ECRI | The Most Trusted Voice in Healthcare

Capital Market Intelligence Online

-Database to support medical equipment evaluation

Lower spending on healthcare capital equipment with more informed, data-driven decisions

$1 billion

Annual savings identified using ECRI benchmarks

ECRI | The Most Trusted Voice in Healthcare

Introducing ECRI

ECRI Asia Pacific

How ECRI Started

Dr. Joel J. Nobel (1934-2014)

"Anger is a great source of energy. I focused it on improving technology and patient safety."

- Joel J. Nobel, MD, Founder of ECRI

MILESTONES

1968

Emergency Care Research Institute (ECRI) is born

1971

Health Devices issues first publication along with the first medical device *Problem Reporting Network*

1973

Testified at the U.S. Senate Hearings on the proposed Medical Device Amendment

1997

Designated an Evidence-Based Practice Center by AHRQ

2008

Patient Safety Organization founded – one of the first 10 PSOs designated by HHS

2020

Official affiliation with Institute for Safe Medication Practices (ISMP)

2021

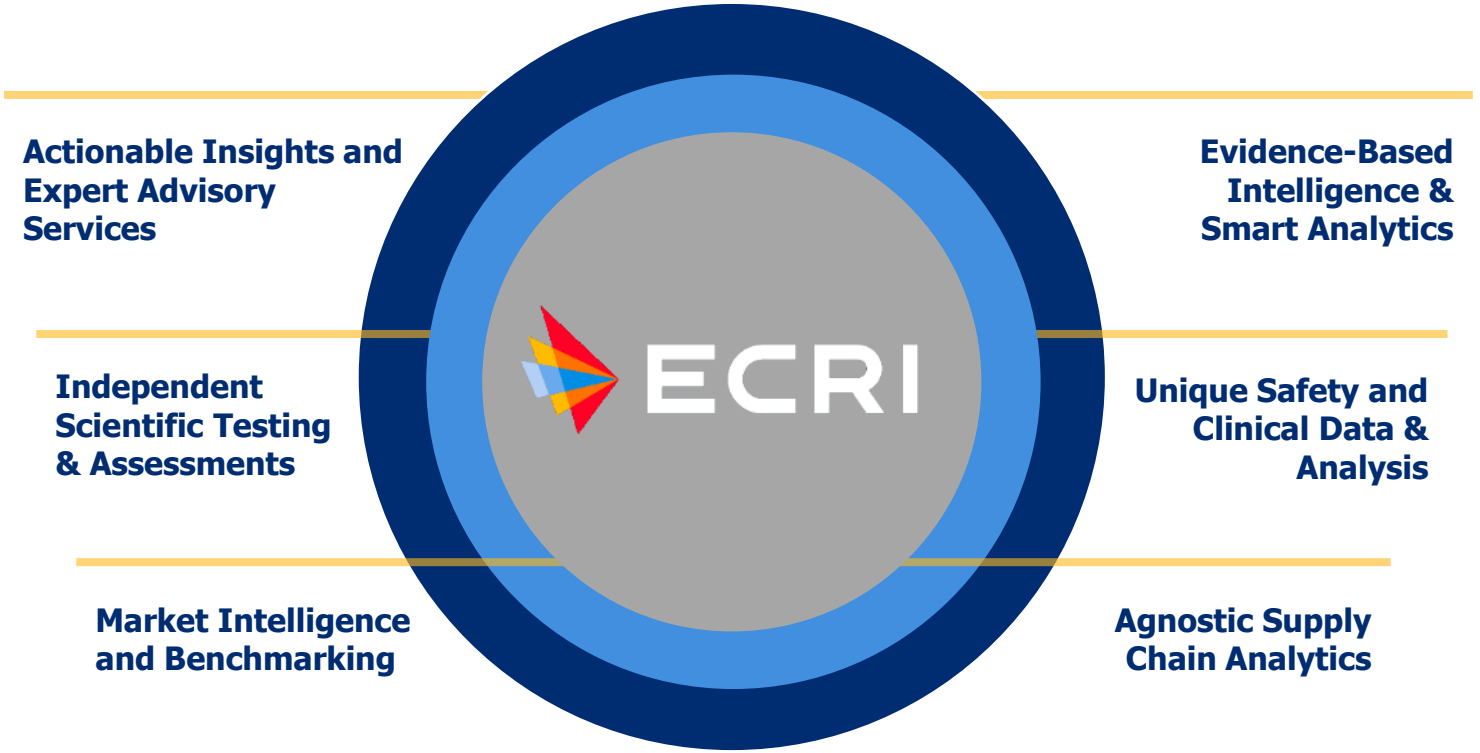
Became a signatory to the Ethical Principles in Healthcare (EPIHC)

Became an institutional member of ASQua (Asian Society for Quality in Health Care)

The ECRI Difference | Data Empowers. ECRI Delivers.

ECRI is a leading independent patient safety expert reducing preventable harm, and making healthcare more transparent and accessible

- 50+ years of experience as a global leader in patient safety and applied human factors engineering
- At the forefront of providing data, expertise, and advisory services related to healthcare technologies, patient safety and evidence-based medicine
- A leading provider of GPO-agnostic price benchmarking and market intelligence



Committed to Integrity, Transparency, and Excellence

The ECRI Difference | Global Impact & Influence.

ECRI is the trusted source for evidence-based guidance for healthcare leaders across the globe

- Designated as an Evidence-based Practice Center by the U.S. Agency for Healthcare Research and Quality
- ECRI and our affiliate Institute for Safe Medication Practices (ISMP) are the premier healthcare quality and safety institutions in the world
- Chosen to develop the first large-scale International Horizon Scanning Database of new and promising pharmaceutical products by the International Horizon Scanning Initiative (IHSI), a multi-nation European group

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Capital Market Intelligence Online (CMI)

Highlights

- $12B+ in total spend from over 3,500 providers with $615M+ total savings identified in 2019
- 102,000+ unique models (13,500+ unique manufacturers) in the DB with average prices paid by hospitals and health systems in the US
- Rigorous, independent testing with comparative configurations on the latest healthcare technologies
- >300 data requests processed daily
- Access to vital hazard and recall information from the largest problem reporting network


ECRI
The Most Trusted Voice in Healthcare
Capital Guide
Market Intelligence Report
Surgical Video Systems
Description
Popular Vendors and Models
Capital Guide Member Interest
Surgical Video Systems, by Vendor
(Feb 2021 - Feb 2022)
Capital Guide Member Interest
Surgical Video Systems, by Model
(Feb 2020 - Feb 2021)
Key Considerations

Capital Market Intelligence

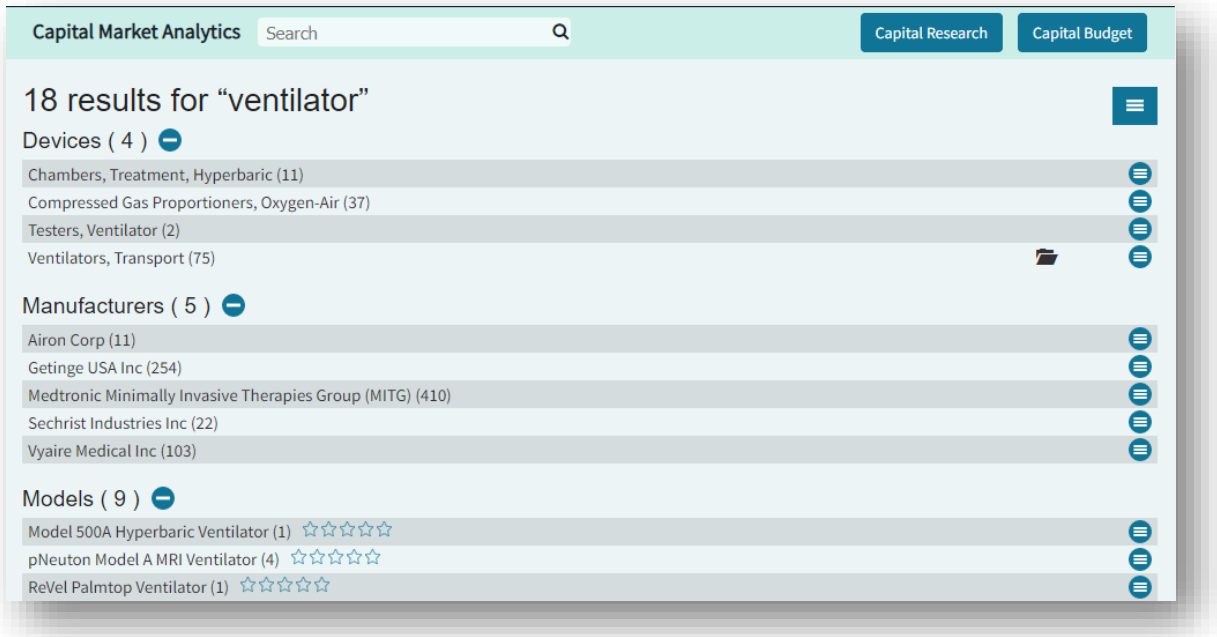
Benchmarking and procurement service to support capital equipment and health information technology information

Lower spending on healthcare capital equipment with more informed, data-driven decisions, using:

Market Analytics

Easy-to-access interactive platform to conduct comprehensive capital equipment market research

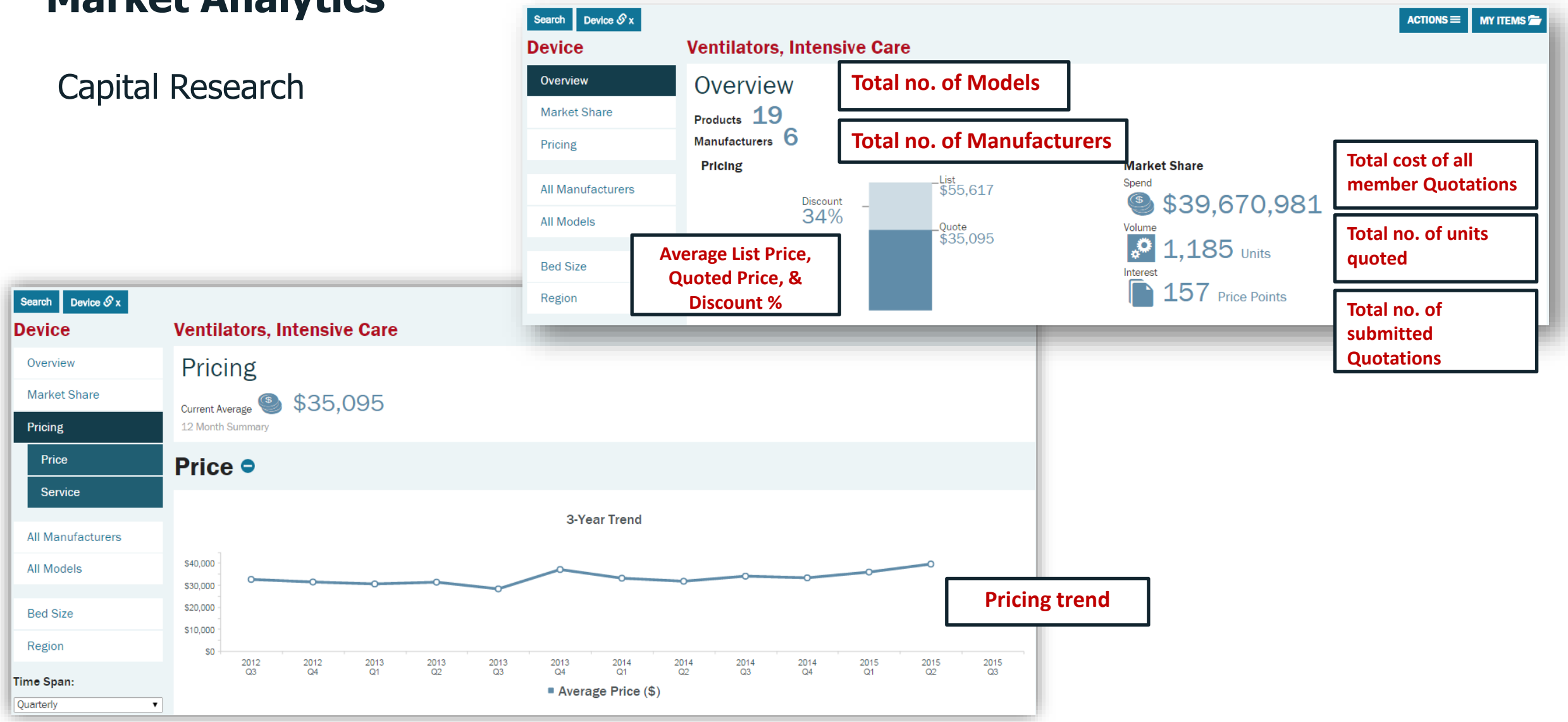
- Most recent pricing information
- Real time database with graphs and charts
- Purchase configuration information (catalog numbers, component descriptions, quantities and line-item pricing)
- Up to 20 most recent quotes and purchase orders
- Transparency to capital budgeting process



- Assist hospitals in capital price budgeting and negotiation
- Be informed of the most popular device brand/model

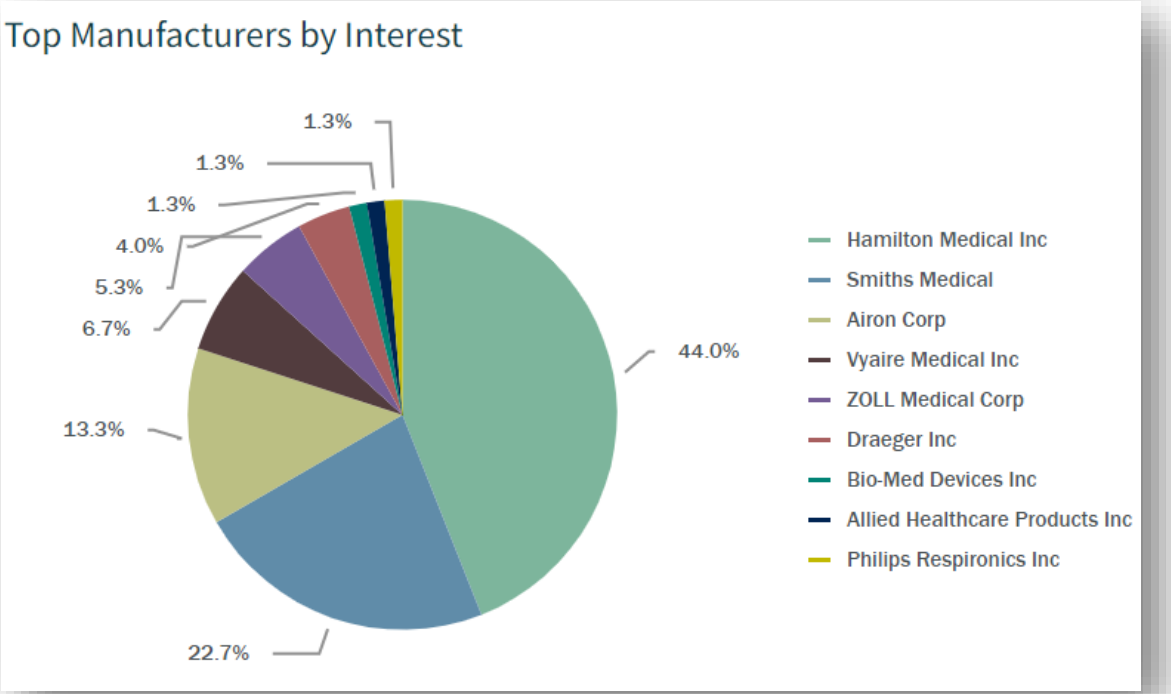
Market Analytics

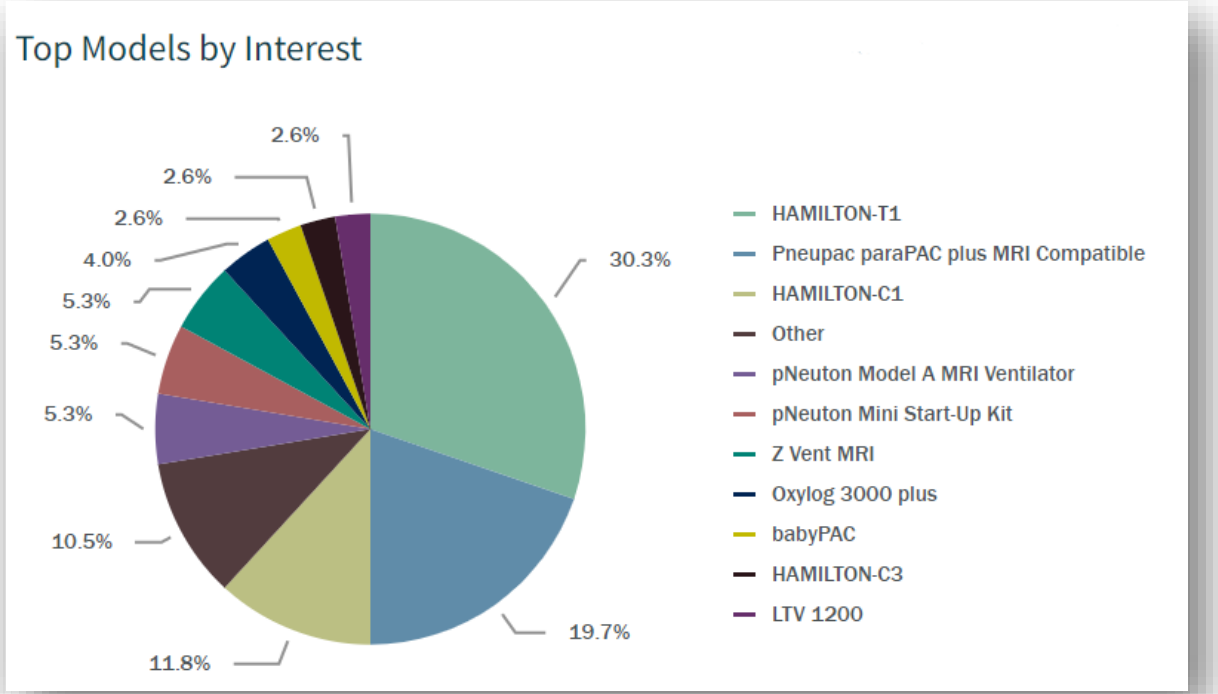
Capital Research



Market Analytics

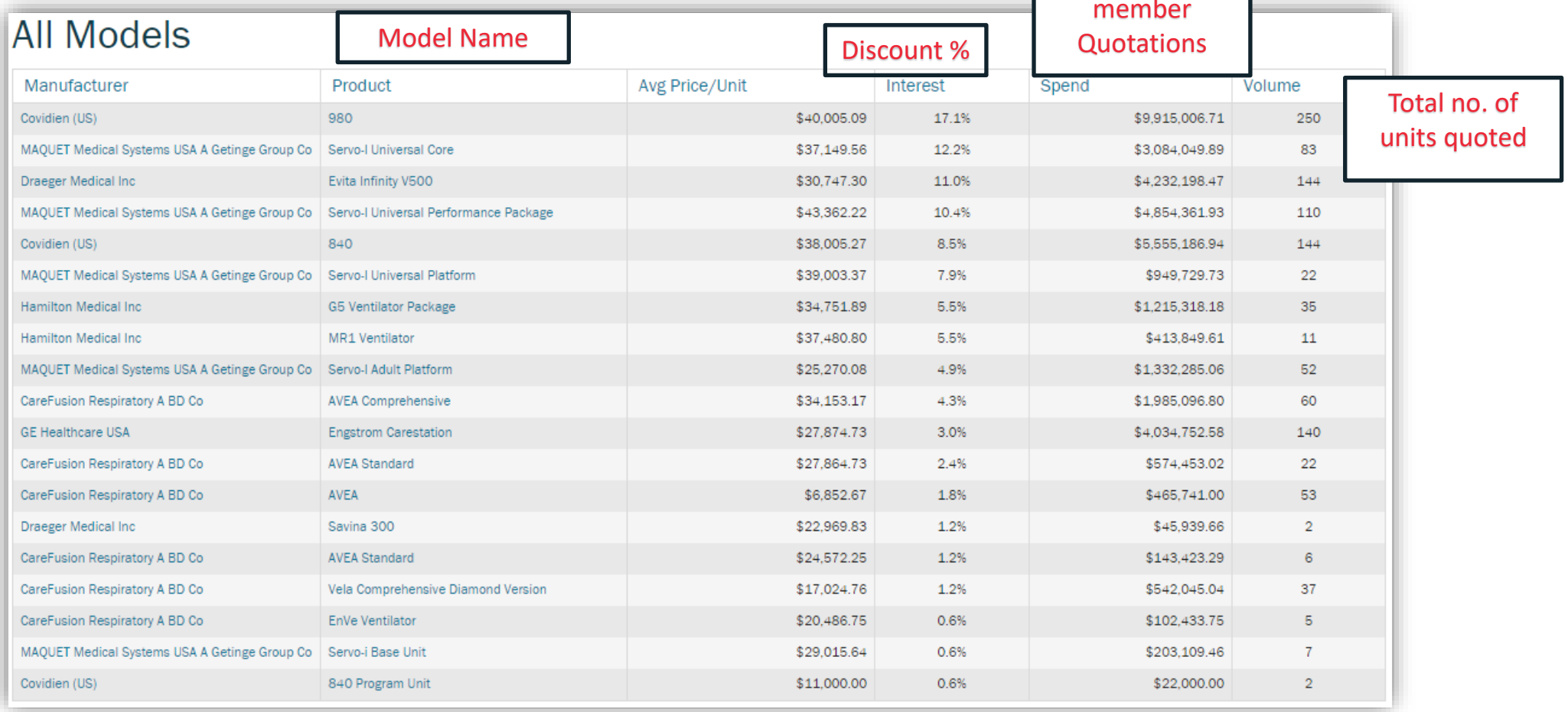
Capital Research





Market Analytics

Capital Research



Manufacturer	Product	Avg Price/Unit	Interest	Spend	Volume
Covidien (US)	980	$40,005.09	17.1%	$9,915,006.71	250
MAQUET Medical Systems USA A Getinge Group Co	Servo-I Universal Core	$37,149.56	12.2%	$3,084,049.89	83
Draeger Medical Inc	Evita Infinity V500	$30,747.30	11.0%	$4,232,198.47	144
MAQUET Medical Systems USA A Getinge Group Co	Servo-I Universal Performance Package	$43,362.22	10.4%	$4,854,361.93	110
Covidien (US)	840	$38,005.27	8.5%	$5,555,186.94	144
MAQUET Medical Systems USA A Getinge Group Co	Servo-I Universal Platform	$39,003.37	7.9%	$949,729.73	22
Hamilton Medical Inc	G5 Ventilator Package	$34,751.89	5.5%	$1,215,318.18	35
Hamilton Medical Inc	MR1 Ventilator	$37,480.80	5.5%	$413,849.61	11
MAQUET Medical Systems USA A Getinge Group Co	Servo-I Adult Platform	$25,270.08	4.9%	$1,332,285.06	52
CareFusion Respiratory A BD Co	AVEA Comprehensive	$34,153.17	4.3%	$1,985,096.80	60
GE Healthcare USA	Engstrom Carestation	$27,874.73	3.0%	$4,034,752.58	140
CareFusion Respiratory A BD Co	AVEA Standard	$27,864.73	2.4%	$574,453.02	22
CareFusion Respiratory A BD Co	AVEA	$6,852.67	1.8%	$465,741.00	53
Draeger Medical Inc	Savina 300	$22,969.83	1.2%	$45,939.66	2
CareFusion Respiratory A BD Co	AVEA Standard	$24,572.25	1.2%	$143,423.29	6
CareFusion Respiratory A BD Co	Vela Comprehensive Diamond Version	$17,024.76	1.2%	$542,045.04	37
CareFusion Respiratory A BD Co	EnVe Ventilator	$20,486.75	0.6%	$102,433.75	5
MAQUET Medical Systems USA A Getinge Group Co	Servo-i Base Unit	$29,015.64	0.6%	$203,109.46	7
Covidien (US)	840 Program Unit	$11,000.00	0.6%	$22,000.00	2

Market Analytics

ECRI

Capital Guide Market Analytics

Robotic, Minimal Invasive

August 27, 2023

Executive Summary

Market data charts are based on price quotations submitted to ECRI by members of the Capital Guide advisory service. This data is harvested f
constantly evolves as quotes and purchase orders for all types of capital equipment are added daily.

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Manufacturer: Intuitive Surgical Inc

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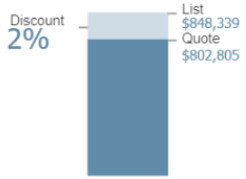


Market Share

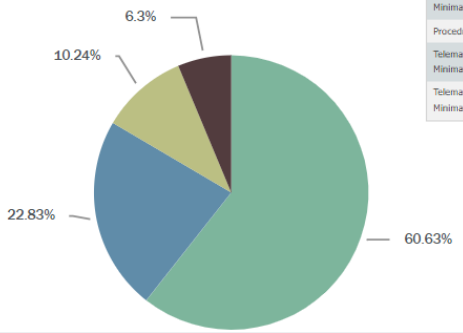
Spend $112,116,277

Volume 202 Units

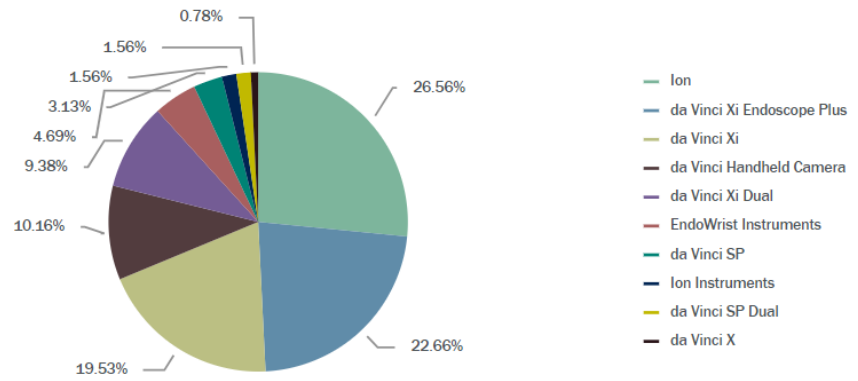
Interest 120 Price Points

12 Month Summary

Top Devices by Interest



Top Models by Interest



Edit Comment

Models

All Models

Device	Product	User Rating	Avg Price/Unit	Interest	Spend	Volume
Telemanipulation Systems, Surgical, Minimally Invasive	Ion		$598,676.47	26.6%	$20,355,000.00	34
Laparoscopes, Surgical	da Vinci Xi Endoscope Plus		$25,464.31	22.7%	$1,755,881.00	69
Telemanipulation Systems, Surgical, Minimally Invasive	da Vinci Xi		$1,906,060.00	19.5%	$47,651,500.00	25
Cameras, Video, Endoscope	da Vinci Handheld Camera		$16,343.77	10.2%	$778,942.00	47
Telemanipulation Systems, Surgical, Minimally Invasive	da Vinci Xi Dual		$2,294,491.25	9.4%	$27,533,895.00	12
Procedure Trays, Surgical	EndoWrist Instruments		$34,911.50	4.7%	$209,469.00	6
Telemanipulation Systems, Surgical, Minimally Invasive	da Vinci SP		$1,896,875.00	3.1%	$7,587,500.00	4
Procedure Trays, Surgical	Ion Instruments		$39,545.00	1.6%	$79,090.00	2
Telemanipulation Systems, Surgical, Minimally Invasive	da Vinci SP Dual		$2,400,000.00	1.6%	$4,800,000.00	2
Telemanipulation Systems, Surgical, Minimally Invasive	da Vinci X		$1,365,000.00	0.8%	$1,365,000.00	1

Market Intelligence

Rapid access market intelligence for healthcare decision makers

- Top models / vendors available
- Key Clinical Specifications
- Avg. list price vs quoted
- Discount history
- Equipment + service costs
- Est total cost of ownership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Capital Guide

Market Intelligence Report

Mobile C-Arm Systems

Description

Mobile R/F units (C-Arm Systems) provide radiographic and fluoroscopic imaging in surgical, orthopedic, critical care, and emergency care procedures. They are used to image patients in radiolucent beds, stretchers, or tables, when it is not feasible to transport the patient to the radiology department. The fluoroscopic feature allows real-time imaging, which permits quick diagnoses and minimal patient time under anesthesia during surgical procedures.

Popular Vendors and Models

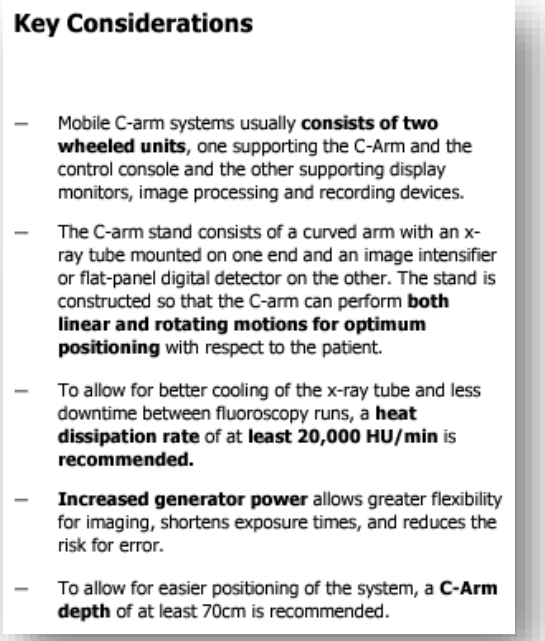
Capital Guide Member Interest
Mobile C-Arm Systems, by Vendor
(Jul 2022 - Jul 2023)
n= 306
71% GE
12% Philips
12% Siemens
5% Ziehm

Capital Guide Member Interest
Mobile C-Arm Systems, by Model
(Jul 2022 - Jul 2023)
n= 306
GE OEC Elite CFD 46%
GE OEC Elite 12%
Philips Zenition 70 9%
GE OEC 3D 7%
GE OEC One CFD 6%
Siemens Cios Flow 5%
Ziehm Vision RFD 3D 5%
Siemens Cios Spin 4%
Siemens Cios Alpha 3%
Philips Zenition 50 3%

Key Considerations

- Mobile C-arm systems usually **consists of two wheeled units**, one supporting the C-Arm and the control console and the other supporting display monitors, image processing and recording devices.
- The C-arm stand consists of a curved arm with an x-ray tube mounted on one end and an image intensifier or flat-panel digital detector on the other. The stand is constructed so that the C-arm can perform **both linear and rotating motions for optimum positioning** with respect to the patient.
- To allow for better cooling of the x-ray tube and less downtime between fluoroscopy runs, a **heat dissipation rate** of at **least 20,000 HU/min** is **recommended.**
- **Increased generator power** allows greater flexibility for imaging, shortens exposure times, and reduces the risk for error.
- To allow for easier positioning of the system, a **C-Arm depth** of at least 70cm is recommended.
- A **wide mAs range is recommended** to achieve better image quality and allow more filtration for enhanced dose reduction.
- **Pulsed Fluoroscopy** mode uses pulses of radiation to update a stored image every 1 or 2 seconds. This **helps reduce** the x-ray dose output.
- Most C-Arm systems **rely on flat panel detectors**. The **benefits** of flat panel detectors over image intensifiers include enhanced image quality and reduced radiation exposure. In addition, the square or rectangular shapes of flat-panel detectors eliminate the edge distortion which occurs with round image intensifiers.

Capital Guide Market Intelligence Report | 1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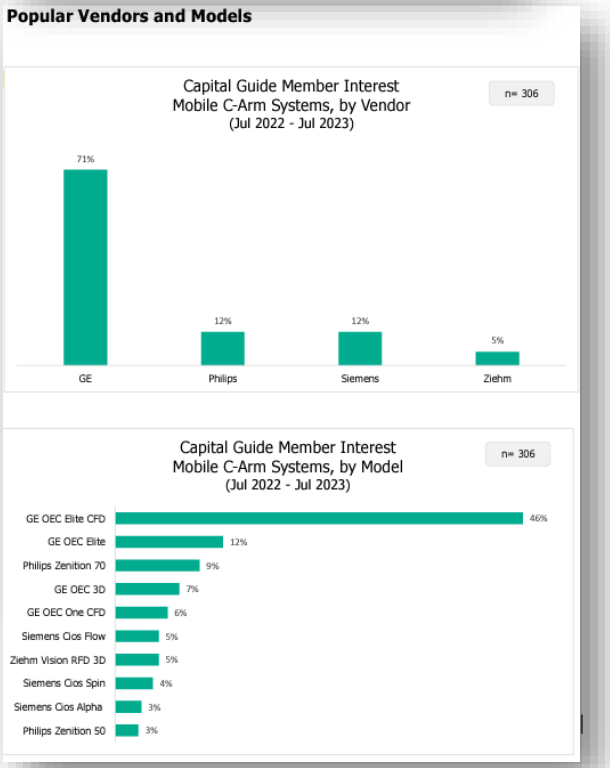
Popular Vendors and Models

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Mobile C-Arm Systems, by Vendor
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GE OEC 3D 7%
GE OEC One CFD 6%
Siemens Cios Flow 5%
Ziehm Vision RFD 3D 5%
Siemens Cios Spin 4%
Siemens Cios Alpha 3%
Philips Zenition 50 3%

Market Intelligence

Feature Comparison for Popular Models

Mobile C-Arm Systems	GE OEC 3D	GE OEC Elite	GE OEC Elite CFD	GE OEC One CFD	Philips Zenition 50	Philips Zenition 70	Siemens Cios Alpha	Siemens Cios Flow	Siemens Cios Spin	Ziehm Vision RFD 3D
Image Detector Type	Flat panel	Image intensifier	Flat panel	Flat panel	Image intensifier	Flat Panel	Flat panel	Flat panel	Cios Spin	Flat Panel
3-D Cone Beam CT Acquisition	Yes	Not Specified	Not Specified	NA	NA	NA	NA	NA	Yes	Yes
C-Arm Depth, inches	29.5	28 inch 12-inch I.I.	26.5 Ergo C 33 super C	26	24	28.7	28.7	28.7	25	27

Other Considerations

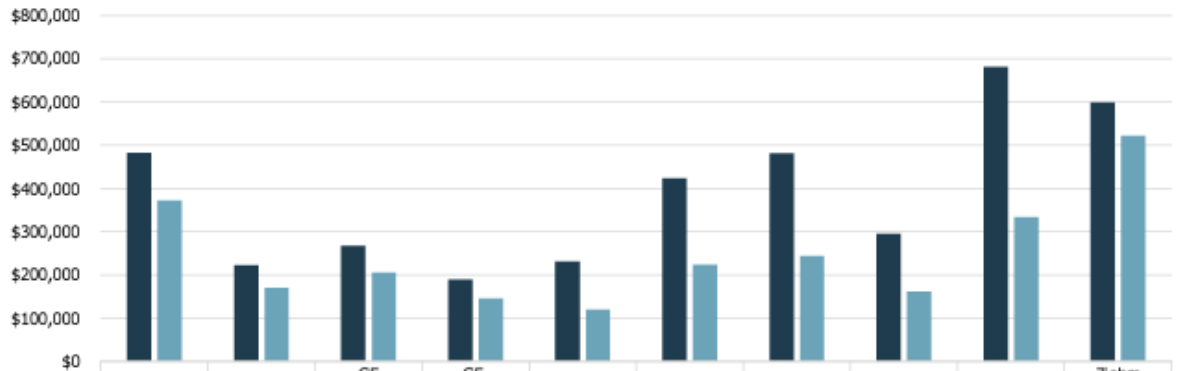
The geometry of C-Arm systems must be conducive to their settings. These devices must be maneuverable around hospitals and provide the greatest positioning flexibility. It is preferable to have the greatest possible C-arm depth; however, this may create difficult maneuverability. The C-arm gantry must have the proper dimensions to be used effectively and easily in the hospital. For instance, it must be deep enough to accommodate obese patients. Additionally, the lower portion of the C-arm must be low enough to fit underneath the hospital's beds and operating room tables. It is also beneficial to have isocentric rotation, in which the center of rotation is the same as the midpoint between the x-ray tube focal spot and the detector.

Digital image processing must be available so that images can be quickly manipulated and sent to PACS. The television (TV) chain system displays the output of an image intensifier on one or more TV monitors during fluoroscopic procedures. If a high-resolution system is needed, it should preferably be able to switch between standard and high resolutions. Other desirable features for the TV chain include a large digital storage capacity and the ability to add alphanumeric characters to a recorded image for patient identification.

Market Intelligence

Pricing Information

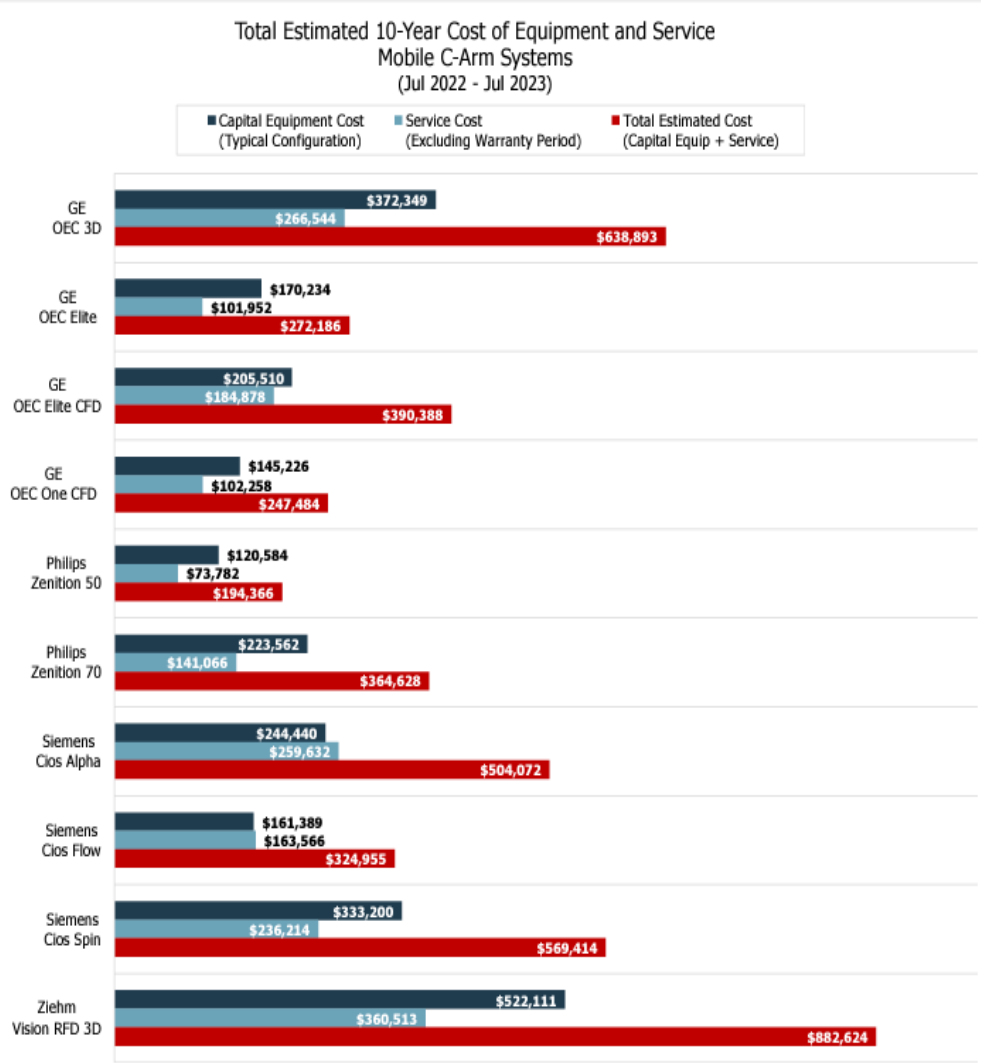
Pricing for Popular Models
Mobile C-Arm Systems
(Jul 2022 - Jul 2023)



	GE OEC 3D	GE OEC Elite	GE OEC Elite CFD	GE OEC One CFD	Philips Zenition 50	Philips Zenition 70	Siemens Cios Alpha	Siemens Cios Flow	Siemens Cios Spin	Ziehm Vision RFD 3D
Average List Price	$482,384	$222,528	$268,229	$189,371	$231,796	$423,548	$480,813	$295,760	$680,475	$598,535
Average Quoted Price	$372,349	$170,234	$205,510	$145,226	$120,584	$223,562	$244,440	$161,389	$333,200	$522,111

Total Estimated Cost

Total Estimated 10-Year Cost of Equipment and Service
Mobile C-Arm Systems
(Jul 2022 - Jul 2023)



Procurement Trends

- Added Monthly
- Updated available upon request

ECRI

PROCUREMENT TRENDS

Digital X-ray Systems

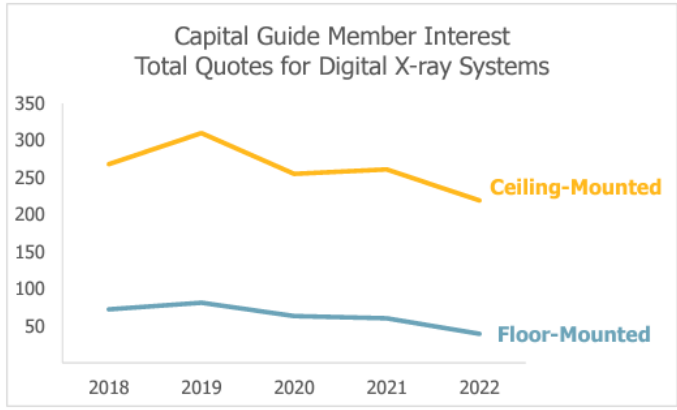
July 2023

Executive Summary

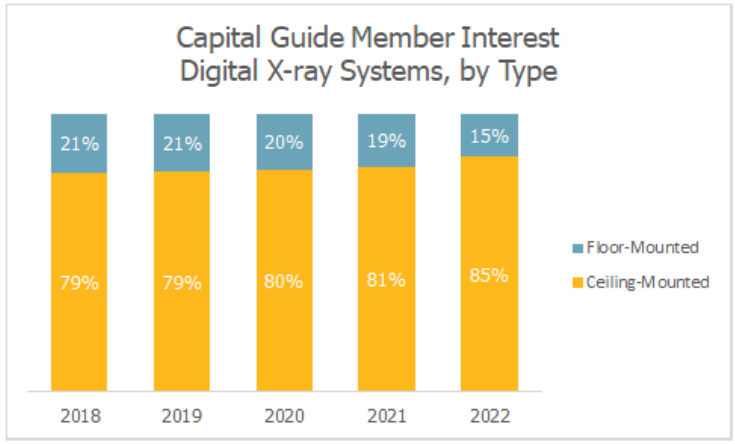
We track overall member interest in digital X-ray systems which has
These imagers can be classified as either ceiling-mounted or floor-mo
quoted prices are compared between the two types of systems.

PROCUREMENT TRENDS

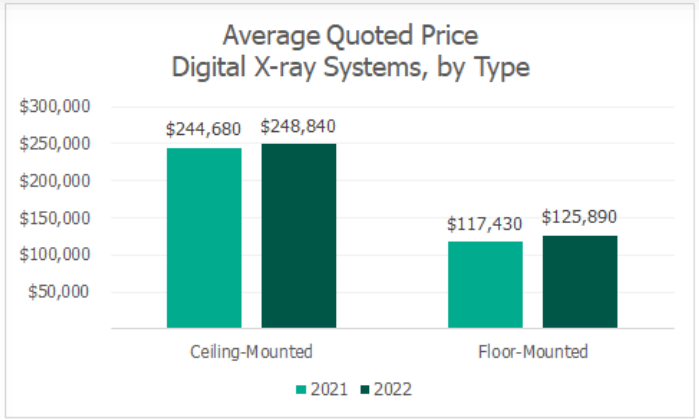
Digital X-ray Systems



Digital X-ray systems (also referred to as general-purpose radiographic systems) are used to perform routine diagnostic X-ray procedures provided by most hospitals, freestanding clinics, physician offices, and urgent care centers. The most basic systems produce individual still images which allow for the examination and differentiation of internal organs and tissue structures. More than 60% of all radiographs taken for routine examinations of the skull, respiratory organs, and skeletal system are produced by general-purpose table systems.



From 2018 to 2022, member interest in ceiling-mounted systems increased from 79% to 85% of all digital X-ray systems. Ceiling-mounted systems are more advantageous in that they open up the floor space and allow the practitioner/technologist to work around the patient and provide an overall benefit to the workflow within the examination room. Also, ceiling-mounted systems can move around the patient to facilitate better positioning and accommodate patients with mobility issues.



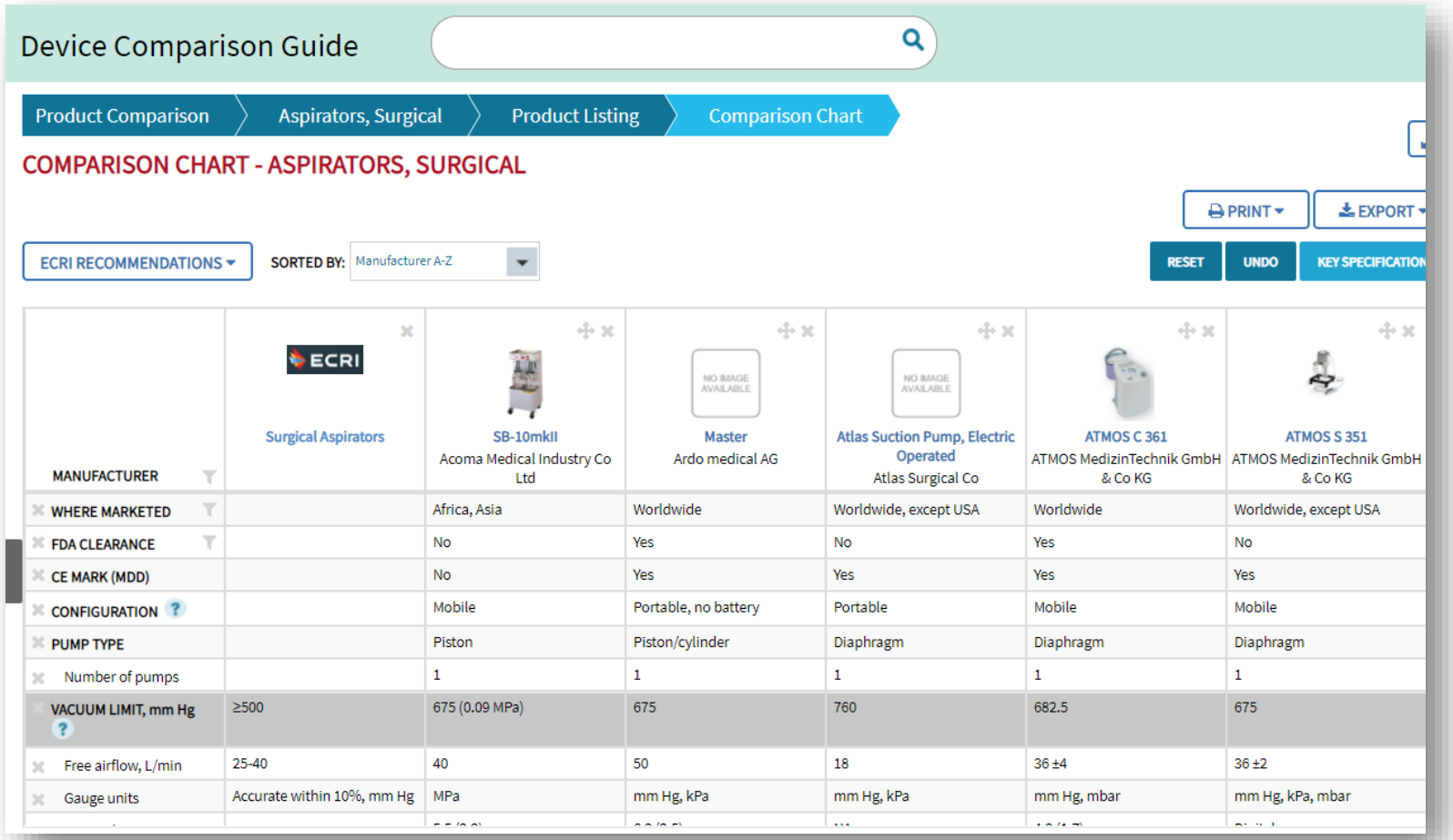
Our database indicates that the average quoted price of ceiling-mounted digital X-ray systems was $244,680 in 2021. In 2022, the average quoted price increased by 2% to $248,840. Meanwhile, the average quoted price of floor-mounted digital X-ray systems increased by 7% from $117,430 to $125,890.

ECRI

Device Comparison Guide: Capital

Largest database of comparative medical equipment

- Largest database of comparative medical equipment
- Specs on over 21,000 domestic and international products
- Includes discussions on operation importance, clinical applications and projected costs/value
- Report updates every 12 to 18 months
- New models can be added within hours if technical specifications are available



MANUFACTURER	Surgical Aspirators	SB-10mkII Acoma Medical Industry Co Ltd	Master Ardo medical AG	Atlas Suction Pump, Electric Operated Atlas Surgical Co	ATMOS C 361 ATMOS MedizinTechnik GmbH & Co KG	ATMOS S 351 ATMOS MedizinTechnik GmbH & Co KG
WHERE MARKETED		Africa, Asia	Worldwide	Worldwide, except USA	Worldwide	Worldwide, except USA
FDA CLEARANCE		No	Yes	No	Yes	No
CE MARK (MDD)		No	Yes	Yes	Yes	Yes
CONFIGURATION		Mobile	Portable, no battery	Portable	Mobile	Mobile
PUMP TYPE		Piston	Piston/cylinder	Diaphragm	Diaphragm	Diaphragm
Number of pumps		1	1	1	1	1
VACUUM LIMIT, mm Hg	≥500	675 (0.09 MPa)	675	760	682.5	675
Free airflow, L/min	25-40	40	50	18	36 ±4	36 ±2
Gauge units	Accurate within 10%, mm Hg	MPa	mm Hg, kPa	mm Hg, kPa	mm Hg, mbar	mm Hg, kPa, mbar

Device Comparison Guide: Capital

Device overview

Device Comparison Guide: Capital - Comparative Data

Carbon Dioxide Monitors, Transcutaneous; Oxygen Monitors, Transcutaneous

Published 1/1/2022

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Summary | Full Text | References | Supplementary Materials | Classifications | Share

Comparison Chart

Carbon Dioxide Monitors, Transcutaneous; Oxygen Monitors, Transcutaneous

Scope of this Product Comparison

This Product Comparison covers stand-alone and modular monitoring devices that measure the partial pressure of transcutaneous carbon dioxide (tcpCO2), transcutaneous oxygen (tcpO2), or both, as well as the sensors included with each device. Some models listed in the chart also measure oxygen saturation (SpO2).

These devices are also called: blood gas physiologic monitors, blood gas transcutaneous monitors, breathing circuit alarms, breathing circuit monitors, operating room monitors, transcutaneous carbon dioxide/oxygen monitors, transcutaneous monitors, transcutaneous oxygen analyzers.

Purpose

The tcpCO2 and tcpO2 monitors provide noninvasive methods of measuring the partial pressure of carbon dioxide (CO2) and oxygen (O2), respectively, at the skin surface. These measurements are not always equal to the arterial partial pressure of CO2 (paCO2) and the arterial partial pressure of O2 (paO2) but can be useful indicators of those values. In a hemodynamically stable patient, the relationship between tcpCO2 and tcpO2 concentrations and arterial blood gas levels can be an accurate indicator of the oxygenation of peripheral tissues.

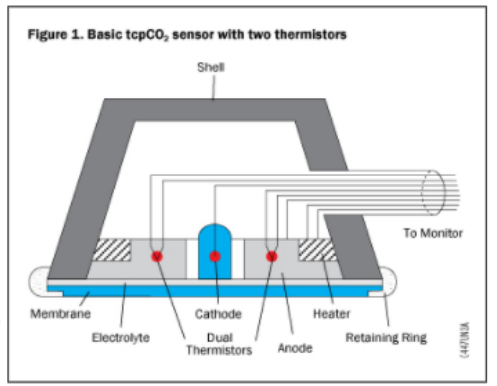
Principles of Operation

Gas exchange between the blood and the skin takes place slightly below the surface of the skin, at the subepidermal capillary level. O2 from the O2-rich arterial blood diffuses out of the capillaries and exchanges with the CO2 generated in the tissues as a by-product of cellular metabolism. The blood gases diffuse upward through the stratum corneum (keratin filaments in a matrix lipid and nonfibrous protein), where their partial pressures can be measured.

$TcpO_2$ Measurement

The partial pressure of oxygen (pO2) at the skin surface is measured by a tcpO2 sensor, which is a modified polarographic Clark electrode consisting of an anode and cathode of noble metals (usually composed of silver and platinum, respectively), an electrolyte, a semipermeable membrane, and a heating element (see Figure 1). For the sensor to accurately measure pO2, an adequate amount of O2 must diffuse through the skin. However, capillary blood flow at the normal skin surface temperature of 28° to 29°C does not deliver the O2 required. Moreover, the dense layer of dead cells that compose the stratum corneum (outer layer of the skin) is an effective barrier to O2 diffusion.

Figure 1. Basic $tcpCO_2$ sensor with two thermistors



Therefore, a small heating ring inside the transcutaneous sensor is used to raise the skin temperature to 43° to 45°C (the temperature required depends on the patient's age and skin thickness), increasing blood gas diffusion to the skin surface. Heating the skin beneath the sensor significantly increases the supply of arterial blood to the dermal capillary bed by capillary vasodilation and by arterialization, a process that promotes the opening and expansion of dormant capillaries to accept blood flow and to deliver more O2 to the tissues. Higher skin temperatures also enhance blood gas diffusion by increasing the rate at which O2 dissociates from hemoglobin in the red blood cells, by elevating the rate at which the vital cells of the skin consume O2 and generate CO2, and by melting the lipid component of the stratum corneum to facilitate O2 diffusion across the skin surface.

Because blood flowing beneath the sensor carries away some heat to the rest of the body, the sensor uses a thermistor to monitor and maintain the desired temperature of the heating ring. Many units use two thermistors to control high and low temperature deviations from the set-point temperature. Thermistors can also be set to trigger audible and/or visual alarms in the event that the heating ring temperature exceeds its preset upper and lower limits. In some units, the heating power in milliwatts is displayed on the monitor and can be printed out.

After permeating the skin surface, O2 diffuses through the sensor's membrane. This membrane has diffusion properties similar to those of the skin, so the rate of O2 diffusion is not affected and the tcpO2 measurement reflects the paO2 levels. Some common types of membrane materials used are Teflon, polyethylene, and polypropylene. The O2 then dissolves in the electrolyte, where a voltage applied between the anode and the cathode reduces the O2 to hydroxyl ions. The current generated by this reaction is directly proportional to the paO2 and is converted to millimeters of mercury (mm Hg) for display on the monitor. Solid-state electrodes are generally considered more stable.

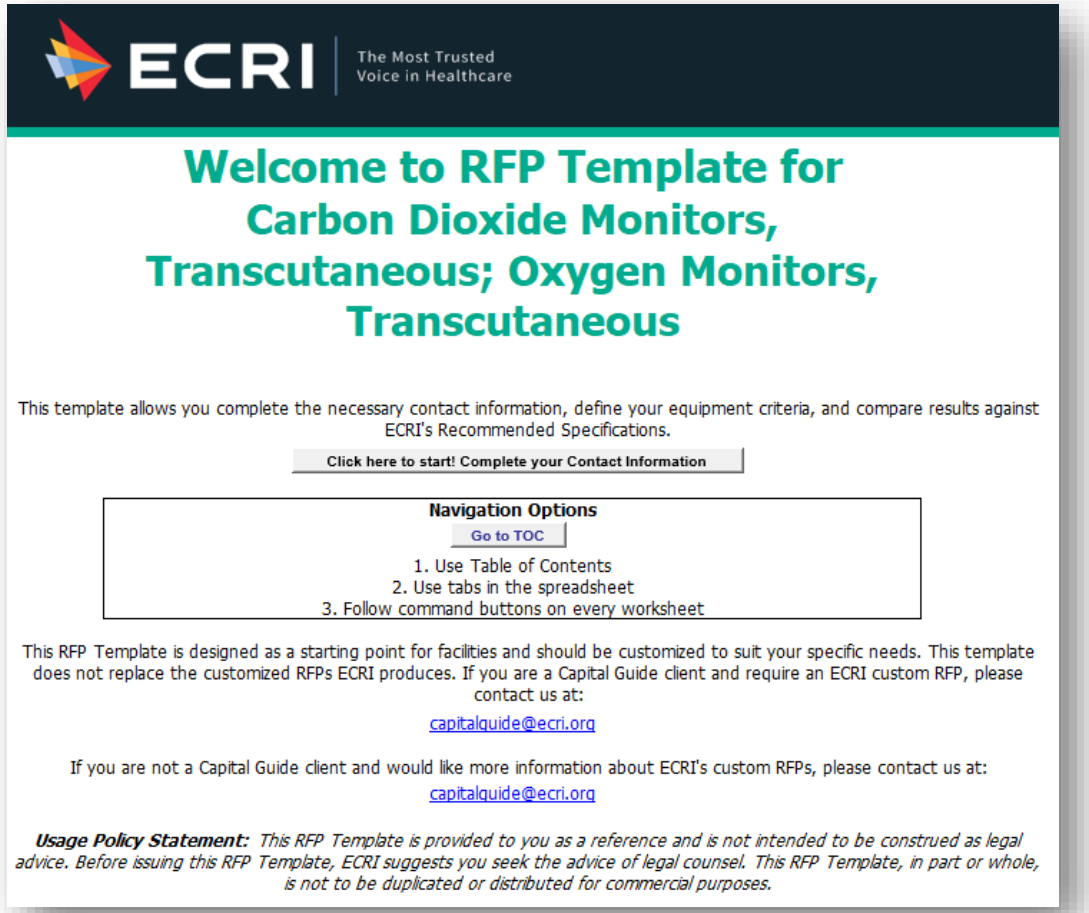
Device Comparison Guide

Request for Proposal Template

Carbon Dioxide Monitors, Transcutaneous; Oxygen Monitors, Transcutaneous

View All Device Comparison Guide RFPs

RFP templates – international standard tender documents templates (MS Excel files) easily customized to be used for procurement of medical technology



ECRI | The Most Trusted Voice in Healthcare

Welcome to RFP Template for Carbon Dioxide Monitors, Transcutaneous; Oxygen Monitors, Transcutaneous

This template allows you complete the necessary contact information, define your equipment criteria, and compare results against ECRI's Recommended Specifications.

Click here to start! Complete your Contact Information

Navigation Options

Go to TOC

1. Use Table of Contents
2. Use tabs in the spreadsheet
3. Follow command buttons on every worksheet

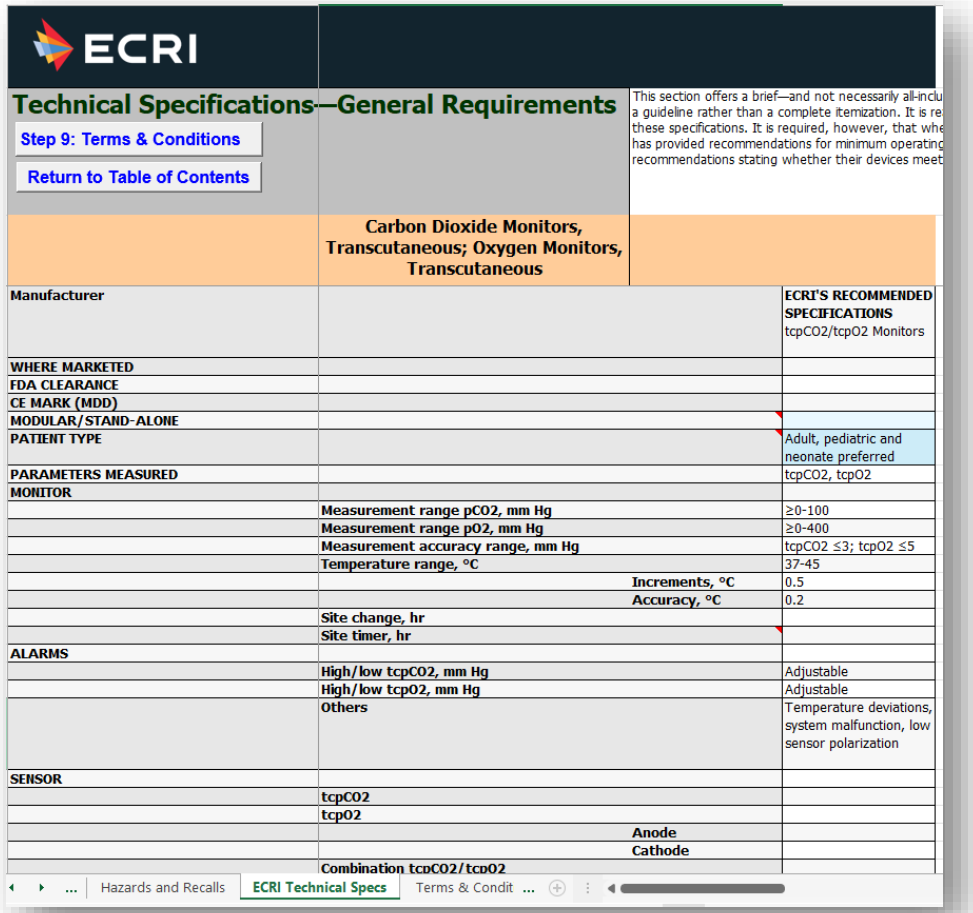
This RFP Template is designed as a starting point for facilities and should be customized to suit your specific needs. This template does not replace the customized RFPs ECRI produces. If you are a Capital Guide client and require an ECRI custom RFP, please contact us at:

capitalguide@ecri.org

If you are not a Capital Guide client and would like more information about ECRI's custom RFPs, please contact us at:

capitalguide@ecri.org

Usage Policy Statement: *This RFP Template is provided to you as a reference and is not intended to be construed as legal advice. Before issuing this RFP Template, ECRI suggests you seek the advice of legal counsel. This RFP Template, in part or whole, is not to be duplicated or distributed for commercial purposes.*



ECRI

Technical Specifications—General Requirements

Step 9: Terms & Conditions

Return to Table of Contents

This section offers a brief—and not necessarily all-inclu a guideline rather than a complete itemization. It is re these specifications. It is required, however, that whe has provided recommendations for minimum operating recommendations stating whether their devices meet

Carbon Dioxide Monitors, Transcutaneous; Oxygen Monitors, Transcutaneous

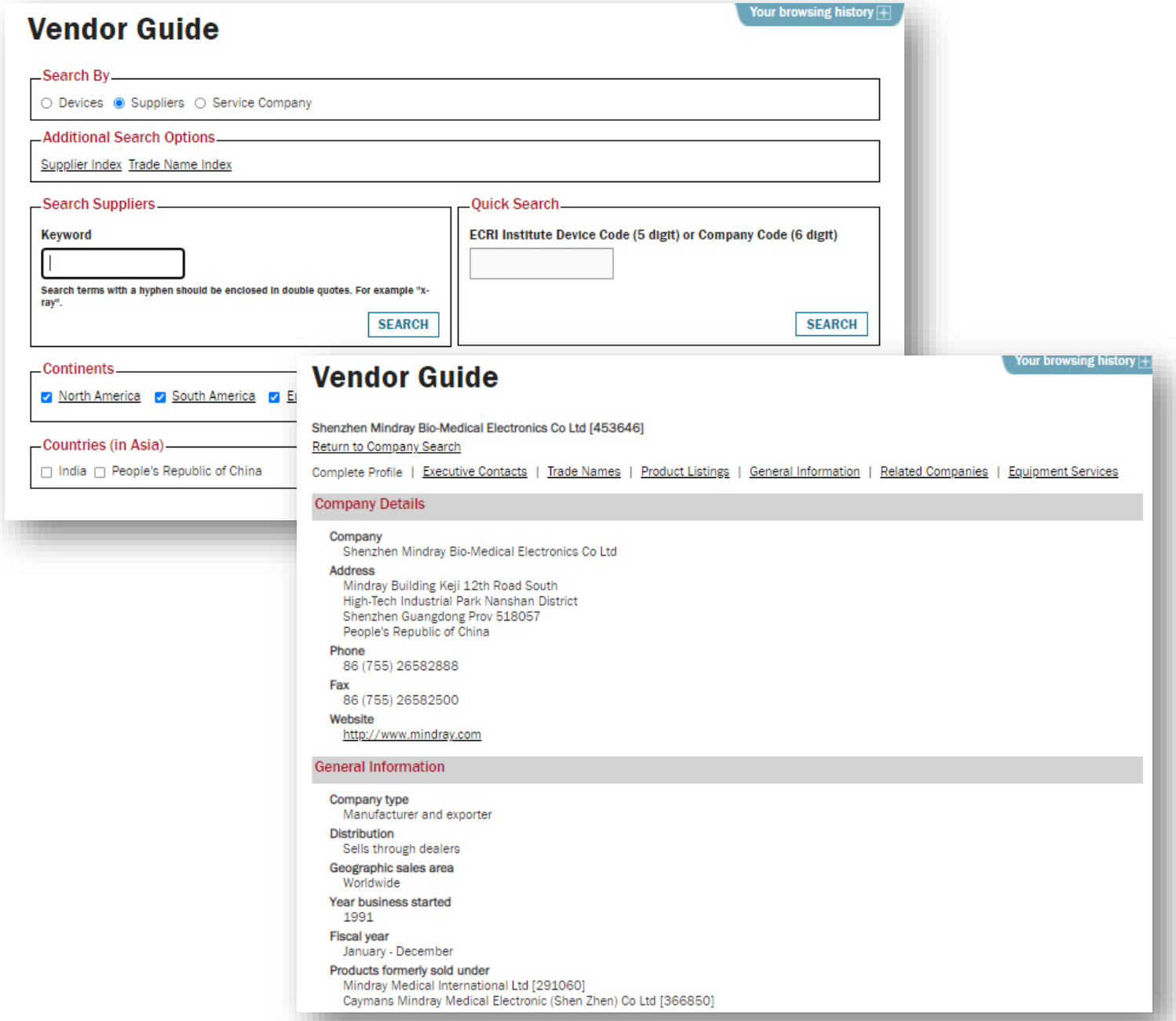
Manufacturer			**ECRI'S RECOMMENDED SPECIFICATIONS** tcpCO2/tcpO2 Monitors
WHERE MARKETED			
FDA CLEARANCE			
CE MARK (MDD)			
MODULAR/STAND-ALONE			
PATIENT TYPE			Adult, pediatric and neonate preferred
PARAMETERS MEASURED			tcpCO2, tcpO2
MONITOR			
	Measurement range pCO2, mm Hg		≥0-100
	Measurement range pO2, mm Hg		≥0-400
	Measurement accuracy range, mm Hg		tcpCO2 ≤3; tcpO2 ≤5
	Temperature range, °C		37-45
		Increments, °C	0.5
		Accuracy, °C	0.2
	Site change, hr		
	Site timer, hr		
ALARMS			
	High/low tcpCO2, mm Hg		Adjustable
	High/low tcpO2, mm Hg		Adjustable
	Others		Temperature deviations, system malfunction, low sensor polarization
SENSOR			
	tcpCO2		
	tcpO2		
		Anode	
		Cathode	
	Combination tcpCO2/tcpO2		

... Hazards and Recalls | ECRI Technical Specs | Terms & Condit ...

Vendor Guide Plus

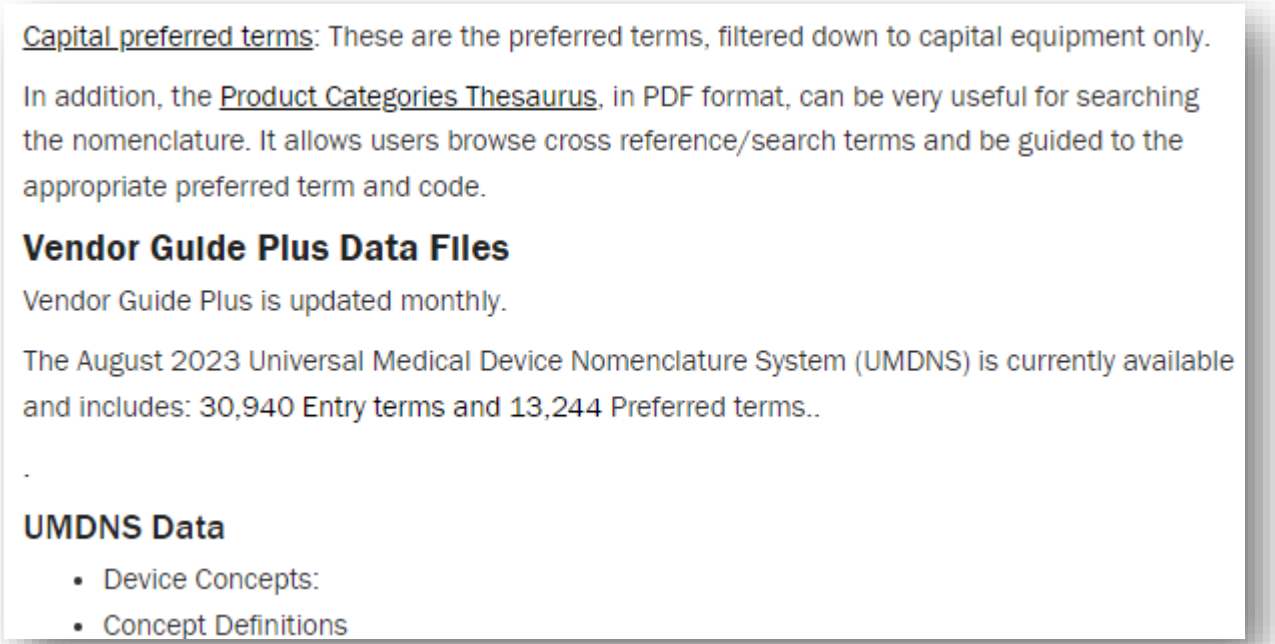
Medical Equipment Purchasing

- Instantly connect to thousands of manufacturers, suppliers, and service companies worldwide
- Quickly narrow down device selection and move health technology purchases forward
  - > 22,400 medical equipment manufacturers and distributors worldwide
  - > 12,000 product categories



Vendor Guide Plus

- Universal Medical Device Nomenclature System (UMDNS)
  - Updated monthly
  - Covers all medical devices and supplies, clinical laboratory equipment and reagents, selected hospital furniture, systems and test equipment.



Capital preferred terms: These are the preferred terms, filtered down to capital equipment only.

In addition, the Product Categories Thesaurus, in PDF format, can be very useful for searching the nomenclature. It allows users browse cross reference/search terms and be guided to the appropriate preferred term and code.

Vendor Guide Plus Data Files

Vendor Guide Plus is updated monthly.

The August 2023 Universal Medical Device Nomenclature System (UMDNS) is currently available and includes: 30,940 Entry terms and 13,244 Preferred terms..

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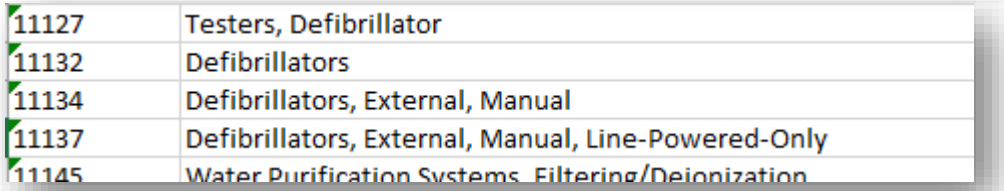
UMDNS Data

- Device Concepts:
- Concept Definitions

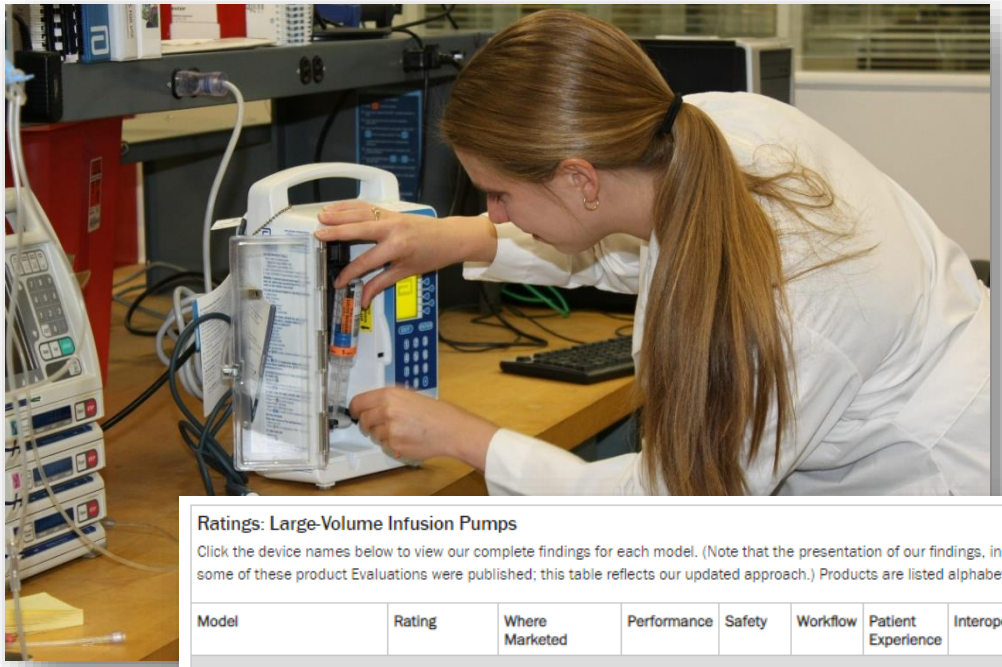


11127	Testers, Defibrillator
11132	Defibrillators
11134	Defibrillators, External, Manual
11137	Defibrillators, External, Manual, Line-Powered-Only
11145	Water Purification Systems, Filtering/Deionization

Evaluation & Guidance

In-depth evaluations and comparative ratings on healthcare products & expert guidance on hot technology topics

- Backed by independent analysis and onsite laboratory testing
- Expert guidance and objective recommendations on current technology issues like alarms, health IT, robotic surgery, radiation hazards



Ratings: Large-Volume Infusion Pumps

Click the device names below to view our complete findings for each model. (Note that the presentation of our findings, including how we categorize our judgments, has been reformulated since some of these product Evaluations were published; this table reflects our updated approach.) Products are listed alphabetically by supplier.

Model	Rating	Where Marketed	Performance	Safety	Workflow	Patient Experience	Interoperability	Cybersecurity	Maintenance	User Experience	Cost of Ownership (Estimated)
Models with Dose Error Reduction Systems (DERS)											
B. Braun Infusomat Space Last updated 7/2020	★★★★☆ (with pump integration) ★★★☆☆ (without pump integration)	Worldwide	Good	Good	Good	Not evaluated	Excellent (with integration) Not evaluated (without integration)	Good	Excellent	Not evaluated	$4,800,000 (over 10 years)
B. Braun Outlook 400ES Last updated 6/2015	★★☆☆☆	Canada, U.S.	Good	Fair	Fair	Not evaluated	Good	Not evaluated	Good	Not evaluated	Not evaluated
Baxter Sigma Spectrum Last updated 10/2016	★★☆☆☆ (with pump integration) ★★★☆☆ (without pump integration)	Canada, Puerto Rico, U.S.	Fair	Good	Excellent	Not evaluated	Fair (with integration) Not evaluated (without integration)	Not evaluated	Fair	Not evaluated	No details available (with integration) $4,800,000 (without integration, over 10 years)
Baxter Spectrum IQ Last updated 4/2020	★★★★☆ (with pump integration) ★★★★☆	Canada, Puerto Rico, U.S.	Good	Excellent	Good	Not evaluated	Good (with pump integration) Not evaluated	Good	Good	Not evaluated	$4,400,000 (without integration, over 10 years)

Evaluation & Guidance

Ratings: Large-Volume Infusion Pumps

Click the device names below to view our complete findings for each model. (Note that the presentation of our findings, including how we categorize our judgments, has been reformulated since some of these product Evaluations were published; this table reflects our updated approach.) Products are listed alphabetically by supplier.

Model	Rating	Where Marketed	Performance	Safety	Workflow	Patient Experience	Interoperability	Cybersecurity	Maintenance	User Experience	Cost of Ownership (Estimated)
Models with Dose Error Reduction Systems (DERS)											
B. Braun Infusomat Space Last updated 7/2020	★★★★½ (with pump integration) ★★★½☆ (without pump integration)	Worldwide	Good	Good	Good	Not evaluated	Excellent (with integration) Not evaluated (without integration)	Good	Excellent	Not evaluated	$4,800,000 (over 10 years)
B. Braun Outlook 400ES Last updated 8/2015	★★½☆☆	Canada, U.S.	Good	Fair	Fair	Not evaluated	Good	Not evaluated	Good	Not evaluated	Not evaluated
Baxter Sigma Spectrum Last updated 10/2016	★★½☆☆ (with pump integration) ★★★½☆ (without pump integration)	Canada, Puerto Rico, U.S.	Fair	Good	Excellent	Not evaluated	Fair (with integration) Not evaluated (without integration)	Not evaluated	Fair	Not evaluated	No details available (with integration) $4,800,000 (without integration, over 10 years)
Baxter Spectrum IQ Last updated 4/2020	★★★½☆ (with pump integration) ★★★★½	Canada, Puerto Rico, U.S.	Good	Excellent	Good	Not evaluated	Good (with pump integration) Not evaluated	Good	Good	Not evaluated	$4,400,000 (without integration, over 10 years)

Evaluation & Guidance

Cybersecurity – Standard in device evaluations

Ratings: Syringe Pumps

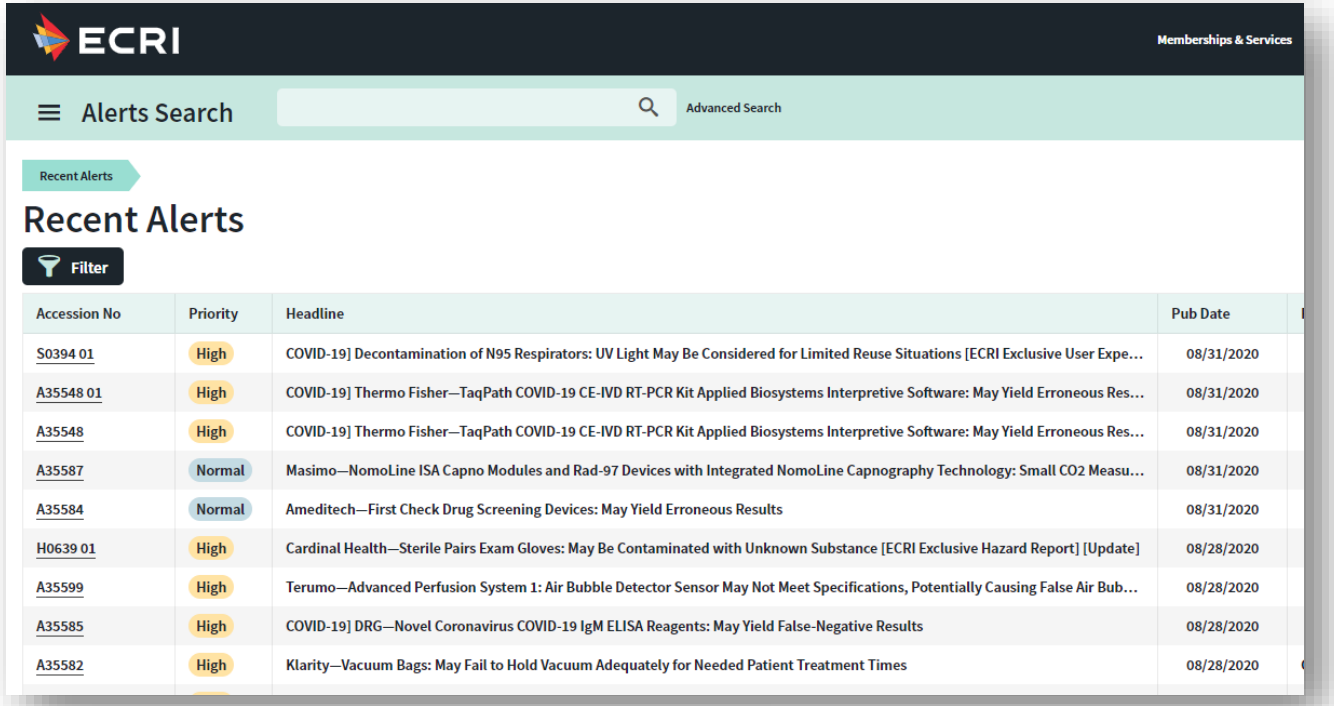
Click the product names below to view our complete findings. Models are listed alphabetically by supplier.

Model	Rating	Where Marketed	Performance	Safety	Workflow	Patient Experience	Interoperability	Cybersecurity	Maintenance	User Experience	Cost of Ownership (Estimated) for 50 Pumps over 10 Years
B. Braun Perfusor Space Last updated 5/2021	★★★★½	Worldwide	Good	Excellent	Good	Not evaluated	Good	Good	Excellent	Not evaluated	$250,000
BD Alaris Syringe Module Last updated 3/2019 **Note:** Available only with certificate of medical necessity	★★★½☆	Worldwide	Good	Fair	Good	Not evaluated	Excellent	Good	Poor	Not evaluated	$1,200,000
Smiths Medical Medfusion 4000 Last updated 3/2019	★★★½☆	Worldwide	Good	Fair	Good	Not evaluated	Good	Good	Good	Not evaluated	$460,000

Hazards & Recalls

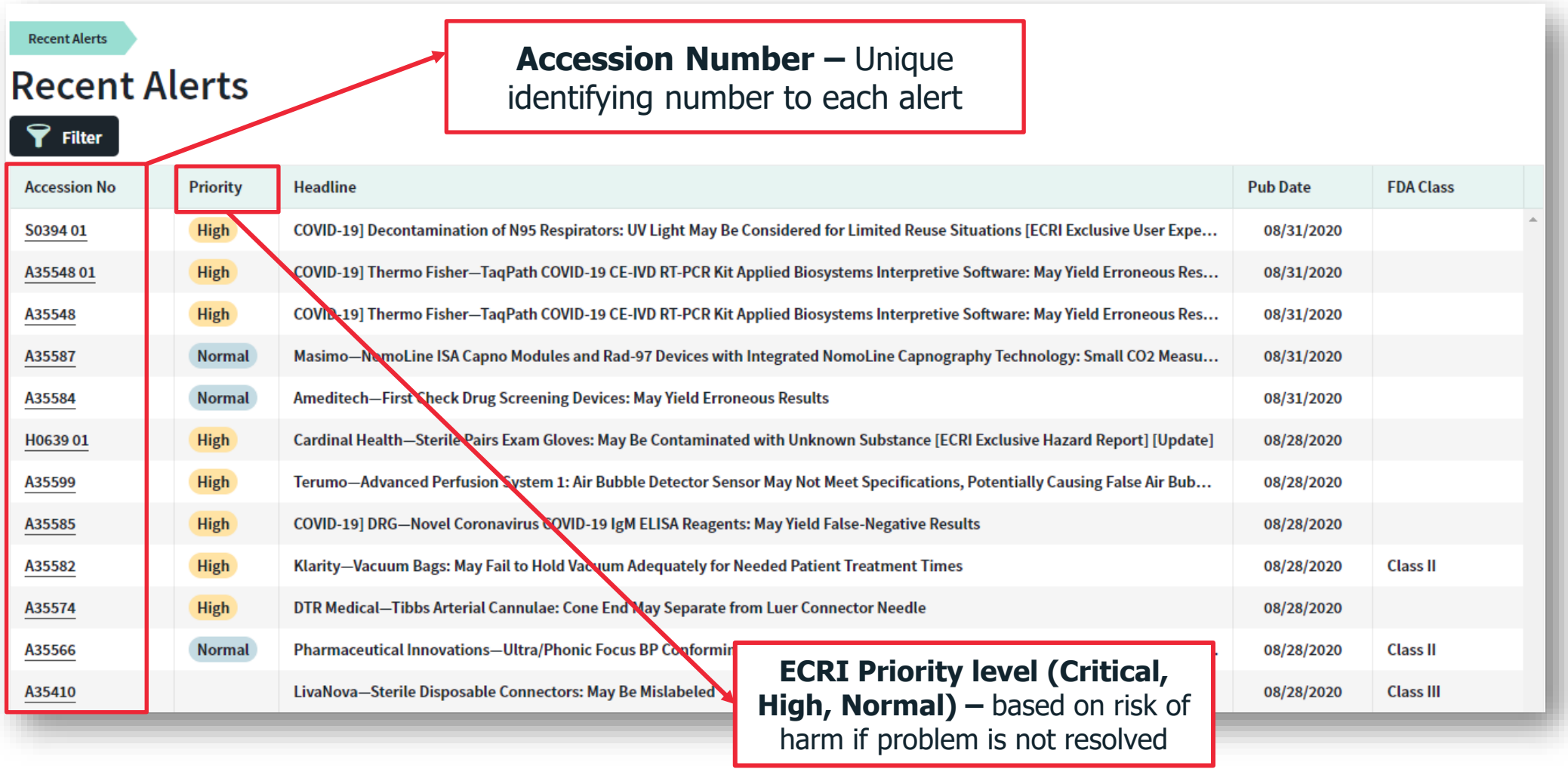
Vital hazard and recall information from the largest problem reporting network

- Critical safety information e-mailed weekly to minimize the chance of missed alerts
- Access exclusive reports and guidance based on problem reports submitted to ECRI by thousands of hospitals worldwide
- ECRI regularly investigates, reports, and frequently corrects the information provided by third parties
- International database to ensure patient safety



Accession No	Priority	Headline	Pub Date
S0394 01	High	COVID-19] Decontamination of N95 Respirators: UV Light May Be Considered for Limited Reuse Situations [ECRI Exclusive User Expe…	08/31/2020
A35548 01	High	COVID-19] Thermo Fisher—TaqPath COVID-19 CE-IVD RT-PCR Kit Applied Biosystems Interpretive Software: May Yield Erroneous Res…	08/31/2020
A35548	High	COVID-19] Thermo Fisher—TaqPath COVID-19 CE-IVD RT-PCR Kit Applied Biosystems Interpretive Software: May Yield Erroneous Res…	08/31/2020
A35587	Normal	Masimo—NomoLine ISA Capno Modules and Rad-97 Devices with Integrated NomoLine Capnography Technology: Small CO2 Measu…	08/31/2020
A35584	Normal	Ameditech—First Check Drug Screening Devices: May Yield Erroneous Results	08/31/2020
H0639 01	High	Cardinal Health—Sterile Pairs Exam Gloves: May Be Contaminated with Unknown Substance [ECRI Exclusive Hazard Report] [Update]	08/28/2020
A35599	High	Terumo—Advanced Perfusion System 1: Air Bubble Detector Sensor May Not Meet Specifications, Potentially Causing False Air Bub…	08/28/2020
A35585	High	COVID-19] DRG—Novel Coronavirus COVID-19 IgM ELISA Reagents: May Yield False-Negative Results	08/28/2020
A35582	High	Klarity—Vacuum Bags: May Fail to Hold Vacuum Adequately for Needed Patient Treatment Times	08/28/2020

Hazards & Recalls



Accession No	Priority	Headline	Pub Date	FDA Class
S0394 01	High	COVID-19] Decontamination of N95 Respirators: UV Light May Be Considered for Limited Reuse Situations [ECRI Exclusive User Expe…	08/31/2020	
A35548 01	High	COVID-19] Thermo Fisher—TaqPath COVID-19 CE-IVD RT-PCR Kit Applied Biosystems Interpretive Software: May Yield Erroneous Res…	08/31/2020	
A35548	High	COVID-19] Thermo Fisher—TaqPath COVID-19 CE-IVD RT-PCR Kit Applied Biosystems Interpretive Software: May Yield Erroneous Res…	08/31/2020	
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A35584	Normal	Ameditech—First Check Drug Screening Devices: May Yield Erroneous Results	08/31/2020	
H0639 01	High	Cardinal Health—Sterile Pairs Exam Gloves: May Be Contaminated with Unknown Substance [ECRI Exclusive Hazard Report] [Update]	08/28/2020	
A35599	High	Terumo—Advanced Perfusion System 1: Air Bubble Detector Sensor May Not Meet Specifications, Potentially Causing False Air Bub…	08/28/2020	
A35585	High	COVID-19] DRG—Novel Coronavirus COVID-19 IgM ELISA Reagents: May Yield False-Negative Results	08/28/2020	
A35582	High	Klarity—Vacuum Bags: May Fail to Hold Vacuum Adequately for Needed Patient Treatment Times	08/28/2020	Class II
A35574	High	DTR Medical—Tibbs Arterial Cannulae: Cone End May Separate from Luer Connector Needle	08/28/2020	
A35566	Normal	Pharmaceutical Innovations—Ultra/Phonic Focus BP Conformi…	08/28/2020	Class II
A35410		LivaNova—Sterile Disposable Connectors: May Be Mislabeled	08/28/2020	Class III

Hazards & Recalls

Accession Number: A38665 01 **ECRI Priority:** Critical **Published:** 02/01/2022

Channel: Devices **FDA:** Not Specified **Last Updated:** 02/01/2022

McKesson—Medtronic MiniMed Insulin Pumps: New and Replacement Pumps May Not Be Pre-Programmed with Basal Rates or Other Verified Settings

Product Identifier: +

Manufacturer(s):
Medtronic Diabetes USA, 18

Distributor(s):
McKesson Corp, 6555 State

Summary:
Update Reason: Distributor subrecall. This Alert provides information on a McKesson subrecall of the above products based on a January 27, 2022, Urgent Medical Device Correction lette. For information on the recall initiated by Medtr

Problem:
In a January 2022 Urgent Medical Device Correction letter, Medtronic st
with their basal rates or other verified settings (i.e., bolus wizard setting
Medtronic also states that it has received reports of serious injuries rela
not setting basal rates. The firm has received one report of death; howe
basal rates. If basal rates are not set in the pump when they should be,
which may lead to life-threatening diabetic ketoacidosis (DKA). The ma

Action Needed:
Determine whether you have any patients with affected pumps. If you h
Device Correction and copy of the Medtronic January 2022 Urgent Medi
are those listed in Alert A38665. Medtronic provides the following instru

Action needed – Guidance on next steps to take if you have an affected product in your inventory

Source Documents – Download letters, documents from original source

Geographic Region(s):
(Impact in additional regions has not been identified or ruled out at the time of this posting), U.S.

Suggested Distribution:
Clinical/Biomedical Engineering, Nursing, Pediatrics, Diabetes Education/Coordination, Home Care, Endocrinology, IV Therapy

Comment:
- This alert is a living document and may be updated when ECRI receives additional information.

Source Documents:

Download	Posted	Source	Description
	02/01/2022	Distributor	McKesson reference no. 22-001
	02/01/2022	Distributor	Medtronic letter

Accession Number: A38665 01 **ECRI Priority:** Critical **Published:** 02/01/2022

Channel: Devices **FDA:** Not Specified **Last Updated:** 02/01/2022

McKesson—Medtronic MiniMed Insulin Pumps: New and Replacement Pumps May Not Be Pre-Programmed with Basal Rates or Other Verified Settings

Product Identifier: +

Manufacturer(s):
Medtronic Diabetes USA, 18000 Devonshire St, Northridge, CA 91325-1219, United States

Distributor(s):
McKesson Corp, 6555 State Hwy 161, Irving, TX 75039, United States

Summary:
Update Reason: Distributor subrecall. This Alert provides information on a McKess

Serial numbers, Batch/Lot, Models numbers

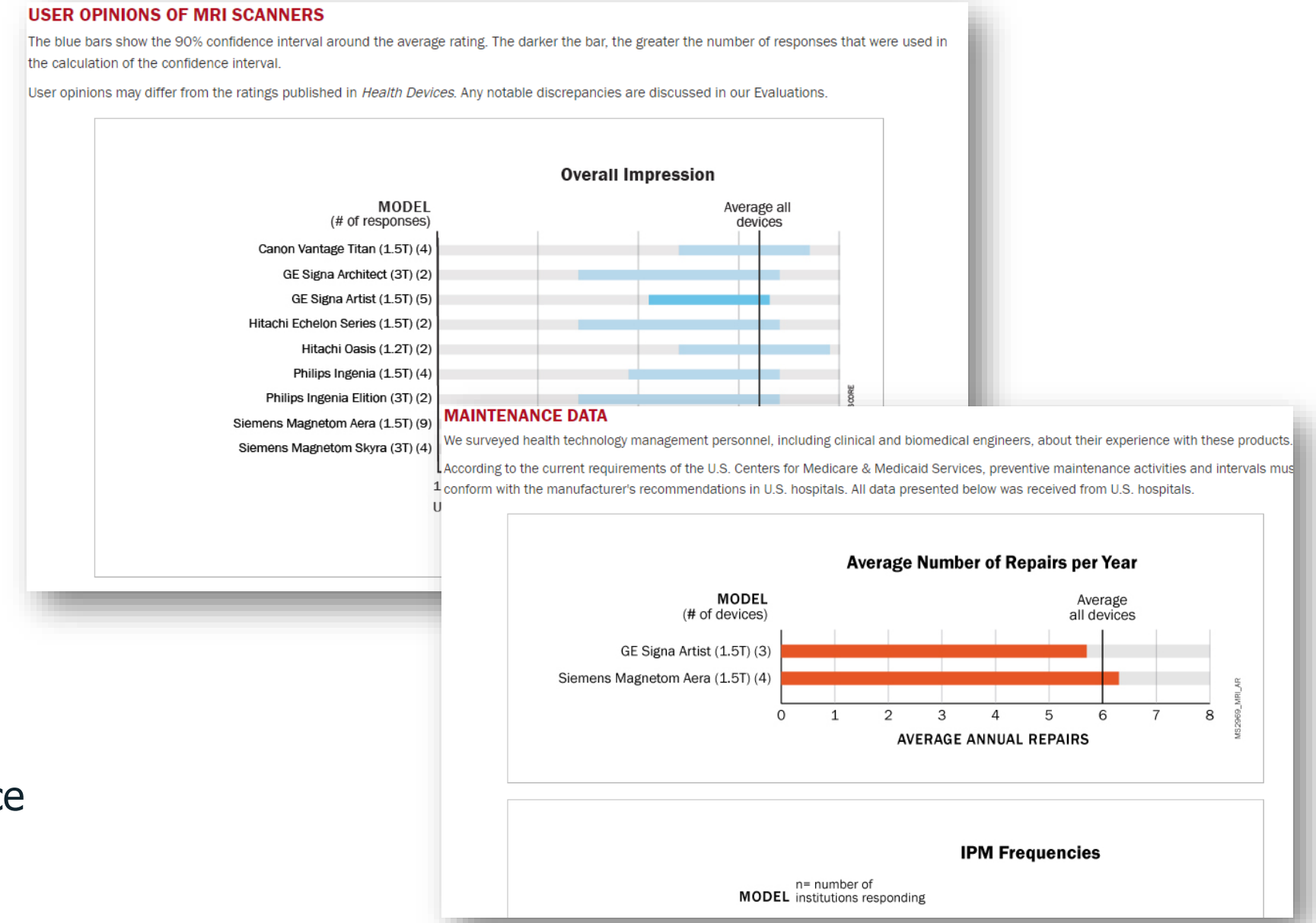
Product Identifier: −

[Capital Equipment]

Product	Medtronic Diabetes USA Model	Model No.
Insulin Pumps	MiniMed 620G	MMT-1750
	MiniMed 630G	MMT-1715, MMT-1754, MMT-1755
	MiniMed 640G	MMT-1711, MMT-1712, MMT-1751, MMT-1752
	MiniMed 670G	MMT-1740, MMT-1741, MMT-1742, MMT-1760, MMT-1761, MMT-1762, MMT-1780, MMT-1781, MMT-1782
	MiniMed 720G	MMT-1809, MMT-1810, MMT-1859, MMT-1860
	MiniMed 740G	MMT-1811, MMT-1812, MMT-1861, MMT-1862
	MiniMed 770G	MMT-1880, MMT-1881, MMT-1882, MMT-1890, MMT-1891, MMT-1892
	MiniMed 780G	MMT-1884, MMT-1885, MMT-1886, MMT-1895, MMT-1896

User Experience

- User survey results on popular health technologies
  - Overall impression
  - Ease of use
  - Feature set
  - Performance
  - Reliability
- Provides insights on the latest user experience information, maintenance data



Device Evaluation Webinars

Free access to webinar archive on health devices

Device Evaluation Webinar Archive

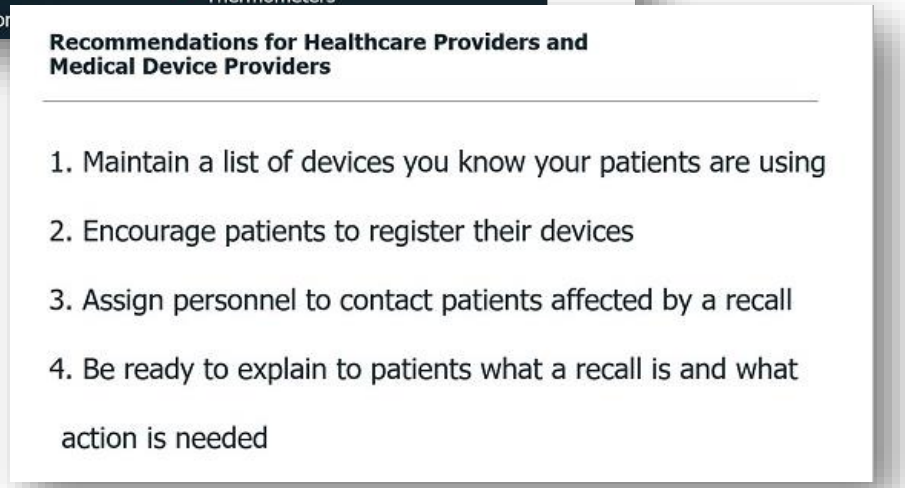
Members receive free access to our interactive webinars on topics of interest to the healthcare community. Here's a list of past webinars, including recordings in MP4 format and associated materials.

2023

- A Look Inside ECRI's Device Testing Process (May 24, 2023)
- Environmental Cleaning and Disinfection: Break the Chain of Infection (March 22, 2023)
- Home-Use Device Recalls: What You Need to Know to Mitigate Risk and Protect Patients (February 1, 2023)

2022

- Mergers and Acquisitions: Assessing the Technology (November 16, 2022)
- Exploring the Evidence and Devices Designed to Prevent Ventilator-Associated Pneumonia (October 26, 2022)
- State of Artificial Intelligence: Viewpoints from ECRI Clinical and Technical Experts (September 28, 2022)
- In-Lab Testing: Device to Reduce Risk of IV Site Infiltrations (August 24, 2022)
- Helping Patients with Recalled Philips CPAP Devices Used in Home (June 23, 2022)
- ENFit: The Time Is Now (May 19, 2022)
- Incidents Happen: Are You Prepared? (April 27, 2022)
- Medical Device Safety: How Can You Make a Difference? (March 16, 2022)
- Navigating Supply Disruption: Collaboration and Information Sharing as a Strategy (February 24, 2022)
- Cybersecurity Incidents—A Threat to Patient Safety and Healthcare Delivery (January 26, 2022)



Thank you

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The Most Trusted
Voice in Healthcare