-----------|--------------------|------------------|----------------|-------------|-----------------|---|
| <b>Mindray A5 Advantage</b><br>Last updated 11/2020     | ★★★★☆   | Worldwide      | Good        | Excellent | Good      | Not evaluated      | Good             | Good           | Good        | Good            | Good; \$83,000                              |
| <b>Mindray A7 Advantage</b><br>Last updated 11/2020     | ★★★★☆   | Worldwide      | Excellent   | Excellent | Good      | Not evaluated      | Good             | Good           | Good        | Good            | Good; \$96,000                              |
| <b>Draeger Apollo</b><br>Last updated 11/2020           | ★★★★☆ WITH CONDITIONS<br>Rating applies only when equipped with optional auxiliary air/oxygen blender | Japan, U.S.    | Excellent   | Excellent | Good      | Not evaluated      | Good             | Good           | Good        | Good            | Good; \$98,000                              |
| <b>Draeger Fabius GS Premium</b><br>Last updated 7/2020 | ★★★★☆ WITH CONDITIONS<br>Rating applies only when equipped with optional auxiliary air/oxygen blender | Worldwide      | Good        | Good      | Good      | Not evaluated      | Good             | Good           | Good        | Good            | Good; \$86,000                              |
| <b>Draeger Fabius Tiro</b><br>Last updated 7/2020       | ★★★★☆ WITH CONDITIONS<br>Rating applies only when equipped with optional auxiliary air/oxygen blender | Worldwide      | Good        | Good      | Excellent | Not evaluated      | Good             | Good           | Good        | Good            | Good; \$76,000                              |
| <b>Draeger Perseus A500</b><br>Last updated 11/2020     | ★★★★☆ WITH CONDITIONS<br>Rating applies only when equipped with optional auxiliary air/oxygen blender | Worldwide      | Excellent   | Excellent | Good      | Not evaluated      | Good             | Good           | Good        | Good            | Good; \$114,000                             |
| <b>GE Aisys CS2</b><br>Last updated 11/2020             | ★★★★☆ WITH CONDITIONS<br>Rating applies only when equipped with optional ACGO                         | Worldwide      | Good        | Excellent | Good      | Not evaluated      | Good             | Good           | Good        | Good            | Good; \$146,000                             |
| <b>GE Avance CS2</b><br>Last updated 11/2020            | ★★★★☆ WITH CONDITIONS<br>Rating applies only when equipped with optional ACGO                         | Worldwide      | Good        | Good      | Excellent | Not evaluated      | Good             | Good           | Good        | Good            | Good; \$126,000                             |
| <b>GE Carestation 650</b><br>Last updated 7/2020        | ★★★★☆ WITH CONDITIONS<br>Rating applies only when equipped with optional ACGO                         | Worldwide      | Good        | Good      | Excellent | Not evaluated      | Good             | Good           | Good        | Good            | Good; \$113,000                             |
| <b>Getinge Flow-c</b><br>Last updated 3/2021            | ★★★★☆ WITH CONDITIONS<br>Rating applies only when unit is equipped with optional AFGO                 | Worldwide      | Good        | Excellent | Excellent | Not evaluated      | Good             | Good           | Good        | Not evaluated   | Good; \$113,000                             |
| <b>Getinge Flow-e</b><br>Last updated 3/2021            | ★★★★☆ WITH CONDITIONS<br>Rating applies only when unit is equipped with optional AFGO                 | Worldwide      | Good        | Excellent | Good      | Not evaluated      | Good             | Good           | Good        | Not evaluated   | Good; \$113,000                             |

ACGO—auxiliary common gas outlet.

AFGO—auxiliary fresh gas outlet.

# Summary of Findings: Anesthesia Units for General-Purpose and Low-Acuity/Ambulatory Surgery Applications

## MINDRAY A5 ADVANTAGE

### Ratings

#### General-Purpose Applications



#### Low-Acuity/Ambulatory Surgery Applications



### Where Marketed

As of the time of publication, this product is sold worldwide; hardware and software configuration varies by country/region.

### Findings

Our ratings are based on the following findings:

#### Performance

- **General-Purpose Applications—Excellent.** The A5 Advantage has advanced ventilation modes that can help when ventilating patients in a general-purpose setting, as well as advanced performance capabilities, which can help with difficult-to-ventilate patients. The Fresh Gas Optimizer feature can help providers use lower fresh gas flows safely and can lead to less wasted agent.
- **Low-Acuity/Ambulatory Surgery Applications—Good.** The use of lower fresh gas flows from Fresh Gas Optimizer is beneficial in low-acuity/ambulatory surgery settings.

**Safety—Excellent.** The unit allows the anesthesia provider to perform manual ventilation with all gases and agent when the unit is not connected to electrical power (i.e., loss of mains power and complete battery depletion). In addition, the unit has a feature that makes it easier and faster to adjust alarm limits in response to an active alarm.

**Workflow—Good.** The unit met our required major workflow criteria.

**Patient Experience—Not evaluated**

**Interoperability—Good.** The unit met our required major interoperability criteria.

**Cybersecurity—Good.** The unit met our required major cybersecurity criteria.

**Maintenance—Good.** The unit met our required major maintenance criteria.

**User Experience—Good.** User comments were generally positive.

**Cost of Ownership—Good; \$83,000-\$87,000 (estimated) over 10 years.** Note that this figure is based on prices for the United States, a major market for the product.

### Considerations for Challenging Environments

There are significant concerns for use of anesthesia units in challenging environments: They must be connected to a high-pressure source of oxygen to ventilate, they require consistent power and a controlled environment (avoiding excessive humidity and temperature extremes), and users require specialized training.

## MINDRAY A7 ADVANTAGE

### Ratings

#### General-Purpose Applications



#### Low-Acuity/Ambulatory Surgery Applications



### Where Marketed

As of the time of publication, this product is sold worldwide; hardware and software configuration varies by country/region.

### Findings

Our ratings are based on the following findings:

**Performance—Excellent.** The A7 Advantage has advanced performance capabilities to help with difficult-to-ventilate patients. The Fresh Gas Optimizer feature can help providers use lower fresh gas flows safely, which can lead to less wasted agent. In addition, the unit returns sampled gas to the breathing system by default, which supports the use of lower fresh gas flows and potentially even closed-circuit anesthesia.

**Safety—Excellent.** The unit allows the anesthesia provider to perform manual ventilation with all gases and agent when the unit is not connected to electrical power (i.e., loss of mains power and complete battery depletion). In addition, the unit has a feature that makes it easier and faster to adjust alarm limits in response to an active alarm.

# Summary of Findings: Anesthesia Units for General-Purpose and Low-Acuity/Ambulatory Surgery Applications

**Workflow—Good.** The unit met our required major workflow criteria.

**Patient Experience—Not evaluated**

**Interoperability—Good.** The unit met our required major interoperability criteria.

**Cybersecurity—Good.** The unit met our required major cybersecurity criteria.

**Maintenance—Good.** The unit met our required major maintenance criteria.

**User Experience—Good.** User comments were generally positive.

**Cost of Ownership—Good; \$96,000-\$100,000 (estimated) over 10 years.** Note that this figure is based on prices for the United States, a major market for the product.

## Considerations for Challenging Environments

There are significant concerns for use of anesthesia units in challenging environments: They must be connected to a high-pressure source of oxygen to ventilate, they require consistent power and a controlled environment (avoiding excessive humidity and temperature extremes), and users require specialized training.

## DRAEGER APOLLO

### Ratings

#### General-Purpose Applications

★★★★☆ WITH CONDITIONS

Rating applies only when unit is equipped with optional auxiliary air/oxygen blender

#### Low-Acuity/Ambulatory Surgery Applications

★★★★☆ WITH CONDITIONS

Rating applies only when unit is equipped with optional auxiliary air/oxygen blender

### Where Marketed

As of the time of publication, this product is sold in Japan and the United States.

### Findings

Our ratings are based on the following findings:

**Performance—Excellent.** In general-purpose settings, the Apollo can set and deliver tidal volume as low as 5 mL (making this unit a very good choice for facilities that operate on neonates), and also has two advanced ventilation modes that can help match ventilation during surgery to pre- and postoperative ventilation strategy. In both general-purpose and low-acuity/ambulatory settings, the Low Flow Wizard feature can help providers use lower fresh gas flows safely, which can lead to less wasted agent. In addition, it returns sampled gas to the breathing system by default, which supports the use of lower fresh gas flows and potentially even closed-circuit anesthesia.

**Safety—Excellent.** The unit allows the anesthesia provider to perform manual ventilation with all gases and agent with no electrical power (i.e., loss of mains power and complete battery depletion). In addition, the unit has a feature that makes it easier and faster to adjust alarm limits in response to an active alarm.

**Workflow—Good.** The unit met our required major workflow criteria.

**Patient Experience—Not evaluated**

**Interoperability—Good.** The unit met our required major interoperability criteria.

**Cybersecurity—Good.** The manufacturer has completed ECRI's cybersecurity questionnaire, which identifies the cybersecurity capabilities of the system. We judged the responses to be satisfactory.

**Maintenance—Good.** The unit met our required major maintenance criteria.

**User Experience—Good.** User comments were generally positive.

**Cost of Ownership—Good; \$98,000-\$105,000 (estimated) over 10 years** for an installation including air/O<sub>2</sub> blender. Note that this figure is based on prices for the United States, a major market for the product.

## Considerations for Challenging Environments

There are significant concerns for use of anesthesia units in challenging environments: They must be connected to a high-pressure source of oxygen to ventilate, they require consistent power and a controlled environment (avoiding excessive humidity and temperature extremes), and users require specialized training.

# Summary of Findings: Anesthesia Units for General-Purpose and Low-Acuity/Ambulatory Surgery Applications

## DRAEGER FABIUS GS PREMIUM

### Ratings

#### General-Purpose Applications

★★★★☆ WITH CONDITIONS

Rating applies only when unit is equipped with optional auxiliary air/oxygen blender

#### Low-Acuity/Ambulatory Surgery Applications

★★★★☆ WITH CONDITIONS

Rating applies only when unit is equipped with optional auxiliary air/oxygen blender

### Where Marketed

As of the time of publication, this product is sold worldwide.

### Findings

Our ratings are based on the following findings:

**Performance—Good.** The unit returns sampled gas to the breathing system by default, which supports the use of lower fresh gas flows and potentially even closed-circuit anesthesia.

**Safety—Good.** The Fabius GS Premium allows the anesthesia provider to perform manual ventilation with all gases and agent when the unit is not connected to electrical power (i.e., loss of mains power and complete battery depletion).

**Workflow—Good.** The unit met our required major workflow criteria.

**Patient Experience—Not evaluated**

**Interoperability—Good.** The unit met our required major interoperability criteria.

**Cybersecurity—Good.** The manufacturer has completed ECRI's cybersecurity questionnaire, which identifies the cybersecurity capabilities of the system. We judged the responses to be satisfactory.

**Maintenance—Good.** The unit met our required major maintenance criteria.

**User Experience—Good.** User comments were generally positive.

**Cost of Ownership—Good; \$86,000 (estimated) over 10 years** for an installation including air/O<sub>2</sub> blender. Note that this figure is based on prices for the United States, a major market for the product.

## Considerations for Challenging Environments

There are significant concerns for use of anesthesia units in challenging environments: They must be connected to a high-pressure source of oxygen to ventilate, they require consistent power and a controlled environment (avoiding excessive humidity and temperatures extremes), and users require specialized training.

## DRAEGER FABIUS TIRO

### Ratings

#### General-Purpose Applications

★★★★☆ WITH CONDITIONS

Rating applies only when unit is equipped with optional auxiliary air/oxygen blender

#### Low-Acuity/Ambulatory Surgery Applications

★★★★☆ WITH CONDITIONS

Rating applies only when unit is equipped with optional auxiliary air/oxygen blender

### Where Marketed

As of the time of publication, this product is sold worldwide.

### Findings

Our ratings are based on the following findings:

**Performance—Good.** The unit returns sampled gas to the breathing system by default, which supports the use of lower fresh gas flows and potentially even closed-circuit anesthesia.

**Safety—Good.** The Fabius Tiro allows the anesthesia provider to perform manual ventilation with all gases and agent when the unit is not connected to electrical power (i.e., loss of mains power and complete battery depletion).

#### Workflow

- **General-Purpose Applications—Good.** The unit met our required major workflow criteria.
- **Low-Acuity/Ambulatory Surgery Applications—Excellent.** The unit has a very small footprint, which allows it to be used in settings where space is at a premium.

**Patient Experience—Not evaluated**

**Interoperability—Good.** The unit met our required major interoperability criteria.

# Summary of Findings: Anesthesia Units for General-Purpose and Low-Acuity/Ambulatory Surgery Applications

**Cybersecurity—Good.** The manufacturer has completed ECRI’s cybersecurity questionnaire, which identifies the cybersecurity capabilities of the system. We judged the responses to be satisfactory.

**Maintenance—Good.** The unit met our required major maintenance criteria.

**User Experience—Good.** User comments were generally positive.

**Cost of Ownership—Good; \$76,000 (estimated) over 10 years** for an installation including air/O<sub>2</sub> blender. Note that this figure is based on prices for the United States, a major market for the product.

## Considerations for Challenging Environments

There are significant concerns for use of anesthesia units in challenging environments: They must be connected to a high-pressure source of oxygen to ventilate, they require consistent power and a controlled environment (avoiding excessive humidity and temperatures extremes), and users require specialized training.

## DRAEGER PERSEUS A500

### Ratings

#### General-Purpose Applications

★★★★★ WITH CONDITIONS

Rating applies only when unit is equipped with optional auxiliary air/oxygen blender

#### Low-Acuity/Ambulatory Surgery Applications

★★★★☆ WITH CONDITIONS

Rating applies only when unit is equipped with optional auxiliary air/oxygen blender

### Where Marketed

As of the time of publication, this product is sold worldwide.

### Findings

Our ratings are based on the following findings:

**Performance—Excellent.** The Perseus A500 has two advantages in a general-purpose setting: four advanced ventilation modes that can help match ventilation during surgery to pre- and post-

operative ventilation strategy, and advanced performance capabilities to help with difficult-to-ventilate patients. Advantageous to both general-purpose and low-acuity/ambulatory settings, the unit has the Low Flow Wizard feature, which can help providers use lower fresh gas flows safely, which in turn can lead to less wasted agent. In addition, it returns sampled gas to the breathing system by default, which supports the use of lower fresh gas flows and potentially even closed-circuit anesthesia.

**Safety—Excellent.** The unit allows the anesthesia provider to perform manual ventilation with all gases and agents with no electrical power (i.e., loss of mains power and complete battery depletion), and alarms when vaporizer level is low, which can help avoid patient awareness during surgery. The alarm “quick setup” window feature makes it easier and faster to adjust alarm limits in response to an active alarm. And the low-minute-volume alarm limit cannot be set to default to zero, making it less likely that the limit will be set too low.

**Workflow—Good.** The unit met our required major workflow criteria.

**Patient Experience—Not evaluated**

**Interoperability—Good.** The unit met our required major interoperability criteria.

**Cybersecurity—Good.** The manufacturer has completed ECRI’s cybersecurity questionnaire, which identifies the cybersecurity capabilities of the system. We judged the responses to be satisfactory.

**Maintenance—Good.** The unit met our required major maintenance criteria.

**User Experience—Good.** User comments were generally positive.

**Cost of Ownership—Good; \$114,000-\$119,000 (estimated) over 10 years** for an installation including air/O<sub>2</sub> blender. Note that this figure is based on prices for the United States, a major market for the product.

## Considerations for Challenging Environments

There are significant concerns for use of anesthesia units in challenging environments: They must be connected to a high-pressure source of oxygen to ventilate, they require consistent power and a controlled environment (avoiding excessive humidity and temperature extremes), and users require specialized training.



# Summary of Findings: Anesthesia Units for General-Purpose and Low-Acuity/Ambulatory Surgery Applications

## GE AISYS CS2

### Ratings

#### General-Purpose Applications

★★★★☆ WITH CONDITIONS

Rating applies only when unit is equipped with optional auxiliary common gas outlet (ACGO).

#### Low-Acuity/Ambulatory Surgery Applications

★★★★☆ WITH CONDITIONS

Rating applies only when unit is equipped with optional ACGO.

### Where Marketed

As of the time of publication, this product is sold worldwide.

### Findings

Our ratings are based on the following findings:

#### Performance

- **General-Purpose Applications—Excellent.** The Aisys CS2 offers two advanced ventilation modes that can, in a general-purpose setting, help match ventilation during surgery to the pre- and postoperative ventilation strategy. In addition, its ecoFLOW feature can help providers safely use lower fresh gas flows, which can lead to less wasted agent.
- **Low-Acuity/Ambulatory Surgery Applications—Good.** The use of lower fresh gas flows from ecoFLOW is beneficial in low-acuity/ambulatory surgery settings.

**Safety—Excellent.** The Aisys CS2 alarms when the vaporizer level is low, which can help avoid patient awareness during surgery. In addition, the unit's Tunneling Alarms feature makes it easier and faster to adjust alarm limits in response to an active alarm.

**Workflow—Good.** The unit met our required major workflow criteria.

**Patient Experience—Not evaluated**

**Interoperability—Good.** The unit met our required major interoperability criteria.

**Cybersecurity—Good.** The manufacturer has completed ECRI's cybersecurity questionnaire, which identifies the cybersecurity capabilities of the system. The device runs an unsupported operating system (OS), and is subject to any known or unknown physical vulnerabilities of that OS. Controlling physical access to

the device, which already occurs with anesthesia units, is recommended to prevent tampering. We also strongly discourage the use of serial device servers with this device due to a documented vulnerability (see *Health Devices Alerts* Accession No. H0531).

**Maintenance—Good.** The unit met our required major maintenance criteria.

**User Experience—Good.** User comments were mixed.

**Cost of Ownership—Good; \$146,000-\$152,000 (estimated) over 10 years** for an installation including ACGO. Note that this figure is based on prices for the United States, a major market for the product.

### Considerations for Challenging Environments

There are significant concerns for use of anesthesia units in challenging environments: They must be connected to a high-pressure source of oxygen to ventilate, they require consistent power and a controlled environment (avoiding excessive humidity and temperature extremes), and users require specialized training.

## GE AVANCE CS2

### Ratings

#### General-Purpose Applications

★★★★☆ WITH CONDITIONS

Rating applies only when unit is equipped with optional auxiliary common gas outlet (ACGO)

#### Low-Acuity/Ambulatory Surgery Applications

★★★★☆ WITH CONDITIONS

Rating applies only when unit is equipped with optional ACGO

### Where Marketed

As of the time of publication, this product is sold worldwide.

### Findings

Our ratings are based on the following findings:

#### Performance

- **General-Purpose Applications—Excellent.** The Avance CS2 offers two advanced ventilation modes that can, in a general-purpose setting, help match ventilation during surgery to the pre- and postoperative ventilation strategy. In addition,

# Summary of Findings: Anesthesia Units for General-Purpose and Low-Acuity/Ambulatory Surgery Applications

its ecoFLOW feature can help providers safely use lower fresh gas flows, which can lead to less wasted agent.

- **Low-Acuity/Ambulatory Surgery Applications—Good.** The use of lower fresh gas flows from ecoFLOW is beneficial in low-acuity/ambulatory surgery settings.

**Safety—Good.** One advantage is that the unit’s Tunneling Alarms feature makes it easier and faster to adjust alarm limits in response to an active alarm.

## Workflow

- **General Purpose—Good.** The unit met our required workflow criteria.
- **Low-Acuity/Ambulatory Surgery—Excellent.** The unit has a very small footprint, which allows it to be used in settings where space is at a premium.

## Patient Experience—Not evaluated

**Interoperability—Good.** The unit met our required major interoperability criteria.

**Cybersecurity—Good.** The manufacturer has completed ECRI’s cybersecurity questionnaire, which identifies the cybersecurity capabilities of the system. The device runs an unsupported operating system (OS), and is subject to any known or unknown physical vulnerabilities of that OS. Controlling physical access to the device, which already occurs with anesthesia units, is recommended to prevent tampering. We also strongly discourage the use of serial device servers with this device due to a documented vulnerability (see *Health Devices Alerts* Accession No. H0531).

**Maintenance—Good.** The unit met our required major maintenance criteria.

**User Experience—Good.** User comments were mixed.

**Cost of Ownership—Good; \$126,000-\$130,000 (estimated) over 10 years** for an installation including ACGO. Note that this figure is based on prices for the United States, a major market for the product.

## Considerations for Challenging Environments

There are significant concerns for use of anesthesia units in challenging environments: They must be connected to a high-pressure source of oxygen to ventilate, they require consistent power and a controlled environment (avoiding excessive humidity and temperature extremes), and users require specialized training.

## GE CARESTATION 650

### Ratings

#### General-Purpose Applications

★★★★☆ WITH CONDITIONS

Rating applies when unit is equipped with optional auxiliary common gas outlet (ACGO)

#### Low-Acuity/Ambulatory Surgery Applications

★★★★☆ WITH CONDITIONS

Rating applies when unit is equipped with optional ACGO

### Where Marketed

As of the time of publication, this product is sold worldwide.

### Findings

Our ratings are based on the following findings:

#### Performance

- **General Purpose—Excellent.** The Carestation 650 offers two advanced ventilation modes that can, in a general-purpose setting, help match ventilation during surgery to the pre- and postoperative ventilation strategy. In addition, its ecoFLOW feature can help providers safely use lower fresh gas flows, which can lead to less wasted agent.
- **Low Acuity/Ambulatory Care—Good.** The use of lower fresh gas flows from ecoFLOW is beneficial in low-acuity/ambulatory care settings.

**Safety—Good.** One advantage is that the unit’s Tunneling Alarms feature makes it easier and faster to adjust alarm limits in response to an active alarm. Note that this unit has an optional Aux O<sub>2</sub> + Air feature that allows the clinician to blend air into O<sub>2</sub> for open delivery (e.g., during monitored anesthesia care). While this reduces the risk of a surgical fire, this feature has some other problems that we believe make it unsuitable (see our detailed explanation on our member website).

#### Workflow

- **General Purpose—Good.** The unit met our required major workflow criteria.
- **Low Acuity/Ambulatory Surgery—Excellent.** The unit has a very small footprint, which allows it to be used in settings where space is at a premium.

# Summary of Findings: Anesthesia Units for General-Purpose and Low-Acuity/Ambulatory Surgery Applications

## Patient Experience—Not evaluated

**Interoperability—Good.** The unit met our required major interoperability criteria.

**Cybersecurity—Good.** The manufacturer has completed ECRI's cybersecurity questionnaire, which identifies the cybersecurity capabilities of the system. The device runs an unsupported operating system (OS), and is subject to any known or unknown physical vulnerabilities of that OS. Controlling physical access to the device, which already occurs with anesthesia units, is recommended to prevent tampering. We also strongly discourage the use of serial device servers with this device due to a documented vulnerability (see *Health Devices Alerts* Accession No. H0531).

**Maintenance—Good.** The unit met our required major maintenance criteria.

**User Experience—Good.** User comments were generally positive.

**Cost of Ownership—Good; \$113,000-\$118,000 (estimated) over 10 years** for an installation including ecoFLOW. Note that this figure is based on prices for the United States, a major market for the product.

## Considerations for Challenging Environments

There are significant concerns for use of anesthesia units in challenging environments: They must be connected to a high-pressure source of oxygen to ventilate, they require consistent power and a controlled environment (avoiding excessive humidity and temperatures extremes), and users require specialized training.

## GETINGE FLOW-C

### Ratings

#### General-Purpose Applications

★★★★☆ WITH CONDITIONS

Rating applies only when unit is equipped with optional auxiliary fresh gas outlet

#### Low-Acuity/Ambulatory Surgery Applications

★★★★☆ WITH CONDITIONS

Rating applies only when unit is equipped with optional auxiliary fresh gas outlet

## Where Marketed

As of the time of publication, this product is sold worldwide.

## Findings

Our ratings are based on the following findings:

### Performance

- **General-Purpose Applications—Excellent.** The Flow-c has a very high peak flow and a very high inspiratory pressure limit, both of which can be beneficial with difficult-to-ventilate patients. This unit also returns sampled gas to the breathing system by default, which supports the use of lower fresh gas flows and potentially even closed-circuit anesthesia.
- **Low-Acuity/Ambulatory Surgery Applications—Good.** The support for lower fresh gas flows provided by the return of sampled gas to the breathing system is beneficial in low-acuity/ambulatory surgery settings.

**Safety—Excellent.** The Flow-c alarms when the vaporizer level is low, which can help avoid patient awareness during surgery. And the low-minute-volume alarm limit cannot be set to default to zero, making it less likely that the limit will be set too low.

### Workflow

- **General-Purpose Applications—Good.** The unit met our required major workflow criteria.
- **Low-Acuity/Ambulatory Surgery Applications—Excellent.** The unit has a very small footprint, which allows it to be used in settings where space is at a premium.

## Patient Experience—Not evaluated

**Interoperability—Good.** The unit met our required major interoperability criteria.

**Cybersecurity—Good.** The manufacturer has completed ECRI's cybersecurity questionnaire, which identifies the cybersecurity capabilities of the system. We judged the responses to be satisfactory.

**Maintenance—Good.** The unit met our required major maintenance criteria.

**User Experience—Not evaluated.** Due to COVID-19 restrictions, we did not perform user experience testing on this device.

**Cost of Ownership—Good; \$113,000 (estimated) over 10 years.** Note that this figure is based on prices for the United States, a major market for the product.

## Considerations for Challenging Environments

# Summary of Findings: Anesthesia Units for General-Purpose and Low-Acuity/Ambulatory Surgery Applications

There are significant concerns for use of anesthesia units in challenging environments: They must be connected to a high-pressure source of oxygen to ventilate, they require consistent power and a controlled environment (avoiding excessive humidity and temperatures extremes), and users require specialized training.

## GETINGE FLOW-E

### Ratings

#### General-Purpose Applications

★★★★☆ WITH CONDITIONS

Rating applies only when unit is equipped with optional auxiliary fresh gas outlet

#### Low-Acuity/Ambulatory Surgery Applications

★★★★☆ WITH CONDITIONS

Rating applies only when unit is equipped with optional auxiliary fresh gas outlet

### Where Marketed

As of the time of publication, this product is sold worldwide.

### Findings

Our ratings are based on the following findings:

#### Performance

- **General-Purpose Applications—Excellent.** The Flow-e has a very high peak flow and a very high inspiratory pressure limit, both of which can be beneficial with difficult-to-ventilate patients. This unit also returns sampled gas to the breathing system by default, which supports the use of lower fresh gas flows and potentially even closed-circuit anesthesia.
- **Low-Acuity/Ambulatory Surgery Applications—Good.** The support for lower fresh gas flows provided by the return of sampled gas to the breathing system is beneficial in low-acuity/ambulatory surgery settings.

**Safety—Excellent.** The Flow-e alarms when the vaporizer level is low, which can help avoid patient awareness during surgery. And the low-minute-volume alarm limit cannot be set to default to zero, making it less likely that the limit will be set too low.

**Workflow—Good.** The unit met our required major workflow criteria.

**Patient Experience—Not evaluated**

**Interoperability—Good.** The unit met our required major interoperability criteria.

**Cybersecurity—Good.** The manufacturer has completed ECRI's cybersecurity questionnaire, which identifies the cybersecurity capabilities of the system. We judged the responses to be satisfactory.

**Maintenance—Good.** The unit met our required major criteria in maintenance.

**User Experience—Not evaluated.** Due to COVID-19 restrictions, we did not perform user experience testing on this device.

**Cost of Ownership—Good; \$113,000 (estimated) over 10 years.** Note that this figure is based on prices for the United States, a major market for the product.

### Considerations for Challenging Environments

There are significant concerns for use of anesthesia units in challenging environments: They must be connected to a high-pressure source of oxygen to ventilate, they require consistent power and a controlled environment (avoiding excessive humidity and temperatures extremes), and users require specialized training.

## MAQUET FLOW-I C20

### Rating

#### General-Purpose Applications

★★★★☆

### Findings

Our rating is based on the following findings:

**Performance—Excellent.** Has advanced performance capabilities to help with difficult-to-ventilate patients.

**Safety—Excellent.** The unit alarms when vaporizer level is low, which can help avoid patient awareness during surgery.

**Workflow—Fair.** The absorber canister is hard to access during a case. It's also hard to insert a new canister when needed.

**Patient Experience—Not evaluated**

**Interoperability—Good**

**Maintenance—Good**

**User Experience—Fair.** User comments were largely negative.

**Cost of Ownership—Good.** Estimated cost is \$100,000 over 10 years.

# Mindray A5 Advantage

Mindray A5 Advantage

## RATINGS

### General-Purpose Applications



### Low-Acuity/Ambulatory Surgery Applications



The Mindray A5 Advantage is a very good choice for general-purpose applications and a good choice for low-acuity/ambulatory surgery applications, receiving a rating of four and three stars, respectively. It has advanced ventilation modes that can help when ventilating patients in a general-purpose setting; advanced performance capabilities, which can help with difficult-to-ventilate patients; Fresh Gas Optimizer, which can help clinicians use less fresh gas; the ability to allow the anesthesia provider to perform manual ventilation with all gases and agent with no electrical power; and a feature that helps clinicians quickly respond to active alarms.

There are significant concerns for use of anesthesia units in challenging environments: They must be connected to a high-pressure source of oxygen to ventilate, they require consistent power and a controlled environment (avoiding excessive humidity and temperature extremes), and users require specialized training.

## PRODUCT DETAILS

- Name: A5 Advantage. Our ratings are based on testing done on a Mindray A5 and information from the vendor on the changes introduced with the A5 Advantage.
- Date evaluated: November 2020 (previously evaluated December 2015)
- Manufacturer: Mindray Medical International [454750]
- Where marketed: Worldwide; hardware and software configuration varies by country/region. The device we evaluated was configured for the North American market.
- Regulatory approvals/clearances
  - CE Mark: Yes
  - U.S. FDA clearance: Yes
- Healthcare Product Comparison System (HPCS) comparison chart: Anesthesia Units (HPCS is available to members of Health Devices Gold and SELECTplus.)
- Software version evaluated: 02.11.00

## PRODUCT DESCRIPTION

1. The A5 Advantage is used for general anesthesia during surgery for the entire range of patients (neonates through adults).
2. The unit can also be used to provide supplemental oxygen (O<sub>2</sub>—typically via a nasal cannula or loose-fitting mask) and capnography during monitored anesthesia care (MAC).
3. Major components and features:
  - a) Minimum dimensions (D × W): 81 × 109 cm (32 × 43 in)
  - b) Ventilator and breathing system
    - (1) 1,500 mL ascending bellows
    - (2) Uses fresh gas compensation to prevent changes in fresh gas flow from affecting delivered tidal volumes
    - (3) Automatically compensates for breathing circuit compliance (breathing circuit compliance must be measured at the start of each case or if the circuit is changed during a case)
    - (4) Bellows are located in the back of the breathing system assembly, on the left side of the unit.
    - (5) Volume during manual ventilation: 3.3 L (including absorber container but not breathing bag)
    - (6) Volume during automatic ventilation: 4.35 L (including absorber container and bellows)
  - c) Fresh gas controls
    - (1) Mechanical valves that control the flows of O<sub>2</sub> (0-15 L/min), air (0-15 L/min), and nitrous oxide (N<sub>2</sub>O) (0-12 L/min)
    - (2) Knobs located on the left side of the front of the unit
    - (3) Flow is measured by electronic flow sensors (as opposed to physical flow tubes).
    - (4) Controls will work in the absence of electrical power.
  - d) Vaporizers
    - (1) The A5 Advantage works only with Selectatec-style vaporizers.
    - (2) The unit can have two or three active vaporizer mounts.

## Mindray A5 Advantage

- (3) In addition, one inactive mount is available on the right side of the active mounting bar.
- e) Absorber
  - (1) Container for either loose-fill absorbent material or absorbent Pre-Paks
  - (2) Bypass valve allows absorbent to be changed during a case without introducing a leak into the breathing system.
  - (3) Container is located under the breathing system on the left side of the unit.
- f) Total flow meter
  - (1) Measures the total fresh gas flow (0-10 L/min)
  - (2) Flow tube located on the front of the unit under the fresh gas control knobs
- g) Pressure gauge
  - (1) Pressure is measured manually, and is also measured electronically and displayed on the screen.
  - (2) If the unit loses all electrical power, the manual pressure gauge continues to function.
  - (3) The pressure gauge is circular and located on the left side of the breathing system assembly.
- h) Illumination
  - (1) The unit has lights on the underside of the top shelf that shine onto the work surface and illuminate the vaporizer control dials.
  - (2) Auxiliary O<sub>2</sub> and air flow meters are also backlit.
  - (3) It offers two levels of brightness.
  - (4) The lights are controlled with a switch on the right side of the unit, above the vaporizer mount location.
- i) Auxiliary O<sub>2</sub> and air
  - (1) There are two mechanical flow controls and flow tubes that deliver a metered flow of gas separate from the normal fresh gas flow: one each for O<sub>2</sub> and air (0-15 L/min).
  - (2) O<sub>2</sub> concentration of auxiliary gas can be controlled indirectly by the relative flows of O<sub>2</sub> and air. A blending chart is provided specifying the O<sub>2</sub> and air flow rates needed to deliver several commonly used O<sub>2</sub> concentrations.
  - (3) Auxiliary O<sub>2</sub> and/or air is typically used with a nasal cannula or loose-fitting mask.
  - (4) Auxiliary flowmeters are located on the left side of the unit to the left of the main display.
  - (5) The ability to blend air into the auxiliary O<sub>2</sub> flow can help reduce the risk of an O<sub>2</sub>-enriched surgical fire.
- j) Work surface—Size (D × W): 33 × 61 cm (13 × 24 in)
- k) Touchpad
  - (1) Can be used instead of the touchscreen to control the unit
  - (2) Pulls out from under the front lip of the work surface
- l) Drawers
  - (1) Three equal-size drawers (H × D × W): 13 × 41 × 43 cm (5 × 16 × 17 in)
  - (2) One lock controls all drawers.
- m) Auxiliary power outlets
  - (1) Unit has four 3 A outlets protected by circuit breakers at the rear.
  - (2) The outlets work when the unit is powered off.
- n) Backup cylinder yokes—Three pin-indexed yokes on the back of the unit
- o) Electronic interfaces
  - (1) One nine-pin serial port for interface with electronic systems
  - (2) Two USB ports for downloading event logs and configuration information or for connecting a mouse
  - (3) Ethernet connection
  - (4) All interfaces are on the top right of the rear of the unit.
- p) GCX-mount-compatible rails
  - (1) Two rails on the left side of the unit (one on top, one on bottom)
  - (2) Three rails on the right side of the unit (one on top, two on bottom)
- q) Standard ventilation modes
  - (1) Manual/spontaneous ventilation

- (2) Volume Control Ventilation—VCV (VC-CMV<sub>s</sub>)\*
- (3) CPAP/Pressure Support
- (4) Pressure Control Ventilation—PCV (PC-CMV<sub>s</sub>)
- (5) Pressure Control Ventilation with Volume Guarantee—PCV-VG (PC-CMV<sub>a</sub>)
- (6) Synchronized Intermittent Mandatory Ventilation with VC mode—SIMV-VC (VC-IMV<sub>s,s</sub>)
- (7) Synchronized Intermittent Mandatory Ventilation with PC mode—SIMV-PC (PC-IMV<sub>s,s</sub>)

#### 4. Optional components and features:

##### a) Gas analyzer

- (1) Although the gas analyzer is electronically integrated into the anesthesia unit, the analyzer module can be removed if needed.
- (2) The gas analyzer can be changed during a case.
- (3) The analyzer takes a sidestream sample from the patient wye at 120, 150, or 200 mL/min (the user can select the sample rate in the Setup menu) and analyzes the inspired and expired concentration of O<sub>2</sub>, CO<sub>2</sub>, and anesthetic gases.
- (4) The gas analyzer bay is on the left side of the unit, behind the breathing system.
- (5) Units without the optional integral gas analyzer measure O<sub>2</sub> concentration with a galvanic sensor.

##### b) Anesthetic gas scavenging system (AGSS)

- (1) Used with vacuum waste-gas disposal systems (i.e., active scavenging)
- (2) This is a small open reservoir canister typically attached to the left side of the unit. It receives scavenged gas via a hose that attaches to back of unit. It connects to the waste-gas disposal system through an outlet on the side of the component.

##### c) Optional ventilation modes

- (1) Synchronized Intermittent Mandatory Ventilation with Volume Guarantee—SIMV-VG (PC-IMV<sub>a,s</sub>) (\$2,100)

- (2) Airway Pressure Release Ventilation—APRV (PC-IMV<sub>s,s</sub>) (\$2,100). This is an inverse-ratio pressure-control mode that is sometimes used for acute respiratory distress syndrome (ARDS) patients.

## SIGNIFICANT FINDINGS

We performed a variety of tests on this product, including physical testing, a review of product literature/specifications, and asking users about their experience with the device. For more details, see the ECRI's Testing section of our Evaluation Background on this technology.

### Performance—Excellent (General Purpose), Good (Low-Acuity/Ambulatory Surgery)

#### Major Advantages (General Purpose)

##### 1. Advanced ventilation modes:

- a) The A5 Advantage has four advanced ventilation modes, all of which we consider advantageous: CPAP/Pressure Support, Pressure Control with VG (PC-CMV<sub>a</sub>), SIMV with VG (PC-IMV<sub>a,s</sub>), and APRV (PC-IMV<sub>s,s</sub>).
- b) Multiple advanced modes support providing anesthesia to patients with compromised lungs who may come from the ICU where they had received an advanced mode of mechanical ventilation. Being able to continue preoperative ventilation modes during surgery is beneficial to the patient.
- c) We do not consider advanced ventilation modes advantageous in low-acuity/ambulatory surgery settings because patients who require such modes should not be treated in a low-acuity setting.

##### 2. High peak flow:

- a) The A5 Advantage can provide peak flow as high as 180 L/min.
- b) This allows pressure-control breaths to be delivered very quickly, which is beneficial for patients with low compliance.
- c) We do not consider high peak flow advantageous in low-acuity/ambulatory surgery settings because patients who require it should not be treated in a low-acuity setting.

\*In addition to listing the ventilation mode names and abbreviations used by the manufacturer, we have included the mode abbreviation according to the taxonomy developed by Robert Chatburn (See: Chatburn et al. 2014, Mireles-Cabodevila et al. 2013).

### 3. High inspiratory pressure capability:

- a) The A5 Advantage can provide inspiratory pressure as high as 100 cm H<sub>2</sub>O.
- b) This allows the unit to ventilate patients with high resistance and/or low lung compliance (e.g., crushing chest trauma).

### **Major Advantage (General Purpose and Low-Acuity/Ambulatory)**

#### 1. Fresh Gas Optimizer:

- a) The A5 Advantage has a low-flow decision-support tool called Fresh Gas Optimizer.
- b) This encourages anesthesia providers to use less fresh gas, which:
  - (1) May assist in keeping the patient warm (since fresh gas is cold)
  - (2) Helps reduce the environmental footprint of the facility (since waste gas contains pollutants and contributes to the greenhouse effect)
  - (3) Saves money by reducing the amount of wasted anesthetic agent and medical gases
- c) For more details on the specific advantages and disadvantages of this feature, as well as similar features from other manufacturers, see our article “A Look at Low-Flow Anesthesia Decision-Support Tools.”

### **Minor Advantages (General Purpose)**

#### 1. Automatic ventilation maneuvers:

- a) The A5 Advantage has two automatic maneuvers:
  - (1) The Recruitment Pressure Adjust is an inspiratory-hold maneuver in which the ventilator will maintain a set pressure for a set amount of time. Note that with highly compliant lungs, delivering a high pressure (e.g., 35 cm H<sub>2</sub>O) will not be possible since that will exceed the volume of the bellows.
  - (2) The Recruitment Preset Procedure delivers a user-determined sequence of pressure breaths (up to seven steps).
- b) These maneuvers provide useful clinical information, typically static compliance and the appropriate positive end-expiratory pressure (PEEP) setting, respectively.

- c) An anesthesia provider can simulate these maneuvers in other ways (e.g., perform them manually in manual ventilation mode), but automating them is more precise, consistent, and convenient.

- d) These maneuvers are useful primarily in a general-purpose setting.

#### 2. Spirometry loop display:

- a) The A5 Advantage displays pressure/volume, flow/volume, and pressure/flow loops. In addition to the real-time loops, it also allows a user to record and display one baseline and up to four reference loops.
- b) Spirometry loops are a useful diagnostic tool (e.g., showing changes in lung compliance).
- c) Loops are useful primarily in a general-purpose setting.

### **Minor Advantages (General Purpose and Low-Acuity/Ambulatory)**

#### 1. Passive scavenging:

- a) The A5 Advantage supports the use of passive scavenging.
- b) This gives facilities more flexibility. Most facilities in the United States use active scavenging, but passive scavenging is still used in some places.

#### 2. Trending:

- a) The A5 Advantage stores up to 48 hours of trended data, which can be displayed both numerically and graphically.
- b) Trended data can help the anesthesia provider detect changes in the patient's condition and anesthetization during a long case. It also supports manual charting efforts to record past data accurately.

#### 3. Condensation management:

- a) The A5 Advantage heats the breathing system to reduce condensation of water within the breathing system and mitigate the impact of condensed water.
- b) The anesthesia provider can disable the breathing system heater if this is necessary for patient care. Breathing system heating can be turned on or off in the Setup menu and is automatically disabled when the unit is operating on battery power.



- c) This is particularly useful during low-flow anesthesia because the higher proportion of warm, humid exhaled gases as compared to cool, dry fresh gas makes rainout more likely.

## Safety—Excellent

### Major Advantages

#### 1. Emergency operation:

- a) The A5 Advantage can deliver O<sub>2</sub>, air, and anesthetic agents without requiring electricity. Only manual ventilation is possible until power is restored.
- b) This allows the anesthesia provider to continue with complete anesthesia care even when power is interrupted and the battery is depleted.
- c) Three features and design decisions work together to make this possible:
  - (1) The vaporizers do not require electricity to work, with the exception of those that deliver desflurane. (All desflurane vaporizers require electricity because of the properties of desflurane.)
  - (2) The fresh gas flow controls are mechanical and there is a physical flow tube that measures and displays the total fresh gas flow.
  - (3) The unit has an analog breathing pressure gauge.
- d) Note that all gas delivery is stopped when the power switch is turned off, regardless of whether the unit has electrical power (i.e., is plugged into the wall or there is charge remaining in the battery).

#### 2. Active alarms preselected:

- a) The A5 Advantage has a feature in which the active alarm is highlighted and preselected when the anesthesia provider opens the alarm menu. Pressing an alarming parameter on the touchscreen will also open the alarm menu with that alarm limit preselected.
- b) This reduces the chance that the provider will accidentally change the wrong limit, and it allows limits to be adjusted more quickly in response to the alarm.
- c) In other systems without a similar feature, to change the limit for an active alarm, the provider has to:

- (1) Open the alarm menu
- (2) Identify the active alarm
- (3) Select the limit to change (i.e., upper or lower, typically by pressing the limit on the screen)
- (4) Turn the control knob to adjust the limit
- (5) Confirm the change (typically by pushing in the control knob)

- d) Because the active alarm is preselected on the A5 Advantage, two of these steps are eliminated (identifying the active alarm and selecting the limit to change).
- e) If more than one alarm is active when the provider opens the alarm menu via the Alarm button on the screen, the highest-priority alarm is preselected. If an alarming parameter is touched, the alarm menu will open with that alarm limit preselected.

#### 3. Minute volume default alarm limits:

- a) The A5 Advantage does not allow a user to set the default low-minute-volume alarm limit below 0.1 L/min for any patient.
- b) This prevents the user from inappropriately setting the default low-minute-volume alarm limit too low. Some other devices allow the user to configure the low-minute-volume default limit to “Off,” to 0, or to such a low value that the alarm will never be triggered.
- c) Minute volume is a key respiratory parameter. While there are situations that may warrant disabling the low-minute-volume alarm, we are aware of incidents in which an inappropriately set low-minute-volume alarm limit contributed to patient harm. Allowing the user to inappropriately set the default low-minute-volume alarm limit to “Off,” to 0, or to a very low value increases the chance of such an event occurring.

### Minor Advantages

#### 1. Expired O<sub>2</sub> measurement:

- a) The A5 Advantage displays expired O<sub>2</sub> concentration and can be configured to display a real-time O<sub>2</sub> concentration waveform (in addition to displaying inspired O<sub>2</sub> concentration); this feature requires the optional integrated gas analyzer.

- b) This provides useful diagnostic information to the anesthesia provider.
2. Customizable default alarm limits:
- a) The A5 Advantage has customizable default alarm limits for neonatal, pediatric, and adult patients.
  - b) This allows facilities to configure default alarm limits that match their practice and patient population.
  - c) Customizing the default limits requires an access code.

### **Minor Disadvantages**

1. Imprecise O<sub>2</sub> concentration setting for auxiliary gas:
- a) The A5 Advantage has two auxiliary gas flowmeters (air and O<sub>2</sub>), which allows the anesthesia provider to deliver auxiliary gas at a controlled O<sub>2</sub> concentration (e.g., below 30%, which reduces the risk of an O<sub>2</sub>-enriched surgical fire). However, the provider cannot directly control the O<sub>2</sub> concentration of this auxiliary gas.
  - b) The anesthesia provider may not be able to accurately control either flow rate or O<sub>2</sub> concentration with this arrangement.
2. No individualized alarm tones for multiple alarm conditions:
- a) If an alarm is annunciating and a different alarm of the same priority occurs, the A5 Advantage does not indicate the new alarm condition with an individualized alarm tone.
  - b) The anesthesia provider may not realize that a new alarm condition has occurred, especially if they are focused on dealing with the first alarm condition.

## **Workflow—Good**

### **Minor Advantages**

1. Anesthetic agent consumption:
- a) The A5 Advantage calculates the amount of anesthetic agent used (i.e., the total amount that exits the vaporizer) during a case with a second gas analyzer used specifically for such measurements.
  - b) This assists in documentation for individual cases.
2. Central wheel brake:
- a) The A5 Advantage has a central brake.

- b) Using a central brake is easier than locking multiple casters individually.

3. Cord and cable management:

- a) The A5 Advantage's casters have built-in sweeps.
- b) OR floors often have many cords, cables, and hoses that can interfere with pushing an anesthesia unit. The sweeps prevent the casters from rolling over these items and the subsequent problems this causes (impeding flow in gas hoses, pulling cables and cords out of devices).

4. Logging of pre-use check results:

- a) The A5 Advantage logs the results of the pre-use check (i.e., whether the check was passed, any error codes associated with failures that occurred during the pre-use check).
- b) Included in the log are the numerical values for system leak and compliance.
- c) The log is useful in tracking how often the pre-use check is run. In addition, the logging of leak and compliance values is useful if there is a subsequent problem during a case, since an investigator can refer back to what was measured during the pre-use check. It can also be used diagnostically if a unit develops a failure over time.

5. Adjustable pressure-limiting (APL) valve pop-off:

- a) Lifting up on the A5 Advantage's APL control knob sets the pressure in the breathing system to zero as long as the knob is lifted.
- b) This allows the anesthesia provider to temporarily relieve the pressure in the breathing system without adjusting the APL valve setting (and potentially setting it inappropriately after turning it to zero).

6. High-pressure O<sub>2</sub> outlet:

- a) The A5 Advantage has a high-pressure (approximately 50 psi) O<sub>2</sub> outlet that can be used as a source for a stand-alone device such as a jet ventilator.
- b) While there are other high-pressure O<sub>2</sub> sources in the OR, this one is conveniently located close to where the device is likely to be used (i.e., near the patient's airway).

## 7. Hot-swappable batteries:

- a) The A5 Advantage has two battery packs that can be replaced one at a time during operation without the need to power off the unit.
- b) This allows extended operation on battery power as long as charged battery packs are available.

## 8. Quick power-on:

- a) The A5 Advantage powered on in 28 seconds during our testing.
- b) A quick power-on means the unit can be ready to use quickly in an emergency, and it could minimize interruptions during a case.
- c) Units are typically powered on long before a case starts, but if it is ever necessary to power cycle a unit during a case, a faster power-on would reduce the amount of time the anesthesia provider must spend performing manual ventilation.

## 9. Highly configurable device mounting options:

- a) The A5 Advantage has five GCX-mount-compatible rails.
- b) This gives facilities significant flexibility in configuring mounting arms for monitors, computers, and other devices.

## 10. Hot-swappable gas analyzer:

- a) The A5 Advantage's optional integral gas analyzer can be replaced in the middle of a case without interrupting the operation of the unit itself.
- b) This allows the gas analyzer to be replaced if it fails in the middle of a case. For systems without hot-swappable analyzers, the entire unit must be replaced or a stand-alone gas analyzer must be used.

### **Notable Finding**

Battery life in our testing was three hours.\*

## **Patient Experience—Not Evaluated**

### **Interoperability—Good**

#### *Minor Advantages*

#### 1. Exports anesthetic agent consumption data:

- a) The A5 Advantage measures the amount of agent used during the case.
- b) In addition to being available to the anesthesia provider on the screen, this information is also communicated electronically to other systems (e.g., electronic medical records [EMRs]).
- c) This is useful for automatic documentation. It also allows facilities to track overall agent usage, which is useful for facilities that want to reduce agent use.

#### 2. Exports fresh gas measurements:

- a) The A5 Advantage communicates fresh gas measurements electronically to other systems.
- b) This is useful for automatic documentation. It also allows facilities to track overall agent usage (i.e., if there is an effort to encourage the use of low-flow anesthesia).

#### 3. Supports data integration:

- a) The A5 Advantage outputs data that complies with the Device Enterprise Communication profile within Integrating the Healthcare Enterprise's (IHE) Patient Care Devices domain (i.e., IHE PCD DEC).
- b) This allows facilities to send data from the A5 Advantage to another system (e.g., EMR) without requiring the use of a third-party integrator.

#### 4. Alarm communication:

- a) The A5 Advantage transmits alarm information, including alarm name and priority, electronically in real time.

\*We operated the system on battery power at the following settings: volume-control mode with a tidal volume of 500 mL and a rate of 12 breaths/min. We set up the test lung to simulate a normal adult patient, with a compliance of 0.1 L/cm H<sub>2</sub>O and a resistance of 5 cm H<sub>2</sub>O/L/sec. We set fresh gas flow at 2 L/min of O<sub>2</sub>. We operated the system until the battery expired and noted the behavior as the battery neared exhaustion.

- b) This information can be used in a number of ways by the facility, one of which is the development of “smart” monitoring algorithms.

## Cybersecurity—Good

The manufacturer has completed ECRI’s cybersecurity questionnaire, which identifies the cybersecurity capabilities of the system. We judged the responses to be satisfactory.

## Maintenance—Good

### *Minor Advantages*

1. Easy-to-clean breathing system:
  - a) Tools are not required to disassemble the A5 Advantage’s breathing system.
  - b) This makes cleaning the breathing system easier.
2. Easy-to-access batteries:
  - a) The A5 Advantage’s batteries are readily accessible and are easy to replace.
  - b) This contributes to the easy PM mentioned above. But it is also useful if there is a problem with a battery before scheduled maintenance.
3. Very easy preventive maintenance (PM):
  - a) The A5 Advantage users we spoke with all reported that performing the PM was very easy.
  - b) This reduces the amount of time a unit is out of service for PM.

### *Minor Disadvantage*

1. Flow sensor calibration:
  - a) The A5 Advantage’s flow sensors require manual calibration when they are changed or cleaned, or when tidal volume measurements are inaccurate. The calibration process requires partial disassembly of the breathing system.
  - b) The need for cumbersome manual calibration could lead to delays during or, more likely, between cases.

## User Experience—Good

### *Positive User Feedback*

1. Users liked the way the screens are organized.
2. Users found the A5 Advantage’s confirm-setting-change prompt to be very intuitive.

### *Mixed User Feedback*

Users had mixed opinions on the A5 Advantage’s numerical entry for settings (compared to the control knob found on most other units). Some users thought numerical entry was more precise. Others disliked the number of key presses required to make a change.

## Cost of Ownership—Good; \$83,000-\$87,000 (Estimated) over 10 Years

This figure is based on the prices for the United States, a major market for the product.

# Mindray A5 Advantage

## ESTIMATING THE TYPICAL COST OF OWNERSHIP FOR THE MINDRAY A5 ADVANTAGE

The costs reported in this table represent typical quotation and purchase costs reported to ECRI's SELECTplus and PriceGuide databases, respectively. Some pricing quotes also provided by Mindray. These figures are provided as a guide only and may vary significantly.

Note that these figures are based on prices for the United States, a major market for the product.

| Factor   | Typical Cost   | Assumptions   |
|--|--|---|
| <b>Purchase Costs</b>  |  |   |
| Capital cost   | General purpose: \$40,000<br>Low-acuity/ambulatory surgery: \$36,000               | Average quoted cost, including gas analyzer, standard accessories, all optional ventilation modes, and Spirometry and Bypass optional features. Based on pricing data in ECRI's SELECTplus database and information provided by the vendor.   |
| Typical accessories  | Sevoflurane vaporizer: \$3,000<br>Desflurane vaporizer: \$7,500                    | Facilities do not always purchase vaporizers with their anesthesia units. But for our purposes we have included the average quoted cost of vaporizers for the two most popular agents (isoflurane vaporizers are priced the same as sevoflurane). Facilities that already have vaporizers or that receive vaporizers as part of their agent contracts will see a lower upfront cost.        |
| Warranty   | \$0  | Three-year warranty included in purchase price.   |
| Clinical staff training  | \$0  | Initial training (e.g., three or four days at time of purchase) is included in the capital cost. Any additional training would cost \$1,500 per day.  |
| Biomedical staff training  | \$14,000   | Two staff members trained at \$6,800 each. Optional training is one week, and on-site training is negotiable.   |
| Infrastructure modifications   | \$0  | None.   |
| <b>Total purchase cost</b>   | General purpose: \$65,000<br>Low-acuity/ambulatory surgery: \$61,000               | —   |
| <b>Annual Operational Costs</b>  |  |   |
| Consumables  | Breathing circuits: \$0  | Breathing circuits contribute to the consumable cost for anesthesia units, but have been excluded from this analysis because circuit cost is not a factor in deciding which unit to purchase (since all breathing circuits can be used with all anesthesia units).  |
|  | Absorbent: \$1,900/yr  | Three per anesthesia unit per week, 52 weeks per year = 156 Pre-Paks at \$12 each. Pre-Paks can be purchased from third parties.  |
|  | Agent: \$0   | Agent is by far the most significant contribution to the consumable cost for anesthesia units, but has been excluded from this analysis because agent cost is not a factor in deciding which unit to purchase (since agent from any supplier can be used with all anesthesia units).  |
| Expected part replacement—averaged throughout life of device                 | \$0  | No replacements expected.   |
| Service  | Preventive maintenance (PM) kits: \$300/yr   | Total cost for all PMs over first 10 years: \$3,000.  |
|  | Batteries: \$0   | Batteries are included in PM costs.   |
|  | Labor: \$0   | \$0 assuming facility opts to pay for biomedical staff training and have clinical engineering perform the annual PM. Alternatively, facility can choose a Mindray service package that includes PM (detailed in the Service and Maintenance section below) or pay for Mindray to service the units on a one-off basis at a rate of \$530/hr. This does not include travel time to facility. |
| Annual license fee   | \$0  | None.   |
| <b>Average annual operational cost</b>                                       | \$2,200  | —   |
| <b>Estimated Total Cost of Ownership (for an estimated life of 10 years)</b> | General purpose: <b>\$87,000</b><br>Low-acuity/ambulatory surgery: <b>\$83,000</b> | Total purchase cost + (annual operational cost × estimated life)  |

## CONSIDERATIONS FOR CHALLENGING ENVIRONMENTS: MINDRAY A5 ADVANTAGE

As of the time of publication, this product is marketed worldwide.

| Category  | Remarks   |
|---|---|
| <b>Physical Environment</b><br>Ability to operate successfully in a variety of adverse conditions | Significant concern: As with other anesthesia units, this unit requires consistent power, and excessive humidity and ambient air temperature extremes must be avoided.  |
| <b>Installation</b><br>Installation requirements compared to other equipment in the same category | Significant concern: Like other anesthesia units, this unit must be connected to a high-pressure source for oxygen and either an air or nitrous oxide source for it to ventilate.   |
| <b>Training and Operation</b><br>Whether the product can be learned and used without undue burden | Significant concern: Anesthesia providers require specialized training.   |
| <b>Servicing</b><br>Whether the product can be serviced without undue burden                      | Moderate concern: Servicing for anesthesia units in remote areas may involve delays and increased shipment costs. Mindray has an extensive global distribution and service network, which partially mitigates these concerns. |

## DISCUSSION OF KEY MANUFACTURER CLAIMS

These claims are drawn from labeling and promotional materials in the United States, a major market for the product.

| Mindray Claim  | Category    | ECRI Perspective   |
|--|-------------|--|
| The A5 provides SIMV-PC and provides Volume Guarantee in PCV mode, as well as in VCV, PCV, CPAP/PS and SIMV-VC ventilation modes, enabling effective care across a wide range of patient acuity types. | Performance | <b>ECRI agrees; we consider this a significant benefit.</b><br>As noted in our Performance findings above, we consider PCV with Volume Guarantee advantageous.   |
| Advanced ventilation modes such as APRV, and SIMV-VG provide optional tools for lung-protective ventilation strategies.  | Performance | <b>ECRI agrees; we consider this a significant benefit.</b><br>As noted in our Performance findings above, we consider advanced ventilation modes advantageous.  |
| Real-time visualization of lung-recruitment therapy during cases helps optimize pulmonary status and minimize postoperative complications.   | Performance | <b>ECRI agrees; we consider this a significant benefit.</b><br>As noted in our Performance findings above, we consider spirometry loops advantageous.  |
| Capability to deliver high inspiratory flow both peak and continuously up to 180L/min and thus adapt to individual patient demands.  | Performance | <b>ECRI agrees; we consider this a significant benefit.</b><br>As noted in our Performance findings above, we consider the ability to deliver a high peak flow advantageous.   |
| Integrated spirometry offers the clinician additional respiratory information.   | Performance | <b>ECRI agrees; we consider this a significant benefit.</b><br>As noted in our Performance findings above, we consider spirometry loops advantageous.  |
| Warmed to body temperature, the breathing system virtually eliminates internal condensation.   | Performance | <b>ECRI agrees; we consider this a significant benefit.</b><br>As noted in our Performance findings above, we consider a heated breathing system advantageous.   |
| Robust safety concept with 2-hour battery backup and the ability to deliver all fresh gas and vaporized agent to the patient, regardless of power state.   | Safety      | <b>ECRI agrees; we consider this a significant benefit.</b><br>As noted in our Safety findings above, we consider the ability to deliver all gases and anesthetic agent without electricity advantageous.  |
| Unique auxiliary O <sub>2</sub> /air cannula allows the blending of air into the nasal cannula to potentially reduce the risk of surgical fire.  | Safety      | <b>ECRI agrees; we consider this a significant benefit.</b><br>Our criteria require that all anesthesia units have a way to blend air into the auxiliary O <sub>2</sub> flow source to reduce the risk of an O <sub>2</sub> -enriched surgical fire. |
| The A5's central brake and integrated cable sweeps enhance device mobility.  | Workflow    | <b>ECRI agrees; we consider this a significant benefit.</b><br>As noted in our Workflow findings above, we consider both the central brake and the cable sweeps advantageous.  |
| Disassembly of the breathing system is achieved with a few simple steps.   | Maintenance | <b>ECRI agrees; we consider this a significant benefit.</b><br>As noted in our Maintenance findings above, we consider the easy-to-clean breathing system advantageous.  |

## RECALLS AND HAZARDS

The following data is based on *Health Devices Alerts* records from July 11, 2017, through July 11, 2020. In addition, our Evaluation Background on general-purpose anesthesia units also has a list of generic anesthesia hazards (i.e., hazards that are not about one or more specific devices).

| HDA Record  | Country   | Priority | Date of Last Update | Category      |
|---|---|----------|---------------------|---------------|
| A34796 01: [COVID-19] Mindray—Anesthesia Devices: Manufacturer Provides Addendum on Procedures for Converting Drive Gas from Oxygen to Air [Update] | U.S.  | High     | 4/28/2020           | User Training |
| A34796: [COVID-19] Mindray—Anesthesia Devices: Manufacturer Addresses Use for Continuous Ventilation  | U.S.  | High     | 3/26/2020           | User Training |
| A28838: Mindray—A-Series Anesthesia Systems: May Be Unable to Enter Standby Mode and/or May Skip Leak Test and Standby Mode at Startup              | (Impact in additional regions has not been identified or ruled out at the time of this posting), U.S. | High     | 4/17/2018           | Hardware      |

## USER SURVEY RESULTS

We surveyed anesthesia machine users about their opinions of a number of current models—including ease of use, performance, and reliability—plus the average number of annual repairs they experience and how often they inspect the devices. See the survey results on our member website.

## SERVICE AND MAINTENANCE

The following information pertains to the United States, a major market for the product. It is provided largely verbatim from the manufacturer.

### Warranty

Standard warranty terms:

1. Three years standard manufacturer’s warranty. This does not include preventive maintenance.
2. Mindray DS USA, Inc. warrants that components within the anesthesia system will be free from defects in workmanship and materials for the number of years shown on the invoice. Under this extended warranty, Mindray DS USA, Inc. will repair or replace any defective component at no charge for labor and/or materials. This extended warranty does not cover consumable items such as (but not limited to) batteries and external cables.

### Inspection and Preventive Maintenance (IPM)

1. IPM frequency: One preventive maintenance required per year.
2. Downtime for IPM: Approximately two hours per preventive maintenance.

### In-House/Third-Party Service

1. Manufacturer supports user repair: Yes, Mindray supports user repair when trained by Mindray technical support.
2. Training required and cost: \$6,800 for biomed course.
3. Availability of service manual: PDF is available on Mindray website.
4. Dedicated test equipment and/or software required: Off-the-shelf equipment can be used to test machine. Mindray software tool required to update software.
5. Availability of manufacturer assistance: Technical support available 24/7.

### OEM Maintenance

1. Standard OEM service options
  - a) Three annual options:
    - (1) Basic
    - (2) Service Only
    - (3) Service Plus One PM
  - b) Description of coverage:
    - (1) Basic—Preventive Maintenance only
    - (2) Service Only—Extended Warranty
    - (3) Service Plus One PM—Extended Warranty and Preventive Maintenance
      - (a) Packages are available in yearly increments, multiple-year agreements are billed annually.

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(b) Hours of coverage: Within normal working hours, upon availability of machine.

(c) Response time: Two hours by phone, no later than 24 hours on site.

2. Remote monitoring—not offered.
3. Software upgrade and update policy: Software updates and functionality upgrades offered to customer at time of service at no charge to customer. Travel and labor costs may apply.



# Mindray A7 Advantage

Mindray A7 Advantage

## RATINGS

### General-Purpose Applications



### Low-Acuity/Ambulatory Surgery Applications



The Mindray A7 Advantage is a very good choice for general-purpose applications and for low-acuity/ambulatory surgery applications, receiving a four-star rating in each application. It has advanced ventilation modes that can help when ventilating patients in a general-purpose setting; advanced performance capabilities, which can help with difficult-to-ventilate patients; and Fresh Gas Optimizer, which can help clinicians use less fresh gas. In addition, it returns sampled gas to the breathing system by default, which supports the use of lower fresh gas flows; it allows the anesthesia provider to perform manual ventilation with all gases and agent with no electrical power; and it has a feature that helps clinicians quickly respond to active alarms.

There are significant concerns for use of anesthesia units in challenging environments: They must be connected to a high-pressure source of oxygen to ventilate, they require consistent power and a controlled environment (avoiding excessive humidity and temperature extremes), and users require specialized training.

## PRODUCT DETAILS

- Name: A7 Advantage. Our ratings are based on testing done on a Mindray A7 and information from the vendor on the changes introduced with the A7 Advantage.
- Date evaluated: November 2020 (previously evaluated February 2017)
- Manufacturer: Mindray Medical International [454750]
- Where marketed: Worldwide; hardware and software configuration varies by country/region. The device we evaluated was configured for the North American market.
- Regulatory approvals/clearances
  - CE Mark: Yes
  - U.S. FDA clearance: Yes
- Healthcare Product Comparison System (HPCS) comparison chart: Anesthesia Units (HPCS is available to members of Health Devices Gold and SELECTplus.)
- Software version evaluated: 03.02.03

## PRODUCT DESCRIPTION

1. The A7 Advantage is used for general anesthesia during surgery for the entire range of patients (neonates through adults).
2. The unit can also be used to provide supplemental oxygen (O<sub>2</sub>—typically via a nasal cannula or loose-fitting mask) and capnography during monitored anesthesia care (MAC).
3. Major components and features:
  - a) Minimum dimensions (D × W): 81 × 109 cm (32 × 43 in)
  - b) Ventilator and breathing system
    - (1) 1,500 mL ascending bellows
    - (2) Uses fresh gas compensation to prevent changes in fresh gas flow from affecting delivered tidal volumes
    - (3) Automatically compensates for breathing circuit compliance (breathing circuit compliance must be measured at the start of each case or if the circuit is changed during a case)
    - (4) Bellows are located in the back of the breathing system assembly, on the left side of the unit.
    - (5) Volume during manual ventilation: 3.3 L (including absorber container but not breathing bag)
    - (6) Volume during automatic ventilation: 4.35 L (including absorber container and bellows)
  - c) Fresh gas controls
    - (1) Fresh gas is controlled electronically through a combination of virtual buttons on the main display and two physical knobs under the buttons.
    - (2) There are two methods of controlling fresh gas:
      - (a) In total flow control mode, the knob on the left controls the total flow rate of all fresh gases. The knob on the right controls the O<sub>2</sub> concentration of fresh gas. The values are displayed on the virtual buttons.
      - (b) In direct flow control mode, the knob on the left controls the flow of balance gas (air or nitrous oxide) and the knob on the right controls the flow of O<sub>2</sub>. The values are displayed on the virtual buttons.

(c) In either method of flow control, pressing either virtual button opens up a menu that allows the user to change the balance gas, switch between the two flow control methods, enter the values (total flow rate or O<sub>2</sub> concentration in total flow control; O<sub>2</sub> or balance gas flow rate in direct flow control) precisely using a numeric keypad, temporarily pause flow, or pick one of four common flow configurations.

(3) The available range of fresh gas flow settings differs based on which flow control method is enabled.

(a) In direct flow control, nitrous oxide flow range is 0-12 L/min. O<sub>2</sub> and air flow ranges are 0-15 L/min.

(b) In total flow control, total flow range is 0.2-18 L/min (fresh gas flow is off when the unit is in standby).

(4) Fresh gas controls do not work when the device experiences a total electrical failure. Emergency flow controls (see below) allow delivery of O<sub>2</sub> and air in such circumstances.

#### d) Backup flow control

(1) Since this unit has an electronic mixer, physical controls are needed in the event of a total electrical failure.

(2) The backup flow control system comprises physical flow valves and meters for air and O<sub>2</sub> that are recessed until enabled. When enabled, they pop out above the main work surface.

(3) Backup flow control is activated by the user pressing the button adjacent to the controls or is enabled automatically in the event of a total electrical failure.

(4) Backup flow control is disabled via the touch-screen controls.

#### e) Vaporizers

(1) The A7 Advantage works only with Selectec-style vaporizers.

(2) The unit has two or three active vaporizer mounts, depending on configuration.

(3) In addition, one inactive mount is available on the right side of the active mounting bar.

#### f) Absorber

(1) Container for either loose-fill absorbent material or absorbent Pre-Paks.

(2) Bypass valve allows absorbent to be changed during a case without introducing a leak into the breathing system.

(3) Container is located under the breathing system on the left side of the unit.

#### g) Total flow meter

(1) Measures the total fresh gas flow (0-10 L/min)

(2) Flow tube located on the front of the unit to the left of the backup flow control.

#### h) Pressure gauge

(1) Pressure is measured manually, and is also measured electronically and displayed on the screen.

(2) If the unit loses all electrical power, the manual gauge continues to function.

(3) The pressure gauge is circular and located on the left side of the breathing system assembly.

#### i) Illumination

(1) The unit has lights on the underside of the top shelf that shine onto the work surface and illuminate the vaporizer control dials.

(2) Auxiliary O<sub>2</sub> and air flowmeters are also backlit.

(3) It offers two levels of brightness.

(4) The lights are controlled with a switch on the right side of the unit, above the vaporizer mount location.

#### j) Auxiliary O<sub>2</sub> and air

(1) There are two mechanical flow controls and flow tubes that deliver a metered flow of gas separate from the normal fresh gas flow: one each for O<sub>2</sub> and air (0-15 L/min).

(2) O<sub>2</sub> concentration of auxiliary gas can be controlled indirectly by the relative flows of O<sub>2</sub> and air. A blending chart is provided specifying the O<sub>2</sub> and air flow rates needed to deliver several commonly used O<sub>2</sub> concentrations.

- (3) Auxiliary O<sub>2</sub> and/or air is typically used with a nasal cannula or loose-fitting mask.
  - (4) Auxiliary flowmeters are located on the left side of the unit to the left of the main display.
  - (5) The ability to blend air into the auxiliary O<sub>2</sub> flow can help reduce the risk of an O<sub>2</sub>-enriched surgical fire.
- k) Work surface
- (1) Main work surface (D × W): 33 × 61 cm (13 × 24 in)
  - (2) Retractable shelf (D × W): approximately 30 × 44 cm (12 × 17.5 in); located underneath the main work surface
- l) Touchpad
- (1) Can be used instead of the touchscreen to control the unit
  - (2) Pulls out from under the front lip of the work surface
- m) Drawers:
- (1) Three equal-size drawers (H × D × W): 13 × 41 × 43 cm (5 × 16 × 17 in)
  - (2) One lock controls all drawers.
- n) Auxiliary power outlets
- (1) Unit has four 3 A outlets protected by circuit breakers at the rear.
  - (2) The outlets work when the unit is powered off.
- o) Backup cylinder yokes—Three pin-indexed yokes on the back of the unit
- p) Electronic interfaces
- (1) One nine-pin serial port for interface with electronic systems
  - (2) Two USB ports for downloading event logs and configuration information or for connecting a mouse
  - (3) Ethernet connection
  - (4) One nine-pin VGA output for use with a secondary display
  - (5) All interfaces are on the top right of the rear of the unit.
- q) GCX-mount-compatible rails
- (1) Two rails on the left side of the unit (one on top, one on bottom)
  - (2) Three rails on the right side of the unit (one on top, two on bottom)
- r) Standard ventilation modes
- (1) Manual/spontaneous ventilation
  - (2) Volume Control Ventilation—VCV (VC-CMV<sub>s</sub>)\*
  - (3) CPAP/Pressure Support
  - (4) Pressure Control Ventilation—PCV (PC-CMV<sub>s</sub>)
  - (5) Pressure Control Ventilation with Volume Guarantee—PCV-VG (PC-CMV<sub>a</sub>)
  - (6) Synchronized Intermittent Mandatory Ventilation with VC mode—SIMV-VC (VC-IMV<sub>s,s</sub>)
  - (7) Synchronized Intermittent Mandatory Ventilation with PC mode—SIMV-PC (PC-IMV<sub>s,s</sub>)
- s) Auxiliary common gas outlet (ACGO)
- (1) Provides fresh gas with anesthetic agent for use with a non-rebreathing circuit (e.g., a Bain or Mapleson system)
  - (2) Volume monitoring is not available when using the ACGO, but pressure and gas monitoring are available.
  - (3) The gas outlet is on the front of the unit and is activated via a virtual button on the touchscreen (most other auxiliary gas outlets are activated with a physical switch next to the outlet).
- t) Patient suction—Integrated suction regulator (0-40 L/min) that works with various sizes of canisters
4. Optional components and features:
- a) Gas analyzer
- (1) Although the gas analyzer is electronically integrated into the anesthesia unit, the analyzer module can be removed if needed.

\*In addition to listing the ventilation mode names and abbreviations used by the manufacturer, we have included the mode abbreviation according to the taxonomy developed by Robert Chatburn (See: Chatburn et al. 2014, Mireles-Cabodevila et al. 2013).

- (2) The gas analyzer can be changed during a case.
  - (3) The analyzer takes a sidestream sample from the patient wye at 120, 150, or 200 mL/min (the user can select the sample rate in the Setup menu) and analyzes the inspired and expired concentration of O<sub>2</sub>, CO<sub>2</sub>, and anesthetic gases.
  - (4) Sampled gas is returned to the breathing system.
  - (5) The gas analyzer bay is on the left side of the unit, behind the breathing system.
  - (6) Units without the optional integral gas analyzer measure O<sub>2</sub> concentration with a galvanic sensor.
  - (7) The unit also has a secondary internal analyzer.
- b) Anesthetic gas scavenging system (AGSS)
- (1) Used with vacuum waste-gas disposal systems (i.e., active scavenging)
  - (2) This is a small open reservoir canister typically attached to the left side of the unit. It receives scavenged gas via a hose that attaches to back of unit. It connects to the waste-gas disposal system through an outlet on the side of the component.
- c) Optional ventilation modes
- (1) Synchronized Intermittent Mandatory Ventilation with Volume Guarantee—SIMV-VG (PC-IMVa,s) (\$2,100)
  - (2) Airway Pressure Release Ventilation—APRV (PC-IMVs,s) (\$2,100). This is an inverse-ratio pressure-control mode that is sometimes used for acute respiratory distress syndrome (ARDS) patients.
- a) The A7 Advantage has four advanced ventilation modes, all of which we consider advantageous: CPAP/Pressure Support, Pressure Control with VG (PC-CMVa), SIMV with VG (PC-IMVa,s), and APRV (PC-IMVs,s).
  - b) Multiple advanced modes support providing anesthesia to patients with compromised lungs who may come from the ICU where they had received an advanced mode of mechanical ventilation. Being able to continue preoperative ventilation modes during surgery is beneficial to the patient.
  - c) We do not consider advanced ventilation modes advantageous in low-acuity/ambulatory surgery settings because patients who require such modes should not be treated in a low-acuity setting.
2. High peak flow:
- a) The A7 Advantage can provide peak flow as high as 180 L/min.
  - b) This allows pressure-control breaths to be delivered very quickly, which is beneficial for patients with low compliance.
  - c) We do not consider high peak flow advantageous in low-acuity/ambulatory surgery settings because patients who require it should not be treated in a low-acuity setting.
3. High inspiratory pressure capability:
- a) The A7 Advantage can provide inspiratory pressure as high as 100 cm H<sub>2</sub>O via the Pmax setting in volume-control modes.
  - b) This allows the unit to ventilate patients with high resistance and/or low lung compliance (e.g., crushing chest trauma).

## SIGNIFICANT FINDINGS

We performed a variety of tests on this product, including physical testing, a review of product literature/specifications, and asking users about their experience with the device. For more details, see the ECRI's Testing section of our Evaluation Background on this technology.

### Performance—Excellent

#### *Major Advantages (General Purpose)*

##### 1. Advanced ventilation modes:

#### *Major Advantages (General Purpose and Low-Acuity/Ambulatory)*

##### 1. Fresh Gas Optimizer:

- a) The A7 Advantage has a low-flow decision-support tool called Fresh Gas Optimizer.
- b) This encourages anesthesia providers to use less fresh gas, which:
  - (1) May assist in keeping the patient warm (since fresh gas is cold)

## Mindray A7 Advantage

- (2) Helps reduce the environmental footprint of the facility (since waste gas contains pollutants and contributes to the greenhouse effect)
- (3) Saves money by reducing the amount of wasted anesthetic agent and medical gases
- c) For more details on the specific advantages and disadvantages of this feature, as well as similar features from other manufacturers, see our article “A Look at Low-Flow Anesthesia Decision-Support Tools.”

### 2. Return of sample gas:

- a) The A7 Advantage returns sampled gas to the breathing system by default.
- b) Facilities will see some cost savings related to less agent use. In addition, this feature supports the use of lower fresh gas flows and potentially even closed-circuit anesthesia, in which only enough fresh gas is introduced to replace the O<sub>2</sub> consumed by the patient.

### *Minor Advantages (General Purpose)*

#### 1. Automatic ventilation maneuvers:

- a) The A7 Advantage has two automatic maneuvers:
  - (1) The Recruitment Pressure Adjust is an inspiratory-hold maneuver in which the ventilator will maintain a set pressure for a set amount of time. Note that with highly compliant lungs, delivering a high pressure (e.g., 35 cm H<sub>2</sub>O) will not be possible since that will exceed the volume of the bellows.
  - (2) The Recruitment Preset Procedure delivers a user-determined sequence of pressure breaths (up to seven steps).
- b) These maneuvers provide useful clinical information, typically static compliance and the appropriate positive end-expiratory pressure (PEEP) setting, respectively.
- c) An anesthesia provider can simulate these maneuvers in other ways (e.g., perform them manually in manual ventilation mode), but automating them is more precise, consistent, and convenient.
- d) These maneuvers are useful primarily in a general-purpose setting.

#### 2. Spirometry loop display:

- a) The A7 Advantage displays pressure/volume, flow/volume, and pressure/flow loops. In addition to the real-time loops, it also allows a user to record and display one baseline and up to four reference loops.
- b) Spirometry loops are a useful diagnostic tool (e.g., showing changes in lung compliance).
- c) Loops are useful primarily in a general-purpose setting.

### *Minor Advantages (General Purpose and Low-Acuity/Ambulatory)*

#### 1. Passive scavenging:

- a) The A7 Advantage supports the use of passive scavenging.
- b) This gives facilities more flexibility. Most facilities in the United States use active scavenging, but passive scavenging is still used in some places.

#### 2. Trending:

- a) The A7 Advantage stores up to 48 hours of trended data, which can be displayed both numerically and graphically.
- b) Trended data can help the anesthesia provider detect changes in the patient's condition and anesthetization during a long case. It also supports manual charting efforts to record past data accurately.

#### 3. Condensation management:

- a) The A7 Advantage heats the breathing system to reduce condensation of water within the breathing system and mitigate the impact of condensed water.
- b) The anesthesia provider can disable the breathing system heater if this is necessary for patient care. Breathing system heating can be turned on or off in the Setup menu and is automatically disabled when the unit is operating on battery power.
- c) This is particularly useful during low-flow anesthesia because the higher proportion of warm, humid exhaled gases as compared to cool, dry fresh gas makes rainout more likely.

## 4. Pause flow:

- a) The A7 Advantage has a pause feature that allows the anesthesia provider to temporarily stop all gas flow and suspend alarms, agent delivery, and ventilation. All resume either when the provider ends the pause or after one minute. The pause can be extended in 30-second increments up to two minutes.
- b) This feature allows OR staff to avoid venting anesthetic gases and agent to the room during planned breathing circuit disconnections without having to change settings (which would need to be reset when the breathing circuit is reconnected).

## Safety—Excellent

### Major Advantages

#### 1. Emergency operation:

- a) The A7 Advantage can deliver O<sub>2</sub>, air, and anesthetic agents without requiring electricity. Only manual ventilation is possible until power is restored.
- b) This allows the anesthesia provider to continue with complete anesthesia care even when power is interrupted and the battery is depleted.
- c) Three features and design decisions work together to make this possible:
  - (1) The vaporizers do not require electricity to work, with the exception of those that deliver desflurane. (All desflurane vaporizers require electricity because of the properties of desflurane.)
  - (2) The A7 Advantage has backup flow controls for both air and O<sub>2</sub> that automatically enable when electrical power is lost.
  - (3) The unit has an analog breathing pressure gauge.
- d) Note that all gas delivery is stopped when the power switch is turned off, regardless of whether the unit has electrical power (i.e., is plugged into the wall or there is charge remaining in the battery).

#### 2. Active alarms preselected:

- a) The A7 Advantage has a feature in which the active alarm is highlighted and preselected when the anesthesia provider opens the alarm menu. Pressing an alarming parameter on

the touchscreen will also open the alarm menu with that alarm limit preselected.

- b) This reduces the chance that the provider will accidentally change the wrong limit, and it allows limits to be adjusted more quickly in response to the alarm.
- c) In systems without a similar feature, to change the limit for an active alarm, the provider has to:
  - (1) Open the alarm menu
  - (2) Identify the active alarm
  - (3) Select the limit to change (i.e., upper or lower, typically by pressing the limit on the screen)
  - (4) Turn the control knob to adjust the limit
  - (5) Confirm the change (typically by pushing in the control knob)
- d) Because the active alarm is preselected on the A7 Advantage, two of these steps are eliminated (identifying the active alarm and selecting the limit to change).
- e) If more than one alarm is active when the provider opens the alarm menu via the Alarm button on the screen, the highest-priority alarm is preselected. If an alarming parameter is touched, the alarm menu will open with that alarm limit preselected.

#### 3. Minute volume default alarm limits:

- a) The A7 Advantage does not allow a user to set the default low-minute-volume alarm limit below 0.1 L/min for any patient.
- b) This prevents the user from inappropriately setting the default low-minute-volume alarm limit too low. Some other devices allow the user to configure the low-minute-volume default limit to “Off,” to 0, or to such a low value that the alarm will never be triggered.
- c) Minute volume is a key respiratory parameter. While there are situations that may warrant disabling the low-minute-volume alarm, we are aware of incidents in which an inappropriately set low-minute-volume alarm limit contributed to patient harm. Allowing the user to inappropriately set the default low-minute-volume alarm limit to “Off,” to 0, or to a very low value increases the chance of such an event occurring.

## Minor Advantages

1. Expired O<sub>2</sub> measurement:
  - a) The A7 Advantage displays expired O<sub>2</sub> concentration and can be configured to display a real-time O<sub>2</sub> concentration waveform (in addition to displaying inspired O<sub>2</sub> concentration); this feature requires the optional integrated gas analyzer.
  - b) This provides useful diagnostic information to the anesthesia provider.
2. Customizable default alarm limits:
  - a) The A7 Advantage has customizable default alarm limits for neonatal, pediatric, and adult patients.
  - b) This allows facilities to configure default alarm limits that match their practice and patient population.
  - c) Customizing the default limits requires an access code.

## Minor Disadvantages

1. Imprecise O<sub>2</sub> concentration setting for auxiliary gas:
  - a) The A7 Advantage has two auxiliary gas flowmeters (air and O<sub>2</sub>), which allows the anesthesia provider to deliver auxiliary gas at a controlled O<sub>2</sub> concentration (e.g., below 30%, which reduces the risk of an O<sub>2</sub>-enriched surgical fire). However, the provider cannot directly control the O<sub>2</sub> concentration of this auxiliary gas.
  - b) The anesthesia provider may not be able to accurately control either flow rate or O<sub>2</sub> concentration with this arrangement.
2. No individualized alarm tones for multiple alarm conditions:
  - a) If an alarm is annunciating and a different alarm of the same priority occurs, the A7 Advantage does not indicate the new alarm condition with an individualized alarm tone.
  - b) The anesthesia provider may not realize that a new alarm condition has occurred, especially if they are focused on dealing with the first alarm condition.

## Workflow—Good

### Minor Advantages

1. Anesthetic agent consumption:
  - a) The A7 Advantage calculates the amount of anesthetic agent used (i.e., the total amount that exits the vaporizer) during a case with a second gas analyzer used specifically for such measurements.
  - b) This assists in documentation for individual cases.
2. Central wheel brake:
  - a) The A7 Advantage has a central brake.
  - b) Using a central brake is easier than locking multiple casters individually.
3. Cord and cable management:
  - a) The A7 Advantage's casters have built-in sweeps.
  - b) OR floors often have many cords, cables, and hoses that can interfere with pushing an anesthesia unit. The sweeps prevent the casters from rolling over these items and the subsequent problems this causes (impeding flow in gas hoses, pulling cables and cords out of devices).
4. Logging of pre-use check results:
  - a) The A7 Advantage logs the results of the pre-use check (i.e., whether the check was passed, any error codes associated with failures that occurred during the pre-use check).
  - b) Included in the log are the numerical values for system leak and compliance.
  - c) The log is useful in tracking how often the pre-use check is run. In addition, the logging of leak and compliance values is useful if there is a subsequent problem during a case, since an investigator can refer back to what was measured during the pre-use check. It can also be used diagnostically if a unit develops a failure over time.
5. Adjustable pressure-limiting (APL) valve pop-off:
  - a) Lifting up on the A7 Advantage's APL control knob sets the pressure in the breathing system to zero as long as the knob is lifted.

- b) This allows the anesthesia provider to temporarily relieve the pressure in the breathing system without adjusting the APL valve setting (and potentially setting it inappropriately after turning it to zero).
6. High-pressure O<sub>2</sub> outlet:
- a) The A7 Advantage has a high-pressure (approximately 50 psi) O<sub>2</sub> outlet that can be used as a source for a stand-alone device such as a jet ventilator.
  - b) While there are other high-pressure O<sub>2</sub> sources in the OR, this one is conveniently located close to where the device is likely to be used (i.e., near the patient's airway).
7. Hot-swappable batteries:
- a) The A7 Advantage has two battery packs that can be replaced one at a time during operation without the need to power off the unit.
  - b) This allows extended operation on battery power as long as charged battery packs are available.
8. Quick power-on:
- a) The A7 Advantage powered on in 24 seconds during our testing.
  - b) A quick power-on means the unit can be ready to use quickly in an emergency, and it could minimize interruptions during a case.
  - c) Units are typically powered on long before a case starts, but if it is ever necessary to power-cycle a unit during a case, a faster power-on would reduce the amount of time the anesthesia provider must spend performing manual ventilation.
9. Highly configurable device mounting options:
- a) The A7 Advantage has five GCX-mount-compatible rails.
  - b) This gives facilities significant flexibility in configuring mounting arms for monitors, computers, and other devices.
10. Hot-swappable gas analyzer:
- a) The A7 Advantage's optional integral gas analyzer can be replaced in the middle of a case without interrupting the operation of the unit itself.
  - b) This allows the gas analyzer to be replaced if it fails in the middle of a case. For systems without hot-swappable analyzers, the entire unit must be replaced or a stand-alone gas analyzer must be used.

### **Notable Finding**

Battery life in our testing was over two hours.\*

## **Patient Experience—Not Evaluated**

### **Interoperability—Good**

#### **Minor Advantages**

1. Exports anesthetic agent consumption data:
  - a) As mentioned above, the A7 Advantage measures the amount of agent used during the case.
  - b) In addition to being available to the anesthesia provider on the screen, this information is also communicated electronically to other systems (e.g., electronic medical records [EMRs]).
  - c) This is useful for automatic documentation. It also allows facilities to track overall agent usage, which is useful for facilities that want to reduce agent use.
2. Exports fresh gas measurements:
  - a) The A7 Advantage communicates fresh gas measurements electronically to other systems.
  - b) This is useful for automatic documentation. It also allows facilities to track overall agent usage (i.e., if there is an effort to encourage the use of low-flow anesthesia).
3. Supports data integration:
  - a) The A7 Advantage outputs data that complies with the Device Enterprise Communication profile within Integrating the Healthcare Enterprise's (IHE) Patient Care Devices domain (i.e., IHE PCD DEC).
  - b) This allows facilities to send data from the A7 to another system (e.g., EMR) without requiring the use of a third-party integrator.

\*We operated the system on battery power at the following settings: volume-control mode with a tidal volume of 500 mL and a rate of 12 breaths/min. We set up the test lung to simulate a normal adult patient, with a compliance of 0.1 L/cm H<sub>2</sub>O and a resistance of 5 cm H<sub>2</sub>O/L/sec. We set fresh gas flow at 2 L/min of O<sub>2</sub>. We operated the system until the battery expired and noted the behavior as the battery neared exhaustion.



### 4. Alarm communication:

- a) The A7 Advantage transmits alarm information, including alarm name and priority, electronically in real time.
- b) This information can be used in a number of ways by the facility, one of which is the development of “smart” monitoring algorithms.

### Cybersecurity—Good

The manufacturer has completed ECRI’s cybersecurity questionnaire, which identifies the cybersecurity capabilities of the system. We judged the responses to be satisfactory.

### Maintenance—Good

#### *Minor Advantages*

#### 1. Easy-to-clean breathing system:

- a) Tools are not required to disassemble the A7 Advantage’s breathing system.
- b) This makes cleaning the breathing system easier.

#### 2. Easy-to-access batteries:

- a) The A7 Advantage’s batteries are readily accessible and are easy to replace.
- b) This contributes to the easy PM mentioned above. But it is also useful if there is a problem with a battery before scheduled maintenance.

### 3. Very easy preventive maintenance (PM):

- a) The A7 Advantage users we spoke with all reported that performing the PM was very easy.
- b) This reduces the amount of time a unit is out of service for PM.

#### *Minor Disadvantage*

#### 1. Flow sensor calibration:

- a) The A7 Advantage’s flow sensors require manual calibration when they are changed or cleaned, or when tidal volume measurements are inaccurate. The calibration process requires partial disassembly of the breathing system.
- b) The need for cumbersome manual calibration could lead to delays during or, more likely, between cases.

### User Experience—Good

#### *Positive User Feedback*

Users liked the ability to change between total flow control and direct flow control.

#### *Negative User Feedback*

Some users found the touchscreen occasionally unresponsive.

### Cost of Ownership—Good; \$96,000-\$100,000 (Estimated) over 10 Years

This figure is based on the prices for the United States, a major market for the product.

# Mindray A7 Advantage

## ESTIMATING THE TYPICAL COST OF OWNERSHIP FOR THE MINDRAY A7 ADVANTAGE

The costs reported in this table represent typical quotation and purchase costs reported to ECRI's SELECTplus and PriceGuide databases, respectively. Some pricing quotes also provided by Mindray. These figures are provided as a guide only and may vary significantly.

Note that these figures are based on prices for the United States, a major market for the product.

| Factor  | Typical Cost  | Assumptions   |
|---|---|---|
| <b>Purchase Costs</b>   |   |   |
| Capital cost  | General-purpose: \$53,000<br>Low-acuity/ambulatory surgery: \$49,000                | Average quoted cost, including gas analyzer, standard accessories, all optional ventilation modes, and Spirometry and Bypass optional features. Based on pricing data in ECRI's SELECTplus database and information provided by the vendor.   |
| Typical accessories   | Sevoflurane vaporizer: \$3,000<br>Desflurane vaporizer: \$7,500                     | Facilities do not always purchase vaporizers with their anesthesia units. But for our purposes we have included the average quoted cost of vaporizers for the two most popular agents (isoflurane vaporizers are priced the same as sevoflurane). Facilities that already have vaporizers or that receive vaporizers as part of their agent contracts will see a lower upfront cost.        |
| Warranty  | \$0   | Three-year warranty included in purchase price.   |
| Clinical staff training   | \$0   | Initial training (e.g., three or four days at time of purchase) is included in the capital cost. Any additional training would cost \$1,500 per day.  |
| Biomedical staff training   | \$14,000  | Two staff members trained at \$6,800 each. Optional training is one week, and on-site training is negotiable.   |
| Infrastructure modifications  | \$0   | None.   |
| <b>Total purchase cost</b>  | General-purpose: \$78,000<br>Low-acuity/ambulatory surgery: \$74,000                | —   |
| <b>Annual Operational Costs</b>   |   |   |
| Consumables   | Breathing circuits: \$0   | Breathing circuits contribute to the consumable cost for anesthesia units, but have been excluded from this analysis because circuit cost is not a factor in deciding which unit to purchase (since all breathing circuits can be used with all anesthesia units).  |
|   | Absorbent: \$1,900/yr   | Three per anesthesia unit per week, 52 weeks per year = 156 Pre-Paks at \$12 each. Pre-Paks can be purchased from third parties.  |
|   | Agent: \$0  | Agent is by far the most significant contribution to the consumable cost for anesthesia units, but has been excluded from this analysis because agent cost is not a factor in deciding which unit to purchase (since agent from any supplier can be used with all anesthesia units).  |
| Expected part replacement—averaged throughout life of device                    | \$0   | No replacements expected.   |
| Service   | Preventive maintenance (PM) kits: \$300/yr  | Total cost for all PMs over first 10 years: \$3,000.  |
|   | Batteries: \$0  | Batteries are included in PM costs.   |
|   | Labor: \$0  | \$0 assuming facility opts to pay for biomedical staff training and have clinical engineering perform the annual PM. Alternatively, facility can choose a Mindray service package that includes PM (detailed in the Service and Maintenance section below) or pay for Mindray to service the units on a one-off basis at a rate of \$530/hr. This does not include travel time to facility. |
| Annual license fee  | \$0   | None.   |
| <b>Average annual operational cost</b>  | \$2,200   | —   |
| <b>Estimated Total Cost of Ownership</b><br>(for an estimated life of 10 years) | <b>General purpose: \$100,000</b><br><b>Low-acuity/ambulatory surgery: \$96,000</b> | Total purchase cost + (annual operational cost × estimated life)  |

## CONSIDERATIONS FOR CHALLENGING ENVIRONMENTS: MINDRAY A7 ADVANTAGE

As of the time of publication, this product is marketed worldwide.

| Category  | Remarks   |
|---|---|
| <b>Physical Environment</b><br>Ability to operate successfully in a variety of adverse conditions | Significant concern: As with other anesthesia units, this unit requires consistent power, and excessive humidity and ambient air temperature extremes must be avoided.  |
| <b>Installation</b><br>Installation requirements compared to other equipment in the same category | Significant concern: Like other anesthesia units, this unit must be connected to a high-pressure source for oxygen and either an air or nitrous oxide source for it to ventilate.   |
| <b>Training and Operation</b><br>Whether the product can be learned and used without undue burden | Significant concern: Anesthesia providers require specialized training.   |
| <b>Servicing</b><br>Whether the product can be serviced without undue burden                      | Moderate concern: Servicing for anesthesia units in remote areas may involve delays and increased shipment costs. Mindray has an extensive global distribution and service network, which partially mitigates these concerns. |

## DISCUSSION OF KEY MANUFACTURER CLAIMS

These claims are drawn from labeling and promotional materials in the United States, a major market for the product.

| Mindray Claim  | Category    | ECRI Perspective   |
|--|-------------|--|
| The fresh gas flow Optimizer indicates the recommended fresh gas flow setting against your current setting value and the minimum O <sub>2</sub> needed of the patient. It enables a safe low flow and minimizes the waste of anesthetic agents and medical gases.                              | Performance | <b>ECRI agrees; we consider this a significant benefit.</b><br>As noted in our Performance findings above, we consider the Fresh Gas Optimizer advantageous.   |
| Sample gas return: The monitoring sample gas returns to breathing circuit, it saves the cost for medical gas and anesthetic agent as well as reducing the waste gas.   | Performance | <b>ECRI agrees; we consider this a significant benefit.</b><br>As noted in our Workflow findings above, we consider the return of sample gas to the breathing system advantageous.   |
| Advanced ventilation modes such as APRV and SIMV-VG provide optional tools for lung-protective ventilation strategies.   | Performance | <b>ECRI agrees; we consider this a significant benefit.</b><br>As noted in our Performance findings above, we consider advanced ventilation modes advantageous.  |
| Real-time visualization of lung-recruitment therapy during cases helps optimize pulmonary status and minimize postoperative complications.   | Performance | <b>ECRI agrees; we consider this a significant benefit.</b><br>As noted in our Performance findings above, we consider spirometry loops advantageous.  |
| Heated breathing system designed to reduce condensation during extensive cases.  | Performance | <b>ECRI agrees; we consider this a significant benefit.</b><br>As noted in our Performance findings above, we consider a heated breathing system advantageous.   |
| Pause Flow functionality ensures that anesthetic gases do not flow into the OR during intubation, inadvertent disconnects, or extubation.  | Performance | <b>ECRI agrees; we consider this a significant benefit.</b><br>As noted in our Performance findings above, we consider a pause gas feature advantageous.   |
| Capability to deliver high inspiratory flow both peak and continuously up to 180L/min and thus adapt to individual patient demands.  | Performance | <b>ECRI agrees; we consider this a significant benefit.</b><br>As noted in our Performance findings above, we consider the ability to deliver a high peak flow advantageous.   |
| A backup mechanical flowmeter with O <sub>2</sub> +AIR will be ejected in case the digital gas mixer fails to work.  | Safety      | <b>ECRI agrees; we consider this a significant benefit.</b><br>As noted in our Safety findings above, we consider the ability to deliver all gases and anesthetic agent without electricity—which the backup flow controls for both O <sub>2</sub> and air contribute to—advantageous. |
| The digital gas mixer makes fresh gas flow setting easier and more precise.  | Workflow    | <b>ECRI agrees, but the benefit is not likely significant.</b><br>The users we spoke with were ambivalent about the digital flow setting. In our testing we found it easy to use, but not significantly better than traditional flow controls.   |
| With the digital gas mixer, users could directly set the total flow and O <sub>2</sub> percentage, or the flow of O <sub>2</sub> and the balance gas respectively. With the traditional easy-to-use knobs, users could set the fresh gas flow value by digital setting of adjusting the knobs. | Workflow    | <b>ECRI agrees.</b><br>As noted in our User Experience findings above, users found that the two methods of flow control (total flow or direct flow) provide some additional flexibility.   |
| The new anesthetic agent calculation software enables you to monitor the real-time agent consumption and keeps cost in mind.   | Workflow    | <b>ECRI agrees; we consider this a significant benefit.</b><br>As noted in our Workflow findings above, we consider the ability to measure agent usage during a case advantageous.   |
| The revolutionary fully-touch and hard key-free control helps you to communicate with the anesthesia system like never before.   | Workflow    | <b>ECRI agrees, but the benefit is not likely significant.</b><br>Some users found the touchscreen unresponsive at times.  |
| A back-up Touch Pad and mouse control enables easy control access for both standing and sitting position.  | Workflow    | <b>ECRI agrees, but the benefit is not likely significant.</b><br>We did not consider the touch pad or mouse control advantageous. Users also did not see much advantage in them.  |
| Disassembly of the breathing system is achieved with a few simple steps.   | Maintenance | <b>ECRI agrees; we consider this a significant benefit.</b><br>As noted in our Maintenance findings above, we consider the easy-to-clean breathing system advantageous.  |

## RECALLS AND HAZARDS

The following data is based on *Health Devices Alerts* records from July 11, 2017, through July 11, 2020. In addition, our Evaluation Background on general-purpose anesthesia units also has a list of generic anesthesia hazards (i.e., hazards that are not about one or more specific devices).

| HDA Record  | Country   | Priority | Date of Last Update | Category      |
|---|---|----------|---------------------|---------------|
| A34796 01: [COVID-19] Mindray—Anesthesia Devices: Manufacturer Provides Addendum on Procedures for Converting Drive Gas from Oxygen to Air [Update] | U.S.  | High     | 4/28/2020           | User Training |
| A34796: [COVID-19] Mindray—Anesthesia Devices: Manufacturer Addresses Use for Continuous Ventilation  | U.S.  | High     | 3/26/2020           | User Training |
| A28838: Mindray—A-Series Anesthesia Systems: May Be Unable to Enter Standby Mode and/or May Skip Leak Test and Standby Mode at Startup              | (Impact in additional regions has not been identified or ruled out at the time of this posting), U.S. | High     | 4/17/2018           | Hardware      |

## USER SURVEY RESULTS

We surveyed anesthesia machine users about their opinions of a number of current models—including ease of use, performance, and reliability—plus the average number of annual repairs they experience and how often they inspect the devices. See the survey results on our member website.

## SERVICE AND MAINTENANCE

The following information pertains to the United States, a major market for the product. It is provided largely verbatim from the manufacturer.

### Warranty

Standard warranty terms:

1. Three years standard manufacturer’s warranty. This does not include preventive maintenance.
2. Mindray DS USA, Inc. warrants that components within the anesthesia system will be free from defects in workmanship and materials for the number of years shown on the invoice. Under this extended warranty, Mindray DS USA, Inc. will repair or replace any defective component at no charge for labor and/or materials. This extended warranty does not cover consumable items such as (but not limited to) batteries and external cables.

### Inspection and Preventive Maintenance (IPM)

1. IPM frequency: One preventive maintenance required per year.
2. Downtime for IPM: Approximately two hours per preventive maintenance.

### In-House/Third-Party Service

1. Manufacturer supports user repair: Yes, Mindray supports user repair when trained by Mindray technical support.
2. Training required and cost: \$6,800 for biomed course.
3. Availability of service manual: PDF is available on Mindray website.
4. Dedicated test equipment and/or software required: Off-the-shelf equipment can be used to test machine. Mindray software tool required to update software.
5. Availability of manufacturer assistance: Technical support available 24/7.

### OEM Maintenance

1. Standard OEM service options
  - a) Three annual options:
    - (1) Basic
    - (2) Service Only
    - (3) Service Plus One PM
  - b) Description of coverage:
    - (1) Basic—Preventive Maintenance only
    - (2) Service Only—Extended Warranty
    - (3) Service Plus One PM—Extended Warranty and Preventive Maintenance
      - (a) Packages are available in yearly increments, multiple-year agreements are billed annually.

(b) Hours of coverage: Within normal working hours, upon availability of machine.

(c) Response time: Two hours by phone, no later than 24 hours on site.

2. Software upgrade and update policy: Software updates and functionality upgrades offered to customer at time of service at no charge to customer. Travel and labor costs may apply.

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## About ECRI

ECRI is an independent, nonprofit organization improving the safety, quality, and cost-effectiveness of care across all healthcare settings. With a focus on patient safety, evidence-based medicine, and health technology decision solutions, ECRI is the trusted expert for healthcare leaders and agencies worldwide. The Institute for Safe Medication Practices (ISMP) is an ECRI affiliate. Visit [ecri.org](http://ecri.org) and follow [@ECRI\\_Org](https://twitter.com/ECRI_Org).



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