Glucose Monitors, Continuous

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EXECUTIVE SUMMARY

Comparison Chart

Glucose Monitors, Continuous

This Product Comparison covers dedicated continuous glucose monitors that measure glucose in interstitial fluid. These devices use implantable sensors and are worn continuously by the patient. Systems that incorporate insulin pumps are excluded. Also excluded are blood glucose analyzers and clinical chemistry analyzers with glucose testing capabilities.

An estimated 366 million people worldwide have diabetes mellitus, a disease in which the pancreas secretes an inadequate supply of insulin and/or the body has an inadequate response to insulin. When blood glucose concentration is high, insulin lowers the glucose level mainly by stimulating tissue uptake through the conversion of extracellular glucose ($C_6H_{12}O_6$) to intracellular glucose (glucose-6-phosphate). When insulin production is deficient or absent, extracellular glucose concentrations in the blood rise above normal levels; this condition is called hyperglycemia. Hyperglycemia can lead to severe damage to the heart, kidneys, eyes, blood vessels, and nerves and can potentially be fatal.

Monitoring glucose to detect hypo- and hyperglycemia is a critical component of diabetes management. These measurements facilitate appropriate adjustments in therapy to keep glucose levels within a normal range. Continuous glucose monitors (CGMs) measure glucose levels in the interstitial fluid surrounding cells and can provide real-time results. CGMs allow physicians and patients to track and analyze day-to-day fluctuations in glucose levels due to diet, exercise, medication, and lifestyle. In addition, CGMs can identify potentially dangerous extremes in patient glucose levels.

The following device terms and product codes as listed in ECRI Institute's Universal Medical Device Nomenclature System™ (UMDNS™) are covered:

- Monitors, Physiologic, Glucose, Personal, [20-184]
- Monitors, Physiologic, Glucose, Personal, Implantable Sensor [20-185]

These devices are also called: CGMs, implantable glucose monitors, interstitial glucose monitors.

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Scope of this Product Comparison

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Purpose

An estimated 366 million people worldwide have diabetes mellitus, a disease in which the pancreas secretes an inadequate supply of insulin and/or the body has an inadequate response to insulin. When blood glucose concentration is high, insulin lowers the glucose level mainly by stimulating tissue uptake through the conversion of extracellular glucose ($C_6H_{12}O_6$) to intracellular glucose (glucose-6-phosphate). When insulin production is deficient or absent, extracellular glucose concentrations in the blood rise above normal levels; this condition is called hyperglycemia. Hyperglycemia can lead to severe damage to the heart, kidneys, eyes, blood vessels, and nerves and can potentially be fatal.

Monitoring glucose to detect hypo- and hyperglycemia is a critical component of diabetes management. These measurements facilitate appropriate adjustments in therapy to keep glucose levels within a normal range. Continuous glucose monitors (CGMs) measure glucose levels in the interstitial fluid surrounding cells and can provide real-time results. CGMs allow physicians and patients to track and analyze day-to-day fluctuations in glucose levels due to diet, exercise, medication, and lifestyle. In addition, CGMs can identify potentially dangerous extremes in patient glucose levels.

CGMs are most beneficial when used by patients who:

- Have hypoglycemia without symptoms
- Have nocturnal hypoglycemia
- Have hypoglycemic and hyperglycemic events that are refractory to multiple adjustments in self-monitoring of blood glucose concentration and insulin administration
- Have large fluctuations in before-meal glucose concentration
- Start insulin therapy for the first time
- Begin an insulin pump regimen

According to manufacturer labeling, CGM measurements are not intended to be used for making therapy adjustments. CGMs are used to supplement information gained by traditional capillary blood glucose measurements.

The intention of a CGM is to “close the loop," which allows the patient to focus more on glucose trending and less on glucose levels obtained by traditional fingersticking.

Principles of Operation

CGMs consist of three main parts: a disposable, short-term sensor that measures glucose levels in interstitial fluid; a transmitter attached to the sensor; and a receiver that displays and stores measured glucose concentrations. Using an applicator, the patient inserts the sensor just under the skin (subcutaneous tissue) of the abdomen. The sensor is a fine wire that is designed to be worn for three to seven days, depending on the model. The sensor measures the level of glucose in the tissue. Sensor signals are transmitted to the receiver by wireless radiofrequency telemetry or Bluetooth. The receiver can be worn on a belt, carried in a pocket, or placed in a purse where it receives information from the sensor/transmitter every one to five minutes. The receiver can display real-time glucose values, glucose trends, rate of glucose change, and can alarm for potentially dangerous high- and low-blood glucose levels. In addition, the receiver can store data for later analysis by the patient or a healthcare professional. Data can be downloaded to a computer for analysis. Trend reports and charts assess the effect of meals, exercise, insulin, and medication on glucose levels.

Patients must initialize and calibrate CGMs whenever a new glucose sensor is inserted. The initialization process lasts about two hours and concludes with an initial fingerstick calibration. These systems also need subsequent calibration every 12 hours, except for one model that requires calibration less than once per day after the initial calibration. The calibration process requires obtaining blood glucose values from a traditional fingerstick sample.

A new CGM recently released on the market has eliminated the need for fingerstick testing to calibrate glucose levels. This system uses a sensor wire inserted below the skin's surface that constantly measures and monitors glucose levels; a mobile reader is waved above the sensor to determine current glucose levels.

The expected shelf life of a glucose sensor is six months.

Reported Problems

To minimize the risk of infection at the sensor insertion site, several precautions are necessary. Sensors come in sterile packages that should be discarded if previously opened or damaged. Hand washing with soap and water before opening the sensor package is necessary. Do not touch sensor surfaces that will come in contact with the body. Choose a skin site devoid of scar tissue. Cleansing the skin site with a topical antimicrobial solution is required before inserting the sensor. After sensor insertion, the site must be checked for redness, bleeding, pain, tenderness, and swelling before going to bed and upon awakening in the morning. If bleeding or soreness develops at the insertion site, the glucose sensor should be removed immediately.

Blistering, redness, or mild swelling may occur at the sensor insertion site. Rotation of sensor sites is recommended; sites that are constrained by clothing, accessories or are subjected to movement during exercise should be avoided.

Failure to recalibrate the sensor as recommended by the manufacturer may result in incorrect glucose readings.

The transmitter signal can travel 6 to 20 feet without obstruction. Wireless communication does not work well through water so the range can be limited if a patient is in a pool, bathtub, etc. Metal chairs, signals in the air, or other objects may interfere with signal transmission.

Interpretation of CGM measurements should be based on the trends and patterns seen with several sequential sensor readings over time. Treatment decisions should not be based solely on CGM results. Compared to current blood glucose analyzers that provide point-in-time results from blood samples, sensors that measure glucose in interstitial fluid are less accurate. The traditional fingerstick method measures blood glucose concentration at the time of blood sampling. During rapid changes in blood glucose levels, the gap between blood and interstitial glucose concentrations can be significant.

Accuracy of real-time CGM can be affected by use errors. Glucose measurements used to calibrate CGMs may be compromised by improper technique, an unclean meter, unclean fingers, and inappropriate site testing. Sensor performance may be affected by calibrating during rapidly changing glucose levels, entering an incorrect meter reading, or waiting to enter a meter reading.

Certain substances such as ascorbic acid, glutathione, isoniazid, paracetamol, salicylate, and uric acid can interfere with CGM measurements causing overestimation of glucose levels. Some CGM models may have drug incompatibilities (e.g., acetaminophen).

Purchase Considerations

ECRI Institute Recommendations

The accompanying comparison chart includes ECRI Institute's recommendations for minimum performance requirements for CGMs.

The range of glucose levels in interstitial fluid measured by the instrument, expressed in milligrams per deciliter, should be 40 to 400. CGM sensors should last for 3 or more days. The time that it takes for the sensor to provide accurate readings once the unit is turned on should be 2 hours or less. The transmitter battery should last the life of the sensor if the model has replaceable or rechargeable batteries.

An often-overlooked, but valuable, CGM receiver feature is the capability to retain data in memory if the battery is removed for replacement. It is recommended that the receiver have a memory to retain at least one day's worth of data, or 288 readings when captured every 5 minutes. More memory is needed for long-term storage of results, physician review or entry into a data management system. Patient software should be user-friendly and information should be easy to download from the receiver to long term data storage.

The CGM receiver display should allow the user to view previous glucose measurements, glucose rate of change, transmitter battery level, and loss of signal. The graph on the display should show at least a 2- to 3-hour period. The receiver battery should have a life of at least 7 days and a low-battery signal. A CGM should be compatible with all drugs.

The transmitter must be water resistant and should have an Ingress Protection (IP) rating of 7 or higher. An IPX7 rating indicates a device is waterproof in water up 1 meter. A water resistant receiver is preferred.

High- and low-level alarms are required while audible signal disable, predictive alarms, and glucose rate of change alarms are preferred.

CGM calibration with traditional capillary blood glucose measurements is another important consideration. CGM calibration frequency should be 12 hours or more.

Other Considerations

Additional software and hardware components may be needed to download all glucose measurements from the CGM receiver onto a computer or other device.

Cost Containment

CGM outpatients may incur additional costs related to training and ongoing monitoring of results. For example, individualized patient training on CGM use may take an hour for the initial appointment followed by several one-hour follow-up sessions in two to three weeks. Patient training can vary for each device. Ongoing monitoring and analysis of results will also add to health care costs. The added costs of using CGM systems may be offset by reduced complications and length of hospital stay associated with improved patient outcomes.

Some CGM systems intended for hospital use will require purchase of capital equipment (e.g., monitors to display results) and ongoing use of disposable sensors. Cost increases may be offset if the incidence of acute complications (i.e., infection, poor wound healing, hypoglycemia) decreases by using these devices.

Many commercial insurance plans are now covering CGMs for personal and professional use.

Stage of Development

Proponents of continuous glucose monitoring hope that it will replace fingerstick testing in the future and ultimately lead to improved patient glucose management: fewer emergency room visits, fewer complications, fewer incidents of undiscovered hypoglycemia, improved quality of life, and fewer hospitalizations.

The use of insulin pumps with subcutaneously placed glucose sensors has become popular in recent years. One manufacturer has released a hybrid closed-loop system (referred to as an artificial pancreas). This system provides steady glycemic control for up to ten days by continuously regulating insulin delivery based on CGM glucose measurements, eliminating the need for patient intervention.

Infrared spectroscopy can also be used to measure blood glucose levels. A beam of light is shined on the skin and penetrates the skin to measure blood glucose. Accuracy can be affected by variations in body temperature and blood pressure; therefore, traditional blood glucose tests are needed in addition to infrared spectroscopy measurements.

Several CGMs are in the early stages of development for the intensive care setting. CGM measurement methods vary and may include the use of intravascular, transdermal, optical, ophthalmic, or implanted glucose sensors. Implantable sensors may pose difficulties in design and development because of the body's tendency to encapsulate foreign substances and the toxicology issues posed. High interest in CGM technology exists because of the increase in diabetes incidence that shows no signs of subsiding.

Software improvements have enabled some CGM receivers to receive and share data wirelessly in real-time via smartphone mobile medical apps.

Efforts are underway by all manufacturers to increase sensor longevity.

Costs associated with CGM sensors have been high, but ultimately, manufacturers aim to mass-produce tiny implantable devices that could be more cost-effective than current point-in-time glucose monitoring systems.

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RESOURCE LIST

Comparison Chart

Glucose Monitors, Continuous

Request for Proposal Template

Glucose Monitors, Continuous

RELATED RESOURCES

Blood Glucose Analyzers

Clinical Chemistry Analyzers, Automated, Discrete; Chemistry/Immunoassay

Clinical Chemistry Analyzers, Manual

Glycohemoglobin Analyzers

Infusion Pumps, Insulin

Point-of-Care Analyzers, Blood Gas/Ph; Chemistry; Electrolyte

TOPICS AND METADATA

UMDNS

Monitors, Physiologic, Glucose, Personal [20-184]
Monitors, Physiologic, Glucose, Personal, Implantable Sensor [20-185]

Manufacturer	**Abbott Diabetes Care Div Abbott Laboratories Inc** FreeStyle Libre Flash Continuous Monitoring System	**Abbott Diabetes Care Div Abbott Laboratories Inc** FreeStyle Libre Flash Glucose Monitoring System	**Abbott Diabetes Care Div Abbott Laboratories Inc** FreeStyle Navigator II	**Dexcom Inc** G4 PLATINUM
WHERE MARKETED	USA	Worldwide	Worldwide, except USA	Worldwide<1>
FDA CLEARANCE	Yes	Not specified	No	Yes
CE MARK	Not specified	Yes	Yes	Yes
PATIENT TYPE	Adult	Adult, pediatric	Adult, pediatric	Adult, pediatric ≥2 years
SAMPLE TYPE	Interstitial fluid	Interstitial fluid	Interstitial fluid	Interstitial fluid
MEASUREMENT RANGE, mg/dL	40-500	40-500	20-500	40-400
SENSOR				
Life, days	≤10	≤14	≤5	≤7
Type	Filament	Filament	Filament	Transcutaneous
Placement	Back of upper arm	Back of upper arm	Abdomen, back of upper arm	Abdomen (adult), abdomen and upper buttocks (pediatric)
Start-up time to accurate readings, hr	12	1	1	2
TRANSMITTER				
Water resistant	Submerged ≤1 m (3 ft) and 30 min	Submerged ≤1 m (3 ft) and 30 min	Submerged ≤1 m (3 ft) and 45 min	Submerged ≤2.4 m (8 ft) and ≤24 hr; IP28
Weight, g (oz)	5 (0.18)	5 (0.18)	12.8 (0.45)	Not specified
Size, H x W x L, cm (in)	0.5 x 3.5 (0.2 x 1.4)	0.5 x 3.5 (0.2 x 1.4)	1.2 x 3.2 x 4 (0.5 x 1.3 x 1.6)	1.3 x 2.3 x 3.8 (0.5 x 0.9 x 1.5)
Battery				
Type (no.)	Silver oxide (1)	Silver oxide (1)	CR2032 lithium coin cell	Silver oxide
Rechargeable/replaceable	No	No	No	Transmitter is replaced when battery dies
Operating time, hr	348	348	1 year	6 months
Low-battery indicator	No	No	No	Yes
RECEIVER				
Smartphone compatible	Yes	Yes	No	No
Water resistant	No	No	No	IP22
Weight, g (oz)	65 (2.3)	65 (2.3)	90.6 (3.2)	82 (2.9)
Size, H x W x D, cm (in)	9.5 x 6 x 1.6 (3.7 x 2.4 x 0.6)	9.5 x 6 x 1.6 (3.7 x 2.4 x 0.6)	9.9 x 6.2 x 1.6 (3.9 x 2.4 x 0.6)	1.3 x 10.2 x 4.6 (0.5 x 4 x 1.8)
Display type	LCD	LCD	LCD	LCD
Parameters displayed	Glucose level, glucose trend arrow, 8-hr glucose graph, messages and notifications (reader reports; logbook, daily graph, average glucose, daily patterns, time in target, low glucose events and sensor usage for 7, 14, 30 and 90 days)	Glucose level, glucose trend arrow, 8-hr glucose graph, messages and notifications (reader reports; logbook, daily graph, average glucose, daily patterns, time in target, low glucose events and sensor usage for 7, 14, 30 and 90 days)	Highest, lowest and average, SD, percentage of time spent within and outside preset target range, number of alarms per day (view reports for past 1, 3, 7, 14, 21, or 28 days)	Multiple time, unit and language formats, depending on country
Frequency of glucose readings shown	Every min (stored every 15 min)	Every min (stored every 15 min)	Every min (stored every 10 min)	Every 5 min
Graph, hr	8 (additional graphs in on-reader reports)	8 (additional graphs in on-reader reports)	2, 4, 6, 12, and 24	1, 3, 6, 12, and 24
Readings recall	Yes	Yes	Yes	No
Rate of change indication	Yes	Yes	Yes	Yes
Transmitter battery level	NA	NA	Yes	No
Loss of signal	NA	NA	Yes	Yes
Screen size, H x W x D cm, (in)	Not specified	Not specified	Not specified	4.6 x 3.5 (1.8 x 1.4)
Battery				
Type (no.)	Lithium-ion	Lithium-ion	Lithium-ion	Not specified
Rechargeable/replaceable	Rechargeable	Rechargeable	Rechargeable	Rechargeable
Life, days	7	7	3	3-5
Low-battery signal	Yes	Yes	Yes	Yes
Memory loss if batteries removed or depleted	No	No	No	No
Memory				
Number of stored readings with timestamp	90 days of normal use including continuous glucose readings (stored every 15 min) and daily blood glucose results	90 days of normal use including continuous glucose readings (stored every 15 min) and daily blood glucose results	60 days of normal use including continuous glucose readings (stored every 10 min) and daily blood glucose results	30 days of data

Manufacturer	**Abbott Diabetes Care Div Abbott Laboratories Inc** FreeStyle Libre Flash Continuous Monitoring System	**Abbott Diabetes Care Div Abbott Laboratories Inc** FreeStyle Libre Flash Glucose Monitoring System	**Abbott Diabetes Care Div Abbott Laboratories Inc** FreeStyle Navigator II	**Dexcom Inc** G4 PLATINUM
AUTOMATIC DISPLAY SHUTOFF	After 60 sec	After 60 sec	After 20 sec	After 30 sec
TRANSMITTER RANGE, m (ft)	0.04 (0.13)	0.04 (0.13)	3 (9.8)	6 (20)
DRUG INCOMPATIBILITY	Salicylic acid and vitamin C have small effect on CGM	Salicylic acid and vitamin C have small effect on CGM	Salicylic acid has small effect on CGM	Acetaminophen
CALIBRATION FREQUENCY, hr	Factory calibrated	Factory calibrated	1, 2, 10, 24, and 72 after insertion	12
DATA MANAGEMENT				
Software	FreeStyle Libre	FreeStyle Libre	CoPilot	Ability to download and view glucose and event log data/patterns
Patient input	Food, insulin, exercise, medication, ≤6 customizable notes; reminders, 3 predefined (check glucose, take insulin, alarm) and ≤9 reminders customizable through software	Food, insulin, exercise, medication, ≤6 customizable notes; reminders, 3 predefined (check glucose, take insulin, alarm) and ≤9 reminders customizable through software	Insulin, meals, exercise, state of health plus 8 customizable generic events	Carbohydrates, exercise, insulin, health events
ALERT INDICATORS, TYPE	Audible or vibrating	Audible or vibrating	Audible or vibrating	Audible, vibrating, visual
ALARMS				
High/low glucose concentration	No	No	Yes	Yes
Rate of change	No	No	Yes	Yes
Predictive	No	No	Yes	None
KIT INCLUDES	Receiver, power adaptor (USB), USB cable, user manual, user tutorial, quick start guide, quick reference guide, sensor applicator, sensor pack, alcohol wipes, sensor kit insert	Reader, power adaptor (USB), USB cable, user manual, quick start guide, sensor applicator, sensor pack, alcohol wipes, sensor kit insert	Receiver, transmitter, AC adaptor (USB), travel charger, user manual, clinical insert, protective silicone skins for receiver	1 receiver, 1 transmitter, power adaptors, download cable, carrying case, instructional materials
PURCHASE INFORMATION				
List price	Not specified	Not specified	Not specified	$4,048<2>
Warranty	Yes	Yes	Yes	1 year receiver, 6 months transmitter
Training	No	No	Yes	Yes
Year first sold	2017	2014	2007	2012
Fiscal year	Not specified	Not specified	Not specified	January to December
OTHER SPECIFICATIONS	Built-in BGM meter uses FreeStyle precision neonatal test strips.	Built-in BGM and blood ketone meter; uses FreeStyle precision test strips, varies by market.	Built-in FreeStyle blood glucose meter; TRU Directional Arrows.	Short-range device. Meets requirements of EN 60601, EN 60601-1-2, and ETSI EN 300 220-1.
UMDNS CODE(S)	20184, 20185	20184, 20185	20184, 20185	20184, 20185
LAST UPDATED	November 2017	November 2017	November 2017	November 2017
Supplier Footnotes				
Model Footnotes				No longer marketed for patient use; available to clinicians for professional diagnostics only.
Data Footnotes				<1>Australia, Canada, Chile, Columbia, Europe, Israel, New Zealand, USA. <2>Pricing information derived from ECRI Institute's PricePaid database.

Manufacturer	**Dexcom Inc** G5 Mobile CGM System	**Medtronic Diabetes USA Div Medtronic Inc** iPro2 Professional CGM
WHERE MARKETED	Worldwide<1>	Worldwide
FDA CLEARANCE	Yes	Yes
CE MARK	Yes	Yes
PATIENT TYPE	Adult, pediatric ≥2 years	Adult, pediatric
SAMPLE TYPE	Interstitial fluid	Interstitial fluid
MEASUREMENT RANGE, mg/dL	40-400	40-400
SENSOR		
Life, days	≤7	3
Type	Transcutaneous	Transcutaneous
Placement	Abdomen (adult), abdomen and upper buttocks (pediatric)	Abdomen
Start-up time to accurate readings, hr	2	2
TRANSMITTER		
Water resistant	Submerged ≤2.4 m (8 ft) and ≤24 hr, IP28	IPX8
Weight, g (oz)	11.3 (0.4) with sensor	5.7 (0.2)
Size, H x W x L, cm (in)	3.8 x 2.3 x 1.3 (1.5 x 0.9 x 0.5)	0.9 x 3.5 x 2.8 (0.4 x 1.4 x 1.1)
Battery		
Type (no.)	Silver oxide	Not specified
Rechargeable/replaceable	Transmitter is replaced when battery dies	Rechargeable
Operating time, hr	3 months	168 immediately following full charge, plus 240 additional battery life immediately following a CGM study
Low-battery indicator	Yes	Yes
RECEIVER		
Smartphone compatible	Yes	Not specified
Water resistant	IP22	IPX8
Weight, g (oz)	68 (2.4)	22.7 (0.8)
Size, H x W x D, cm (in)	1.3 x 10.2 x 4.6 (0.5 x 4 x 1.8)	2.8 x 5.1 x 6.4 (1.1 x 2 x 2.5)
Display type	LCD	None (uses CareLink iPro software)
Parameters displayed	Multiple time, unit and language formats, depending on country	Glucose level, 24-hr glucose graph
Frequency of glucose readings shown	Every 5 min	Every 5 min (via CareLink iPro)
Graph, hr	1, 3, 6, 12, and 24	24
Readings recall	On smart device	Via CareLink iPro
Rate of change indication	Yes	Via CareLink iPro
Transmitter battery level	No	Via CareLink iPro
Loss of signal	Yes	Via CareLink iPro
Screen size, H x W x D cm, (in)	4.6 x 3.5 (1.8 x 1.4)	Not specified
Battery		
Type (no.)	Not specified	Not specified
Rechargeable/replaceable	Rechargeable	Rechargeable or replaceable
Life, days	3-5	≥7
Low-battery signal	Yes	Yes
Memory loss if batteries removed or depleted	No	Yes
Memory		
Number of stored readings with timestamp	30 days of data	7 days of data

Manufacturer	**Dexcom Inc** G5 Mobile CGM System	**Medtronic Diabetes USA Div Medtronic Inc** iPro2 Professional CGM
AUTOMATIC DISPLAY SHUTOFF	After 30 sec	NA
TRANSMITTER RANGE, m (ft)	6 (20)	1.8 (6)
DRUG INCOMPATIBILITY	Acetaminophen	Not specified
CALIBRATION FREQUENCY, hr	12	12
DATA MANAGEMENT		
Software	Dexcom Clarity (web-based diabetes management software, automatically uploads data when using a smart device)	CareLink iPro
Patient input	Carbohydrates, exercise, insulin, health events	Event markers for meals, insulin injections, exercise, others
ALERT INDICATORS, TYPE	Audible, vibrating, visual	Audible or vibrating
ALARMS		
High/low glucose concentration	Yes	Yes
Rate of change	Yes	Yes
Predictive	None	Yes
KIT INCLUDES	1 receiver, 1 transmitter, power adaptors, download cable, carrying case, instructional materials	1 iPro recorder, 1 iPro dock, 3 cleaning plugs, power adaptor, wall plugs, USB cable, glucose sensor (4 pack), Sen-Serter insertion device (4 pack), iPro2 resource kit
PURCHASE INFORMATION		
List price	Not specified	Not specified
Warranty	1 year receiver, 3 months transmitter	1 year
Training	Yes	Yes
Year first sold	2015	2011
Fiscal year	January to December	May to April
OTHER SPECIFICATIONS	Short-range device; users get CGM data and alerts directly on smart device without needing receiver; Bluetooth built into transmitter and glucose data is sent wirelessly from transmitter to compatible smart device. Meets requirements of EN 60601, EN 60601-1-2, and ETSI EN 300 220-1.	Multipatient use iPro2 recorder; web-based user guide.
UMDNS CODE(S)	20184, 20185	20184, 20185
LAST UPDATED	November 2017	April 2018<1>
Supplier Footnotes		
Model Footnotes		
Data Footnotes	<1>Australia, Austria, Belgium, Canada, Czech Republic, Denmark, Finland, France, Germany, Hong Kong, Ireland, Israel, Italy, Jordan, Lebanon, Luxembourg, the Netherlands, New Zealand, Norway, Oman, Qatar, South Africa, Spain, Sweden, Switzerland, United Arab Emirates, United Kingdom, USA.	<1>Specificatons updated using manufacturer's website.