EVALUATION

ICU Physiologic Monitoring Systems, Focusing on the Mindray BeneVision N17

A Report Excerpted from *Health Devices* | February 2021

Also Includes Ratings and Purchasing Advice for:

Draeger Infinity Acute Care System
Fukuda Denshi Dynascope DS-8400
GE Carescape B850
Nihon Kohden America Life Scope G9 CSM-1901
Philips Healthcare IntelliVue MX800

Left: The BeneVision N Series bedside monitors. Bottom row, left to right: N1, N17, N19, and N22. Top row: N19 and N22. Right: The Distributed Monitoring System (DMS) WorkStation. (Images courtesy of Mindray.)

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EVALUATION

ICU Physiologic Monitoring Systems, Focusing on the Mindray BeneVision N17

A Report Excerpted from *Health Devices* | February 2021

This report focuses on our Evaluation of the Mindray BeneVision N17 ICU physiologic monitoring system. For perspective, it also includes our findings for the other products we evaluated: the Draeger Infinity Acute Care System, Fukuda Denshi Dynascope DS-8400, GE Carescape B850, Nihon Kohden America Life Scope G9 CSM-1901, and Philips Healthcare IntelliVue MX800.

A summary of our findings is presented below and on the next 3 pages. Our detailed Evaluation results for the BeneVision N17 begin on page 7.

RATINGS: ICU PHYSIOLOGIC MONITORING SYSTEMS

Model	Rating	Where Marketed	Performance	Safety	Workflow	Patient Experience	Interoperability	Cybersecurity	Maintenance	User Experience	Cost of Ownership (Estimated) over 10 Years
Mindray BeneVision N17 Last updated 9/2020	★★★★☆	Worldwide	Excellent	Good	Good	Good	Good	Good	Excellent	Good	$2,000,000
Draeger Infinity Acute Care System Last updated 3/2018	★★☆☆☆	Worldwide	Good	Poor	Good	Good	Good	Not evaluated	Excellent	Good	$2,600,000
Fukuda Denshi Dynascope DS-8400 Last updated 7/2018	★★☆☆☆	Worldwide	Poor	Poor	Good	Good	Fair	Not evaluated	Good	Good	$2,300,000
GE Carescape B850 Last updated 12/2017	★★★★☆	Worldwide	Excellent	Good	Good	Good	Good	Not evaluated	Excellent	Good	$3,300,000
Nihon Kohden Life Scope G9 CSM-1901 Last updated 5/2020	★★★☆☆	Worldwide	Excellent	Fair	Good	Good	Excellent	Good	Excellent	Good	$3,300,000
Philips IntelliVue MX800 Last updated 12/2017	★★★★☆	Worldwide	Excellent	Fair	Good	Good	Good	Not evaluated	Excellent	Good	$3,700,000

Summary of Findings: ICU Physiologic Monitoring Systems

MINDRAY BENEVISION N17

Where Marketed

As of the time of publication, this product is sold worldwide. (This Evaluation covers the version that has been cleared by FDA for the U.S. market.)

Findings

Our rating is based on the following findings:

Performance—Excellent. The system allows full-disclosure data caching during network downtime with automatic transfer upon reconnection and offers data caching during electronic medical record unavailability.

Safety—Good. The system offers patient profiles with customizable display layout.

Workflow—Good. The product met our required criteria for workflow.

Patient Experience—Good. The product met our required criteria for patient experience.

Interoperability—Good. The product met our required criteria for interoperability.

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—Excellent. The system offers global configuration management.

User Experience—Good. The product met our required criteria for user experience.

Cost of Ownership—$2,000,000 (estimated) over 10 years. Note that this calculation is based on prices for the United States, a major market for the product.

Considerations for Challenging Environments

There is a moderate concern for use of this product in challenging environments: The system can function in relative humidity up to 95%; in regions where the relative humidity regularly reaches 100%, this could cause problems. However, all components of the monitoring system can withstand reasonable physical damage, and the system has an ingress protection rating sufficient to protect it from vertically falling water drops. Installation requirements are similar to those of comparable monitoring systems. This is a complex monitoring technology, and the installation requirements would depend on the facility infrastructure already in place.

DRAEGER INFINITY ACUTE CARE SYSTEM

Findings

Our rating is based on the following findings:

Performance—Good. The system offers data caching during electronic medical record unavailability as well as several minor advantages.

Safety—Poor. The system lacks alarm escalation, and alarms for lethal arrhythmias can be turned off if the system is configured in one specific way. The system does not allow customization of medium-priority alarms. Moreover, alarms can be indefinitely suspended. On the plus side, the system offers patient profiles with customizable display layout and alarm settings to meet facility needs.

Workflow—Good

Patient Experience—Good

Interoperability—Good

Maintenance—Excellent. The supplier offers a global configuration management feature that facilitates the management of default device configurations in a given care area by an individual with the appropriate authority and clinician password, potentially saving clinician/biomedical engineering time.

User Experience—Good

Cost of Ownership—$2,600,000 (estimated) over 10 years

FUKUDA DENSHI DYNASCOPE DS-8400

Findings

Our rating is based on the following findings:

Performance—Poor. Full-disclosure waveforms are displayed at the bedside, so they will still be available when the network is down. However, Fukuda Denshi does not provide alarm analytics

services, and the alarm history tab does not provide a way of visually differentiating between events from multiple patients, which could potentially lead to errors.

Safety—Poor. The system lacks alarm escalation, and alarm threshold limits are not synced between the bedside monitor and central station. The system allows priorities for the same alarm conditions to be configured differently at the bedside monitor than at the central station. However, the system offers patient profiles with customizable display layout and alarm settings to meet facility needs.

Workflow—Good

Patient Experience—Good

Interoperability—Fair. Fukuda Denshi has not provided details on how the system prevents missed data through tools such as data transmission acknowledgment.

Maintenance—Good

User Experience—Good

Cost of Ownership—$2,300,000 (estimated) over 10 years

GE CARESCAPE B850

Findings

Our rating is based on the following findings:

Performance—Excellent. The system offers data caching during electronic medical record unavailability.

Safety—Good. The system offers patient profiles with customizable display layout and alarm settings to meet facility needs.

Workflow—Good

Patient Experience—Good

Interoperability—Good

Maintenance—Excellent. The supplier offers a global configuration management feature that facilitates the management of default device configurations in a care area by an individual with the appropriate authority and clinician password, potentially saving clinician/biomed time.

User Experience—Good

Cost of Ownership—$3,300,000 (estimated) over 10 years

NIHON KOHDEN AMERICA LIFE SCOPE G9 CSM-1901

Where Marketed

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

Findings

Our rating is based on the following findings:

Performance—Excellent. The system allows full-disclosure data caching during network downtime and automatic transfer upon reconnection.

Safety—Fair. The system offers advantageous configurable default patient profiles. However, it does not meet our expectations for information displayed during alarm silencing and suspension, and also offers only one level of password-protected access, limiting users' ability to safely tailor alarms to individual patient conditions.

Workflow—Good. The product met our required criteria for workflow.

Patient Experience—Good. The product met our required criteria for patient experience.

Interoperability—Excellent. The system is capable of exporting waveform data to electronic medical records (EMRs).

Cybersecurity—Good. The product met our required criteria for cybersecurity.

Maintenance—Excellent. The system offers global configuration management.

User Experience—Good. The product met our required criteria for user experience.

Cost of Ownership—$3,300,000 (estimated) over 10 years. Note that this calculation is based on prices for the United States, a major market for the product.

Considerations for Challenging Environments

There is a moderate concern for use of this product in challenging environments: The system can function in relative humidity only up to 85%, which could cause problems in regions where the relative humidity regularly reaches 100%. However, all components of the monitoring system can withstand reasonable physical damage, and the system has an ingress protection

rating sufficient to protect it from vertically falling water drops. This is a complex monitoring technology, and the installation requirements would depend on the facility infrastructure already in place.

PHILIPS HEALTHCARE INTELLIVUE MX800

Findings

Our rating is based on the following findings:

Performance—Excellent. The system offers data caching during electronic medical record unavailability as well as several minor advantages.

Safety—Fair. Alarms for lethal arrhythmias can be turned off by setting the audio pause alarm feature to an indefinite time period via a password-protected configuration menu. On the plus side, the system offers patient profiles with customizable display layout and alarm settings to meet facility needs.

Workflow—Good

Patient Experience—Good

Interoperability—Good

Maintenance—Excellent. The supplier offers a global configuration management feature that facilitates the management of default device configurations in a given care area by an individual with the appropriate authority and clinician password, potentially saving clinician/biomedical engineering time.

User Experience—Good

Cost of Ownership—$3,700,000 (estimated) over 10 years

Mindray BeneVision N17

RATING

The Mindray BeneVision N17 monitoring system is a very good choice for physiologic monitoring applications in an ICU environment. The system allows full-disclosure data caching during network downtime with automatic transfer upon reconnection and offers data caching during electronic medical record (EMR) unavailability. The system offers patient profiles with customizable display layout and also offers global configuration management.

There is a moderate concern for use of this product in challenging environments: The system can function in relative humidity up to 95%; in regions where the relative humidity regularly reaches 100%, this could cause problems. However, all components of the monitoring system can withstand reasonable physical damage, and the system has an ingress protection rating sufficient to protect it from vertically falling water drops. Installation requirements are similar to those of comparable monitoring systems. This is a complex monitoring technology, and the installation requirements would depend on the facility infrastructure already in place.

PRODUCT DETAILS

- Name: BeneVision N17 Patient Monitor
- Date evaluated: September 2020
- Manufacturer: Mindray [454750]
- Where marketed: Worldwide
- U.S. FDA clearance: Yes; CE Mark: Yes (BeneVision N17, BeneVision N1, and BeneVision DMS WorkStation)
- Healthcare Product Comparison System (HPCS) comparison chart: Physiologic Monitoring Systems, Acute Care; Neonatal; ECG Monitors; Monitors, Central Station
  (HPCS is available to members of Health Devices Gold and SELECTplus.)
- Software version evaluated:
  - BeneVision N17 bedside patient monitor: V01.15.00
  - BeneVision N1 transport monitor/module: V01.06
  - BeneVision Distributed Monitoring System (DMS) Server: V04.03
  - BeneVision DMS WorkStation: V04.03

PRODUCT DESCRIPTION

1. Depending on their configuration, physiologic monitoring systems measure and display waveforms and numeric data for various parameters, including ECG, respiratory rate, noninvasive blood pressure (NIBP) and invasive blood pressure (IBP; systolic, diastolic, and mean), body temperature, pulse rate, arterial hemoglobin oxygen saturation (SpO_2), mixed venous oxygen saturation (SvO_2), central venous oxygen saturation ($ScvO_2$), regional oxygen saturation (rSO_2), cardiac output, continuous cardiac output, end-tidal carbon dioxide ($EtCO_2$), intracranial pressure, electroencephalogram (EEG), and airway gas concentrations (particularly during the administration of anesthesia).

2. Major components and software features:

   a) BeneVision N1 transport monitor: This unit offers a 14 cm (5.5 in) color touchscreen LCD display and is intended for continuous measurement of adult, pediatric, and neonatal physiologic parameters. The N1 transport monitor communicates wirelessly to the BeneVision DMS using an IEEE 802.11 a/b/g/n connection and can also be docked to the BeneVision N Series bedside monitors as a patient measurement module.

   b) BeneVision N17 bedside monitor: A high-acuity bedside monitor intended for continuous monitoring of adult, pediatric, and neonatal patients.*

      (1) The N17 is intended to:

         (a) Admit and discharge patients via an automatically populated list from the hospital's admit/discharge/transfer (ADT) system by using a bar-code scanner or through a patient search feature

         (b) Display numeric data, graphical trends, and parametric waveforms received from a data acquisition unit (N1 transport module) as well as visual and audible alarm signals

         (c) Serve as a connectivity hub to integrate patient data from different stand-alone medical devices connected to the patient (e.g., ventilators, hemodynamic monitors, infusion pumps)

* Mindray's N19 and N22 bedside monitors support the same features/operation as, and have the same user interface as, the N17 but offer larger screen sizes, options for landscape or portrait displays, and additional simultaneous parameter measurements that may be a benefit in some ICU settings.

(d) Communicate and transfer patient data to the BeneVision DMS or eGateway over a wired or wireless LAN connection through Mindray's Distributed Monitoring System network. Alternatively, patient data can be transferred directly to the hospital EMR over the hospital's wired or wireless network.

(2) BeneVision N17 specifications:

(a) Display: 47 cm (18.5 in) LCD touchscreen

(b) Parameters monitored using the N17, with the N1 as the measurement module, are shown in the table below.

MONITORED PARAMETERS: BENEVISION N17 BEDSIDE MONITOR WITH BENEVISION N1 AS THE MEASUREMENT MODULE

Standard Parameters	Maximum Number of Channels
Three-, five-, six-, or 10-lead ECG, including arrhythmia, ST segment, and QT/QTc analysis	—
Respiration (impedance)	1
NIBP	1
SpO_2 (Mindray, Nellcor, or Masimo)	1
Temperature	2
IBP	2 (Note: When the unit is in transport, the N1 can support one more two-channel IBP module in addition to the two channels of IBP monitoring integrated into the N1, for a total of four channels of IBP monitoring)
$EtCO_2$	1

c) The BeneVision DMS (Distributed Monitoring System), which consists of two primary components:

(1) BeneVision DMS Servers, which centrally store and manage communications to the patient monitoring devices

(2) BeneVision DMS WorkStations, which allow access to the data. The BeneVision DMS WorkStation allows a centralized view of up to 32 patients on one to three screens and is intended to enable viewing of patient information collected from the bedside monitors and telemetry transmitters (this information is stored on the BeneVision DMS Server). The BeneVision DMS WorkStation is used to:

(a) Admit and discharge patients via an automatically populated list from the hospital's ADT system by using a bar-code scanner or through a patient search feature

(b) View near-real-time numeric data, alarm history, full-disclosure waveforms, graphical and tabular trends, and 12-lead and ST analysis

(c) Serve as a secondary source of audible and visual alarm signals

(d) View discharge patient list alarm history and full-disclosure waveforms

(3) Specifications for standard features for both components are listed in the tables below.

SPECIFICATIONS: BENEVISION DMS SERVER

Maximum number of DMS Servers per network	Up to 30 servers; does not include redundant servers
Maximum number of patients per DMS Server	Two models are offered: DMS Server (which is capable of hosting 32 patients) or Enterprise DMS Server (capable of hosting 128 patients)
Full-disclosure storage	Up to 240 hours of full-disclosure parameter data for all monitoring waveforms/parameters
Event storage	Up to 3,000 events per patient with three 32-second waveform snippets
12-lead ECG waveform storage	Up to 720 12-lead ECG waveforms
Storage of data from discharged patients	Stores data from 1,000+ discharged patients

SPECIFICATIONS: BENEVISION DMS WORKSTATION

Maximum number of WorkStations that can be connected	Up to 120 WorkStations per network Up to 16 WorkStations per DMS Server Up to 32 WorkStations per Enterprise DMS Server
Display	58.4 cm (23 in) flat LCD touchscreen. Mouse and keyboard can be connected.
Maximum number of viewed beds per WorkStation	Up to 32 with a monitor having a display resolution of 1920 × 1080
Dual-display monitoring	One to three displays depending on configuration

d) Alarm statistics tool: The Mindray Alarm Statistics Tool is included with all BeneVision DMS systems, at no additional cost. It allows hospitals to quantitatively analyze alarms and clinician responses. Hospitals can use this tool, along with the logs stored within the BeneVision DMS Server, either to generate pre-developed alarm reports or to export the raw data to CSV files. The CSV data can be incorporated into hospital reports or combined with other clinical alarm data available within their facility.

e) Mindray eGateway: Windows-based server software used for clinical information management. The eGateway Integration Solution provides bidirectional communication between networked Mindray clinical solutions and ADT, clinical information system (CIS), EMR, and alarm management systems. It is used to send patient vitals data and notifications to the patient EMR via Integrating the Healthcare Enterprise's Patient Care Device Domain, Health Level Seven (IHE-PCD HL7) interface (supports four configurable channels) at a hospital-defined interval.

(1) Sends alarm notifications with waveform snippets using the IHE Alarm Communication Management (IHE-ACM) profile through three configurable independent alarm channels. Communicates to third-party secondary notification systems or middleware solutions for clinical notification and alarm management.

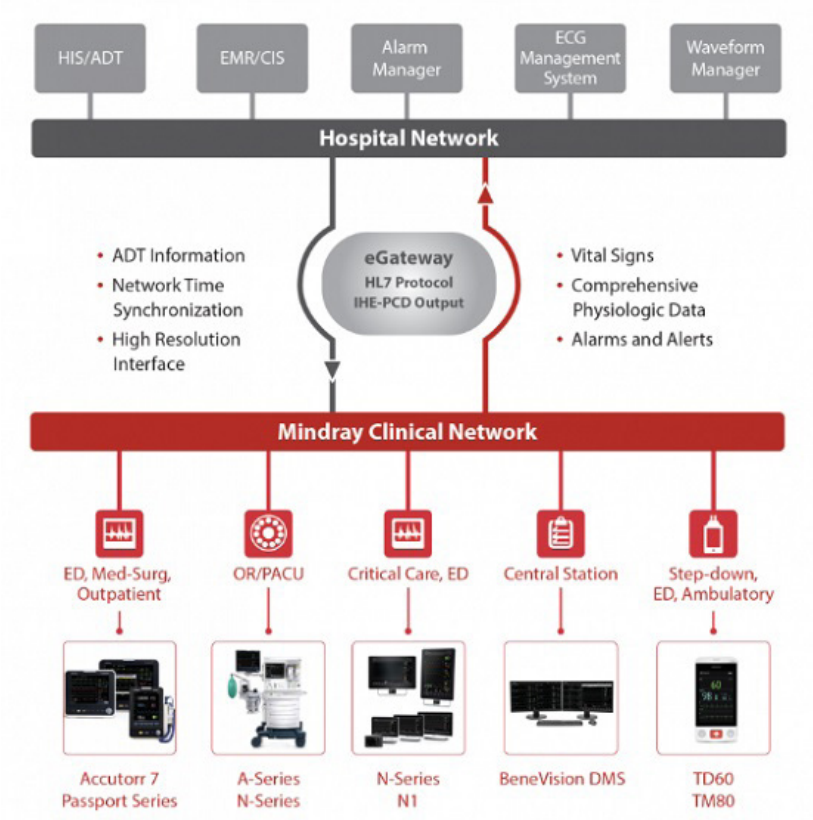
(2) Sends near-real-time waveforms, vitals, and alarms to the EMR using IHE-PCD Waveform Content Module (WCM) through one high-resolution channel

(3) Supports three independent document-sharing channels using a Coldfeed or HL7 interface to allow PDF reports (waveform reports, charting reports, 12-lead ECG reports, etc.) to be transmitted to the EMR for storage. Document-sharing channels also can be configured for XML Waveform snippets and XML 12-lead ECG reports.

(4) Each channel can be independently configured to use Transport Layer Security (TLS) 1.2 for communications

SPECIFICATIONS: MINDRAY EGATEWAY

Maximum number of eGateways that can be connected	6
Maximum number of patients per eGateway	200
Data storage	48 hours of data



Overview of the Mindray system network. (Image courtesy of Mindray.)

3. Optional components
   a) BeneVision Central Monitoring System (CMS) viewer: An optional PC-based application that allows all data stored on the BeneVision DMS Server to be accessed by clinicians anywhere within the hospital enterprise via role/department-based access. Deployment models include standalone, deployed via Citrix, and embedded within an EMR with patient context.
   b) BeneVision Mobile Viewer: An optional server-based software application that can be deployed on a physical server, VMWare Server, or HyperV server, allowing the Mindray Mobile Viewer application (iOS and Android) access to a read-only view of real-time patient data and alarms
   c) BeneLink module: Optional module that connects peripheral medical devices to Mindray's N Series monitors using matching ID adapters. The BeneVision N Series monitor supports up to two BeneLink modules. The BeneLink module is connected with peripheral devices via the serial ports (physical interfaces are RJ45 connectors and peripheral-device-specific ID adapters); one BeneLink module can connect up to four external devices simultaneously. BeneVision N Series monitors can output the parameter measurements, alarm limit settings, and alarm status to external devices via the DIAP protocol (Datascope Improved ASCII Protocol).
   d) Recorder module: prints patient information, parameter measurements, and waveforms. The module* supports manual or scheduled reporting to a printer or recorder, or electronic printing.
   e) Optional parameter modules: Used to acquire and process the patient's data and send the data to the bedside monitor
      (1) Microstream CO_2 module and Sidestream CO_2 module: Used for measuring $EtCO_2$ partial pressure and respiration rate
      (2) AG module: Supports AG monitoring, integrates O_2 (paramagnetic) monitoring
      (3) INVOS rSO_2 module: Supports rSO_2 monitoring
      (4) Cardiac output (CO) module: Supports CO monitoring
      (5) Continuous cardiac output (CCO) module: Supports CCO monitoring
      (6) CCO/SvO_2 module: Connects Edwards Vigilance II, Vigileo, EV1000, or HemoSphere monitor; supports CCO and SvO_2 monitoring
      (7) Central venous oxygen saturation ($ScvO_2$) module: Supports $ScvO_2$ monitoring
      (8) Electroencephalogram module: Supports EEG monitoring
      (9) NMT (neuromuscular transmission) module: Supports NMT monitoring
      (10) Bispectral index (BIS) module: Supports BIS monitoring
      (11) IBP module: Supports two channels of IBP monitoring
      (12) Temperature module: Supports two channels of temperature monitoring
      (13) SpO_2b module: Supports SpO_2 monitoring (Mindray, Nellcor, or Masimo)

ADDITIONAL PARAMETERS MONITORED USING BUILT-IN AND SATELLITE MODULE RACK

These additional parameters can be monitored either through a built-in module within the main monitor unit or as part of a separate satellite module rack connected to the monitor.

Parameter	Maximum Number of Channels
SpO_2b (Mindray, Nellcor, or Masimo)	1
Temperature	6
IBP	6
CO	1
rSO_2	1
$ScvO_2$	1
SvO_2	1
EEG	1

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 product. For more details, see the ECRI's Testing section of our Evaluation Background on this technology. Our criteria focused on alarm management features that are intended to help facilities improve alarm management safety practices.

* The module is built-in with N17 monitors and is an optional component with the N19 and N22 monitors only.

Performance—Excellent

Major Advantages

1. Full-disclosure data cache during network downtime and automatic transfer upon reconnection:

   a) The system offers viewing of retrospective full-disclosure waveforms, trends, alarms, and 12-lead ECG waveforms at the bedside. This data is automatically transmitted to the BeneVision DMS Server upon network reconnection for viewing and analysis at the BeneVision DMS WorkStation.

   b) In the event of network downtime, the ability to view retrospective full-disclosure waveforms recorded during the downtime allows clinicians to perform retrospective analysis.

2. Data caching during EMR unavailability:

   a) BeneVision DMS, N Series monitors, and eGateway offer caching and allow up to 48 hours of vital signs data, trends, alarms, and waveforms to be backfilled in the eGateway in the event that monitoring devices go offline.

   b) EMR or network downtime may occur due to either planned outages or emergency situations. Clinicians prefer that patient data is not lost during these times.

Minor Advantages

1. Alarm-generation delays:

   a) The system supports a configurable delay of up to eight seconds in the generation of all parametric alarms, including low-SpO_2 alarms. The option to delay ST alarms is also available and can be set independently, with configurations of 30 sec, 45 sec, 1 min, 1.5 min, 2 min, and 3 min. Zero-respiration-rate alarms can also be set independently, with configurations from 10 to 40 sec in increments of 5 sec.

   b) This functionality can ensure that self-correcting conditions don't generate alarm signals and contribute to alarm fatigue.

2. Alarm analytics software:

   a) The supplier offers the Alarm Statistics Tool, which allows users to either generate pre-developed alarm reports or export the raw data into CSV files. The tool is offered at no additional cost to the facility.

   b) This tool can help alarm management committees perform the data analysis required to understand problematic areas, justify policy changes, and track compliance and improvements.

3. Alarm event log filtering:

   a) The Alarm Statistics Tool allows hospital users to export alarm data in CSV format and allows filtering based on a specified date range or time of day.

   b) Facilities may wish to drill down on particular types of alarm conditions or care areas as part of their alarm management activities.

4. System storage log duration:

   a) The BeneVision DMS stores alarm logs for up to one year.

   b) This time frame will help hospitals assess the impact of any alarm management policies by measuring the metrics before and after the introduction of a policy in order to track improvements.

5. Alarm data analysis templates:

   a) Mindray's Alarm Statistics Tool includes data analysis templates. Data is offered in CSV format and as pre-developed alarm templates in Excel format. The Excel report can be customized to meet facility needs, or the CSV file can be imported into an enterprise-wide alarm management system.

   b) Alarm data templates and reports make it easier for the alarm management committee to review the alarm load metrics.

Notable Finding

BeneVision DMS WorkStation central station interactive views: All interactive displays at the WorkStation, including the single-patient view (enlarged view of one patient's parameters and waveforms), automatically time out after a configurable time period of inactivity (five minutes as tested). If a clinician forgets to close an interactive display, this feature will prevent the display from remaining open indefinitely at the BeneVision DMS WorkStation.

Safety—Good

Major Advantage

1. Configurable default patient profiles:

a) When admitting a patient, the clinician can select from up to 25 profiles based on patient type (i.e., adult, pediatric, and neonate); each profile includes a customized display layout and alarm settings. Facilities may use this feature to establish different alarm defaults for specific patient categories (e.g., neuro versus cardiac, pediatric).

b) Having configurable default alarm profiles for specific patient populations or conditions (e.g., cardiac) aids clinician workflow.

Minor Advantages

1. New-alarm annunciation during alarm-silenced interval:

a) When a new alarm condition occurs for a patient while a previously sounding alarm for that patient has been silenced, the system can be configured such that the new condition produces an audible alarm that annunciates until acknowledged.

b) A new alarm condition may have nothing to do with the condition causing the alarm that was silenced, and therefore should be brought to the clinician's attention. Typically, during the silenced interval, physiologic monitoring system suppliers allow annunciation of alarms whose priority is the same as or higher than the alarm that was silenced.

2. Customization of access controls:

a) Facilities can set a custom number of access-control levels to modify configuration settings. Access can be given based on either individual user accounts or role-based accounts the facility has defined. The user accounts also can be integrated with the hospital user directory, providing user and password management consistent with hospital policy.

b) Customizability of access levels offers hospitals added flexibility in meeting department and facility needs.

Minor Disadvantages

1. Alarms for lethal arrhythmias:

a) Alarms for lethal arrhythmias (e.g., asystole, ventricular fibrillation) can be disabled by the end user if this capability has been granted by an administrator. By default, this capability is not enabled. The ability for end users to enable/disable lethal-arrhythmia alarms is configured behind a password-protected administrator configuration setup.

b) Arrhythmia detection is an integral part of a physiologic monitoring system and alerts clinicians to patients who need intervention. Although the Mindray system provides a visual indicator denoting that lethal-arrhythmia alarms are off, ECRI believes that users in the ICU should not be able to completely turn off alarms for lethal arrhythmias.

c) If the lethal-arrhythmia alarms are disabled, an end user is immediately notified of this configuration using the following method: When lethal-arrhythmia alarms are disabled, the bedside monitor and BeneVision DMS WorkStation display a clear message in the ECG waveform window indicating that the lethal-arrhythmia alarms are off.

2. Alarm suspension time-out:

a) Alarm suspension ("Alarm Pause") can be set for an indefinite/permanent pause (no time-out duration). The ability to modify the alarm suspension time is behind a password-protected configuration setting. By default, this is configured for a two-minute time-out.

b) An alarm suspension with an indefinite duration could result in a clinician forgetting to reset alarms. During this infinite alarm pause, the system would not provide a visual or audible alarm for lethal arrhythmias (e.g., asystole, ventricular fibrillation).

c) This configuration is brought to the end user's attention using the following methods:

(1) A warning message is presented to the user when they configure the alarm suspend setting to permanent pause.

(2) Another warning message is presented to the user when they initiate the alarm suspend/alarm pause feature.

(3) Once the indefinite/permanent alarm pause is initiated, there is a prominent indication that all the alarms are off, as well as a periodic reminder tone.

Notable Findings

1. Alarm escalation: The bedside monitor can be configured to automatically increase the volume of an active alarm if the alarm condition remains unacknowledged for a preset time period. The alarm volume will increase over a defined time interval until the alarm is acknowledged. This feature helps alert caregivers to alarm conditions that might otherwise be missed.

2. Display of forwarded information: The system allows a way to silence/reset active alarms occurring on one bedside monitor from a different bedside monitor. The permissions to allow the end user to reset the alarms occurring on a remote bedside monitor are configurable behind a password-protected screen. The vendor offers two configurations for resetting alarms from a remote bed:

   a) Allowing a monitor to reset a remote bed's alarms—Within the system setup, the user can configure whether a particular monitor can remotely reset alarms occurring on another monitor. If this capability is disabled, the remote view screen only annunciates the alarms and does not show the "Alarm Reset" button.

   b) Allowing a monitor to have its alarms reset by another bed—Within the system setup, the user can configure whether one monitor can have its alarms reset remotely by another monitor. Note that if this capability is disabled on one monitor, but another monitor is configured to be able to reset remote monitor alarms, the remote view window on the second monitor still shows the option for "Alarm Reset," which may cause confusion. However, the user can find out that the alarm reset is not activated based on the fact that no check mark appears next to the alarm messages in the remote view window when the "Alarm Reset" button is pressed. To avoid confusion among end users, ECRI recommends that facilities work with the vendor to properly understand these settings and configure the system with their help to best suit the facility's needs.

Workflow—Good

Minor Advantages

1. Patient-specific alarm prioritization:

   a) Patient-specific alarm priority customization is available through the bedside monitor and BeneVision WorkStation.

   b) Many alarm conditions are not associated with lethal events and in some instances are not actionable. In those instances, being able to adjust alarm priority level for the specific patient can help reduce alarm fatigue. Depending on patient status, the same alarm signal (e.g., high heart rate) may have different implications, and thus it is important that the notification system be able to characterize the alarm signal based on the implications for a given patient.

2. Ventricular tachycardia (V-tach) latching:

   a) The bedside monitor allows users to disable latching for V-tach alarms by modifying a password-protected configuration setting.

   b) Some patients may have controlled V-tach that is not viewed as life-threatening. Repeated alarming and latching of V-tach for such patients can increase alarm load.

Patient Experience—Good

The system has been evaluated against ECRI's criteria for patient experience and found to meet all criteria.

Notable Finding

Alternative operating modes at bedside: The bedside monitor offers four different modes (Privacy Mode, Night Mode, Intubation Mode, and CPB [Cardio-Pulmonary Bypass] Mode). These features allow customization of visual and audible settings at the patient's bedside per time of day (e.g., lower volume and brightness level in night mode), thereby promoting patient rest and comfort. None of the modes (except Intubation Mode) are automatically timed, so the clinician would have to manually start and stop the modes.

Interoperability—Good

Minor Advantages

1. Exporting of data to the EMR:

   a) Alarm event data, patient parameters, and waveforms can be exported to the EMR using the eGateway at customized time intervals.

   b) The ability to automatically populate episodic or continuous information within the EMR for clinician validation can increase clinical workflow efficiency.

2. Ventilator integration:

   a) The supplier has successful live implementation sites using some of the ventilators from CareFusion, Draeger Medical, GE Healthcare, Hamilton, Maquet, Medtronic, Newport Medical, Philips (Respironics), Puritan Bennett, and ResMed. Integration to ventilators is achieved using an optional BeneLink Module along with the peripheral-device-specific ID adapter.

b) Ventilators are typically the second largest sources of alarms after patient monitoring systems and can be challenging to integrate due to the lack of built-in networking capabilities.

3. Preferred medical device integration:

a) Integration to peripheral medical devices is achieved using an optional BeneLink Module along with the peripheral-device-specific ID adapter. One user ECRI spoke with mentioned integrating their ICP monitor from Codman with Mindray's monitoring system. Mindray also offers integration with cardiac output monitors, anesthesia machines, ventilators, transcutaneous gas (tcGas) machines, infusion pumps, pulse co-oximetry devices, and neuromuscular transmission (NMT) monitors. The most up-to-date list on the vendors can be found on Mindray's website.

b) Integration of physiologic monitors with peripheral medical devices (e.g., beds, dialysis machines, cardiac output monitors) can allow these devices to annunciate alarms through the monitoring system and any ancillary alarm notification systems. Without integration to monitoring systems, nonnetworked devices would require point-of-care hardware (e.g., serial-to-Ethernet converter) to facilitate sending alarms over the network.

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.

Notable Finding

1. A fully implemented system that includes the eGateway offers complete encryption in transit. This includes HL7 over TLS from the eGateway to compatible systems. Features include:

a) TLS 1.2 is utilized for all communications both within the system and to the EMR.

b) AES128 is used to protect all protected health information (PHI) at rest.

Maintenance—Excellent

Major Advantage

1. Global configuration management:

a) The vendor offers the ability to manage default settings, centrally manage software upgrades, and manage assets using the BeneVision DMS. This capability is standard on all BeneVision systems.

b) This feature facilitates the management of default device configurations in a care area by an individual with the appropriate authority and clinician password, potentially saving clinician/biomedical engineering time.

User Experience—Good

Minor Advantage

1. Transport monitor Wi-Fi communication:

a) The BeneVision N1 transport monitor supports 802.11 a/b/g/n wireless communication.

b) Wireless transmission of information to a central station through Wi-Fi during transport allows the clinician to continue near-real-time patient surveillance from a remote location over the facility's nonproprietary wireless network.

Cost of Ownership—$2,000,000 (Estimated) over 10 Years

Note that this calculation is based on prices for the United States, a major market for the product.

ESTIMATING THE TYPICAL COST OF OWNERSHIP FOR THE MINDRAY BENEVISION N17 ICU PHYSIOLOGIC MONITORING SYSTEM

The costs reported in this table represent typical quotation and purchase costs reported to ECRI's SELECTplus and PriceGuide databases, and as reported by Mindray. These figures are provided as a guide only and may vary significantly. Estimating cost of ownership of any monitoring system is complex and is highly dependent on a number of factors, including the size of the installation, group purchasing discounts, whether the system being replaced is from the same vendor, and the negotiating skill of the facility.

The cost estimate is based on the following clinical scenario: A hospital is replacing monitors in five 16-bed ICUs. Each ICU needs one bedside monitor per room, a central station, and two remote displays. The cost analysis also includes alarm management services offered, as well as interfaces to Maquet Servo-U ventilators for all bedside monitors and to the Epic EMR for all central stations, including ADT features as well as parametric data export.

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

Factor	Typical Cost	Assumptions
Purchase Costs		
Capital cost	$1,125,340	Eighty BeneVision N17 bedside monitors equipped with ICU software package @ $6,464/monitor: $517,120. Eighty BeneVision N1 transport monitors/modules @ $5,591/module: $447,280. Five BeneVision Distributed Monitoring (DMS) systems @ $26,904/DMS system: $134,520. (The BeneVision DMS system needed to support this clinical scenario is made up of only the DMS Servers with five DMS WorkStations.) Ten remote displays @ $2,642/display screen: $26,420.
Typical accessories	$152,650	Includes the following accessories for the clinical scenario defined above: — Mindray eGateway bed licenses for EMR connectivity, and ADT features: $33,450 (includes licenses for up to 200 beds). Costs include mapping to Epic and implementation services. — Eighty ventilator interface modules and Maquet Servo-U drivers for sending peripheral data to the network from Maquet Servo-U ventilators: $1,490/bedside: $119,200. — Mindray Alarm Statistics Tool: $0 (included in the purchase of the BeneVision DMS). — Eighty SpO_2 cables @ $0 (included in purchase). — Eighty ECG lead-wire sets and trunk cables @ $0 (included in purchase). — Eighty temperature cables @ $0 (included in purchase). — Eighty NIBP hose and connectors @ $0 (included in purchase).
Warranty	$0	The BeneVision N Series monitoring system includes a standard five-year field-based on-site service warranty covering parts and labor (not a depot-style warranty); BeneVision DMS includes a one-year on-site service warranty covering parts and labor.
Clinical staff training	$0	Mindray offers a minimum of three days of clinical education with a typical monitoring system purchase; the length of time is generally based on the acuity of the department and the amount of equipment purchased.
Biomedical staff training	$7,550	Training on central stations costs $6,800 per slot; computer-based training on monitors costs $750.
Infrastructure modifications	$0	Typically, no major IT network or major building modifications are necessary for Mindray monitoring solutions.
Total purchase cost	$1,300,000	—
Annual Operational Costs		
Consumables	$68,320/yr	Cost of consumables (includes SpO_2 sensors, ECG electrodes, disposable temperature probes, NIBP cuffs, recording paper): $7/patient. Assumes an average three-day length of stay for each patient and 100% occupancy. A single bedside would accommodate 122 patients/year. Eighty ICU beds would have 9,760 patients/year. Total cost of consumables: $68,320.
Expected part replacement—averaged throughout life of product	$1,472/yr	Assumes 80 ECG lead-wire sets and temperature cables are replaced one time within the 10-year life of monitoring equipment. Eighty ECG cables and lead-wire sets @ $152/set: $12,160. Eighty temperature cables @ $32/cable: $2,560.
Service	$6,000/yr	Systems are typically serviced in-house by biomedical and clinical engineering teams annually for electrical safety tests and calibration. Service time is approximately one hour/monitor. Hourly biomedical engineering cost: $75.
Annual license fee	$0	None.
Average annual operational cost	$76,000	—
Estimated Total Cost of Ownership (for an estimated life of 10 years)	**$2,000,000**	Total purchase cost + (annual operational cost × estimated life, excluding warranty period)

CONSIDERATIONS FOR CHALLENGING ENVIRONMENTS: MINDRAY BENEVISION N17 ICU PHYSIOLOGIC MONITORING SYSTEM

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

Category	Remarks
Physical Environment Ability to operate successfully in a variety of adverse conditions	Moderate concern: The manufacturer states that the product can function in relative humidity up to 95%; in regions where the relative humidity regularly reaches 100%, this could cause problems. However, all components of the monitoring system can withstand reasonable physical damage, and the system has an ingress protection (IP) rating sufficient to protect it from vertically falling water drops: The N1 transport module has an IP44 rating, and the N17 bedside monitor has an IPX1 rating. The DMS WorkStation does not have an IP rating, but the device usually would be placed in a controlled environment and thus would not be routinely exposed to liquids.
Installation Installation requirements compared to other equipment in the same category	Moderate concern: Installation requirements are similar to those of comparable monitoring systems. This is a complex monitoring technology, and the installation requirements would also depend on the facility infrastructure already in place. However, the vendor performs an on-site survey for analyzing the installation requirements before system design and implementation.
Training and Operation Whether the product can be learned and used without undue burden	No significant challenges or concerns. The vendor offers on-site training to the support staff. Operator manuals, the administrator's guide, and clinical reference guides are thorough and easily obtained. Online clinical training videos for the N1 and N Series monitors are also available to Mindray customers. These videos can be used by staff that are unable to attend the on-site training or as continuing education.
Servicing Whether the product can be serviced without undue burden	No significant challenges or concerns. Cleaning and maintenance instructions are available in the user manual. The vendor also provides service manuals. Training and service are available in all geographic regions. In some regions, in order to ensure timely support, Mindray's distributors provide this training and service after being trained by Mindray. Mindray states that if distributors are unable to address all of the issues a customer may have, Mindray service will step in and resolve the issues.

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
Purposefully designed with a flat user interface, N-Series monitors enable 90% of common operations to be performed in just two steps, reducing both workflow complexities and required training time.	User Experience	**Unknown.** ECRI has no data or information to support an opinion. Users we spoke with were satisfied with the monitors but didn't provide specific input on the reduction in workflow complexities or training time.
N1 provides continuous monitoring throughout a healthcare facility. Seamlessly integrating into the hospital IT environment, the N1 is a multi-parameter module within the N12, N15, N17, N19, and N22; when removed, it instantly converts to a wireless transport monitor, ensuring a gap-free patient record, from admittance through discharge.	User Experience	**ECRI agrees.** As noted in the User Experience discussion under Significant Findings above, the transport monitor supports 802.11 a/b/g/n wireless communication. In the software version tested at ECRI (V01.06), we observed gaps in full-disclosure data (less than 10 seconds) at the bedside monitor and the central workstation when the N1 transport module was undocked from the bedside monitor and when the N1 module was re-docked to the bedside monitor. Mindray states that effective December 2020, monitors are being shipped with a new software version (V01.15.00) that does not exhibit data gaps when the transport module is undocked from or re-docked to the monitor. Mindray will provide this software release at no additional cost to existing customers. ECRI recommends that existing users contact Mindray and receive this software update.
Bed-to-bed remote viewing and alarm watch expand a clinician's reach while at the bedside.	Safety and Workflow	**ECRI partially agrees.** The vendor does provide remote viewing. However, as discussed in the Safety section under Significant Findings above, we recommend that facilities work with the vendor to properly understand these settings and configure the system with the vendor's help to best suit their needs and avoid confusion related to the ability to reset alarms for the remote monitor.
BeneVision DMS provides clinicians immediate access to timely and relevant patient data including real-time patient data, tabular trends, graphics trends, alarm events, 12 Lead and full disclosure. The customized BeneVision DMS WorkStations in the department or remote workstations between facilities, provide centralized monitoring and nurses station access to patient data. For remote viewing, our tablet/laptop and smartphone software applications (CMS Viewer and Mobile App) provide real-time comprehensive or clinician-centric views of your patient's data and support both iOS and Android platforms.	Workflow	**ECRI agrees, but other products offer the same benefit.** Having the ability to keep an eye on clinical data from a remote workstation or platform can help ensure that clinicians are aware of important status changes or alarm conditions. However, ECRI believes that the ability of the BeneVision DMS to provide clinicians with immediate access to timely and relevant patient data is comparable to that of other available central monitor displays.
The Mindray eGateway Integration Solution is a powerful informatics component for bi-directional communications between networked Mindray clinical solutions and hospital ADT, CIS, EMR and alarm management systems. Interoperability is simplified through the adoption of standard HL7 protocols and the IHE PCD (including ACM and WCM) profiles for seamless connectivity.	Interoperability	**ECRI agrees; significance unknown.** Users we spoke with reported a positive overall experience with interoperability and EMR integration. As of the time of publication, users reported no issues with sending parametric and event data to the EMR. However, no users we spoke with were able to confirm the ability to export waveforms or snippets to the EMR.
[Mindray] utilizes disinfectant resistant medical grade polymers compatible with a broad range of commonly used hospital cleaning/disinfecting agents.	Maintenance	**Unknown.** ECRI has no data or information to support an opinion.

RECALLS AND HAZARDS

A search of ECRI's *Health Devices Alerts* records from November 2015 through July 2020 did not disclose any relevant alerts.

USER SURVEY RESULTS

Separately from our Evaluation testing, we surveyed users of physiologic monitors to obtain their opinions on ease of use, performance, and reliability, along with the average number of annual repairs required and the inspection intervals they use. 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: 5 year on-site parts and labor warranty on N Series patient monitors; 1 year on-site parts and labor warranty on BeneVision DMS

Inspection and Preventive Maintenance (IPM)

1. IPM frequency: Once every two years
2. Downtime for IPM: Approximately 30 minutes

In-House/Third-Party Service

1. Manufacturer supports user repair: Yes
2. Training required and typical cost: $6,800 for biomedical training on central stations; $750 for biomedical computer-based training on monitors
3. Availability of service manual: Yes. Electronic copy available for all to download
4. Dedicated test equipment and/or software required: Standard tools are used; for software upgrades a USB thumb drive or DMS server is required
5. Availability of manufacturer assistance: 24/7 x 365 remote clinical and technical support for the life of the product, on-site support by Field Service Representative available within the warranty period or under service contract.

OEM Maintenance

1. Standard OEM service options
   a) Name of the option: (1) Basic (2) Platinum (3) Platinum Plus/Complete
   b) Description of coverage: (1) Mail-in repair includes parts and labor (2) On-site repair includes parts, travel, and labor
   c) Hours of coverage: 8:30am – 5:30pm local
   d) Response time: Call back within 2 hours, on-site within 24 hours
   e) Uptime guarantee and standard penalty: Not applicable
2. Remote monitoring: Not available
3. Software upgrade and update policy
   a) Software updates entail a labor cost unless under a software contract.
   b) Software upgrades are available for purchase unless under a service contract.

OTHER PURCHASE OPTIONS

Mindray also offers operational and capital leasing options as well as promotion financing if needed.

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 and follow @ECRI_Org.

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