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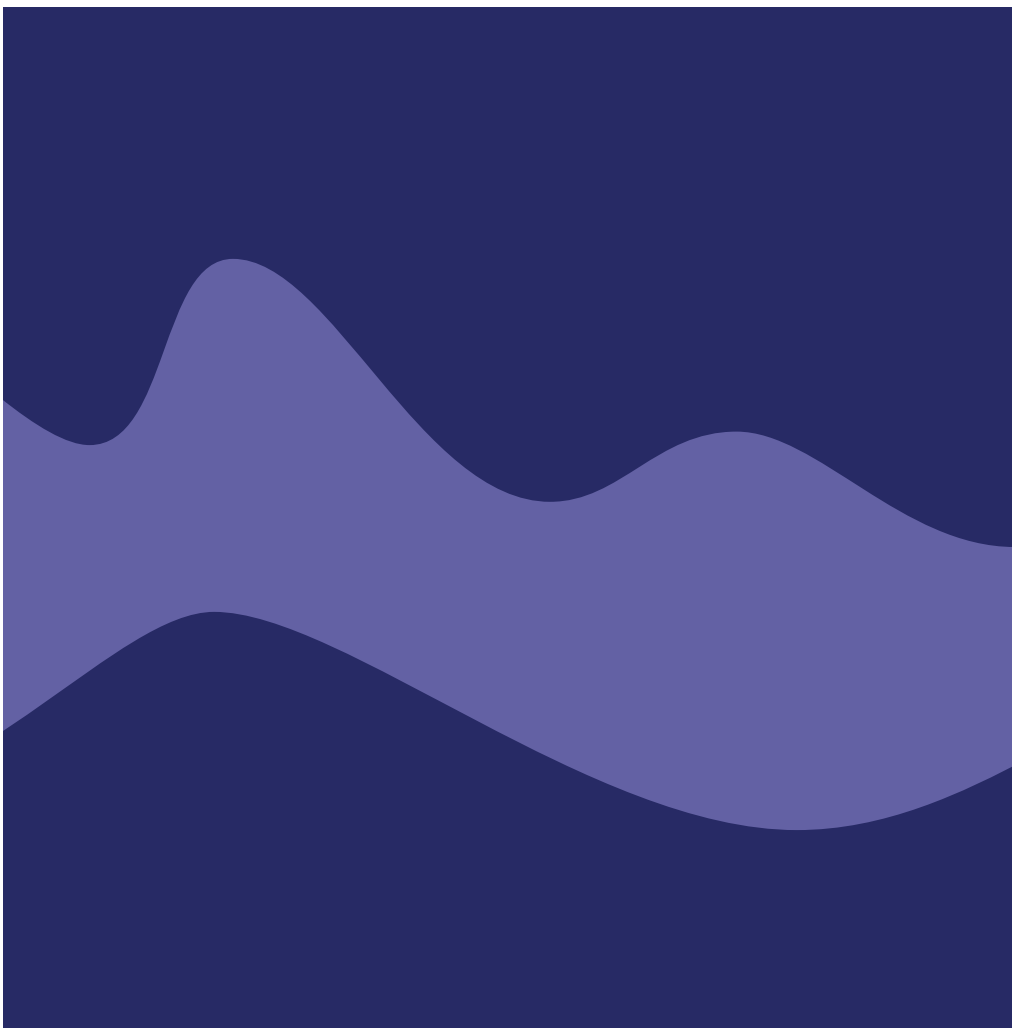
Instinct

Sensor User Guide

Made by Abbott



Instinct Sensor

The latest version of this user guide is available at manuals.medtronic.com. A printed copy is available upon request.

If using with a compatible system, please refer to and follow the instructions that came with that system before making any treatment decisions.

Important Safety Information

Instinct sensor

- 15 day wear duration
- Can be used by children age 2 and older
- Can be used with compatible automated insulin dosing (AID) systems
- Taking more than 1000 mg of Vitamin C per day may falsely raise sensor readings, which could cause you to miss a severe low glucose event. You can take up to 1000 mg of Vitamin C per day and can still use the sensor readings to make treatment decisions.

Warnings:

- **Do not ignore symptoms that may be due to low or high blood glucose:** If you are experiencing symptoms that are not consistent with your glucose readings, consult your health care professional.
- Use your blood glucose meter to make treatment decisions when your sensor reading doesn't match how you feel or has no number, during the first 12 hours of sensor wear, or if you see the symbol during the first 12 hours of wearing a sensor, if your sensor glucose reading does not match how you feel, or if the reading does not include a numbersymbol. You cannot use sensor values to make treatment decisions during the first 12 hours.
- **Choking hazard:** The sensor contains small parts that may be dangerous if swallowed.

Cautions and Limitations

What to know before using the sensor:

- Review all product information before use.
- Take standard precautions for transmission of blood borne pathogens to avoid contamination.
- Make sure that your devices and sensor kits are kept in a safe place, and maintain your devices under your control during use. This is important to help prevent anyone from accessing or tampering with the sensor.

Who should not use the sensor:

- **Do not use the sensor in people under the age specified in the Indications for Use.** The sensor is not cleared for use in people under this age.
- **Do not use the sensor if you are on dialysis or critically ill.** The sensor is not cleared for use in these groups and it is not known how different conditions or medications common to these populations may affect performance of the sensor.
- Performance of the sensor when used with other implanted medical devices, such as pacemakers, has not been evaluated.

What should you know about wearing a sensor:

- Wash application site on the back of your upper arm using a plain soap, dry, and then clean with an alcohol wipe. This will help remove any oily residue that may prevent the sensor from

sticking properly. Allow site to air dry before proceeding. Carefully preparing the site according to these instructions will help the sensor stay on your body for the full wear duration specified by your sensor insert and help prevent it from falling off early.

- The sensor can be worn for up to the wear duration specified by your sensor insert. Remember to always have your next sensor available before your current one ends so you can keep getting your glucose readings.
- In the event that your sensor stops working and you do not have another sensor readily available, you must use an alternate method to measure your glucose levels and inform your treatment decisions.
- The sensor is designed to detect certain conditions which may occur where the sensor is not working as intended and needs to shut off. When informed of the condition please replace your sensor. This may occur if the sensor gets knocked off from the skin or if the sensor detects that the sensor may not be performing as intended. Contact Customer Service if you receive a replace sensor message before the end of the wear duration.
- Some people may be sensitive to the adhesive that keeps the sensor attached to the skin. If you notice significant skin irritation around or under your sensor, remove the sensor. Contact your health care professional before continuing to use the sensor.
- Intense exercise may cause your sensor to loosen due to sweat or sensor movement. If the sensor gets loose or its tip comes out of your skin, you may get no readings or unreliable low readings. Remove your sensor and apply a new one. Don't attempt to reinsert the old one! Call Customer Service if any sensor gets loose or falls off before the end of your wear time.
- Do not reuse sensors. The sensor and sensor applicator are designed for single use. Reuse may result in no glucose readings and infection. Not suitable for resterilization. Further exposure to irradiation may cause unreliable low results.
- If a sensor breaks inside your body, call your health care professional.

How to store the sensor kit:

- Store the sensor kit between 36 °F and 82 °F. Storage outside of this range may cause inaccurate sensor glucose readings.
- If you suspect that the temperature may exceed 82 °F (for example, in an un-airconditioned home in summer), you should refrigerate your sensor kit. Do not freeze your sensor kit.
- Store your sensor kit in a cool, dry place. Do not store your sensor kit in a parked car on a hot day.
- Store the sensor kit between 10-90% non-condensing humidity.

When not to use the sensor:

- Do NOT use if the sensor kit package or sensor applicator appear to be damaged or if tamper label indicates sensor applicator has already been opened due to risk of no results and/or infection.
- Do NOT use if sensor kit contents are past expiration date.

What to know about the sensor:

- The Instinct sensor is intended for use by a single person. It must not be used by more than one person due to the risk of misinterpreting glucose information.

What to know before you apply the sensor:

- Wash application site on the back of your upper arm using a plain soap, dry, and then clean with an alcohol wipe. This will help remove any oily residue that may prevent the sensor from sticking properly. Allow site to air dry before proceeding. Carefully preparing the site

according to these instructions will help the sensor stay on your body for the full wear duration specified by your sensor insert and help prevent it from falling off early.

- Clean hands prior to sensor handling/insertion to help prevent infection.
- Change the application site for the next sensor application to prevent discomfort or skin irritation.
- Only apply the sensor to the back of the upper arm. If placed in other areas, the sensor may not function properly.
- Select an appropriate sensor site to help the sensor stay attached to the body and prevent discomfort or skin irritation. Avoid areas with scars, moles, stretch marks, or lumps. Select an area of skin that generally stays flat during normal daily activities (no bending or folding). Choose a site that is at least 1 in away from an insulin injection site.

When is Sensor Glucose different from Blood Glucose:

- Physiological differences between the interstitial fluid and capillary blood may result in differences in glucose readings between the sensor and results from a fingerstick test using a blood glucose meter. Differences in glucose readings between interstitial fluid and capillary blood may be observed during times of rapid change in blood glucose, such as after eating, dosing insulin, or exercising.

When to remove the sensor:

- If the sensor is becoming loose or if the sensor tip is coming out of your skin, you may get no readings or unreliable readings, which may not match how you feel. Check to make sure your sensor has not come loose. If it has come loose, remove it, apply a new one, and contact Customer Service.
- If you believe your glucose readings are not correct or don't match how you feel, do a blood glucose test on your finger to check your glucose. If the problem continues, remove the sensor, apply a new one, and call Customer Service.

Interfering Substances

Taking more than 1000 mg of Vitamin C per day may falsely raise your sensor readings, which could cause you to miss a severe low glucose event. Vitamin C can be found in supplements including multivitamins and cold remedies such as Airborne® and Emergen-C®. See your health care professional to understand how long Vitamin C is active in your body.

MRI Safety Information

You can safely have a 1.5T or 3T MRI exam while wearing your sensor, under the conditions provided on the insert that came with your sensor. Refer to the sensor insert for more details. Injury may result if the conditions are not followed. Leave your connected devices outside of the exam room. Sensor readings may be inaccurate during the MRI, but sensor function returns fully back to normal after 1 hour.

Using the Sensor

Sensor Kit

The sensor kit includes:

- Sensor applicator
- Product insert

The sensor (only visible after applied) measures and stores glucose readings when worn on your body. By following the instructions, you use the sensor applicator to apply the sensor on the back

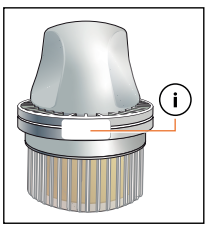
of your upper arm. The sensor has a small, flexible tip that is inserted just under the skin. The sensor can be worn for up to the wear duration specified by your sensor insert.

Note: The sensor applicator is sterile and non-pyrogenic unless opened or damaged. Using a non-sterile or pyrogenic sensor might cause infection.

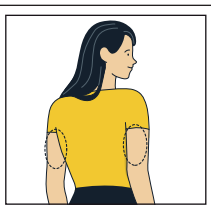
Applying Your Sensor

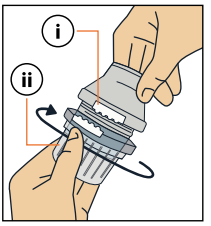
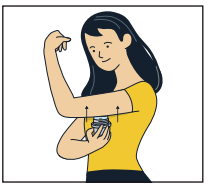
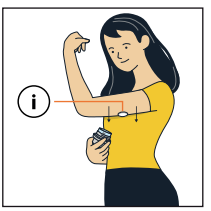
CAUTION: Intense exercise may cause your sensor to loosen due to sweat or sensor movement. If the sensor gets loose or its tip comes out of your skin, you may get no readings or unreliable low readings. Remove your sensor and apply a new one. Don't attempt to reinsert the old one! Call Customer Service if any sensor gets loose or falls off before the end of your wear time.

IMPORTANT: Before using your sensor applicator, make sure you have an alcohol wipe (70% isopropyl alcohol) on hand to prepare the application site. This is not included in the sensor kit.



i - Tamper Label

Step	Action	
1		Apply sensors only on the back of your upper arm. If placed in other areas, the sensor may not function properly and could give you inaccurate readings. Avoid areas with scars, moles, stretch marks, or lumps. Select an area of skin that generally stays flat during your normal daily activities (no bending or folding). Choose a site that is at least 1 in (2.5 cm) away from an insulin injection site. To prevent discomfort or skin irritation, you should select a different site other than the one most recently used.
2		Wash application site using a plain soap, dry, and then clean with an alcohol wipe. This will help remove any oily residue that may prevent the sensor from sticking properly. Allow site to air dry before proceeding. **Note:** The area **MUST** be clean and dry following these instructions, or the sensor may not stay on for the full wear duration specified by your sensor insert.

Step	Action	
3		Unscrew the cap (3ii) from the sensor applicator and set the cap aside. **CAUTION:** • Do NOT use if the sensor kit package or sensor applicator appear to be damaged or tamper label (3i) indicates sensor applicator has already been opened. • Do NOT put cap back on as it may damage the sensor. • Do NOT touch inside sensor applicator as it contains a needle.
4		Place the sensor applicator over the prepared site and push down firmly to apply the sensor to your body. **CAUTION:** Do NOT push down on the sensor applicator until placed over prepared site to prevent unintended results or injury.
5		Gently pull the sensor applicator away from your body. The sensor (5i) should now be attached to your skin. **Note:** Applying the sensor may cause bruising or bleeding. If there is bleeding that does not stop, remove the sensor and contact your health care professional.
6		Make sure the sensor is secure after application. Put the cap back on the sensor applicator. Discard the used sensor applicator according to local regulations.

* Sensor application images © Abbott

Making Treatment Decisions - Getting Started

If you are using the Instinct sensor with a compatible system, follow the instructions that came with that system before making treatment decisions.

Before you start using the sensor for treatment decisions, make sure you have a good understanding of how the sensor works for your body. **Continue to use your blood glucose meter for treatment decisions until you are comfortable with the information you receive from your sensor and ALWAYS follow the instructions provided with your compatible system before using sensor glucose (SG) values for treatment decisions.** This includes understanding that: sensor performance can vary in between sensors, within a sensor wear period (duration specified by your sensor insert), and in different situations. There may be variations between sensors during the first 12 hours after insertion, so pay attention to how each newly inserted sensor is working for you when deciding whether to make treatment decisions based on your sensor readings.

Getting familiar with the sensor could take days, weeks, or even months. The more you check readings from the sensor with a blood glucose meter, the better you will understand how the sensor works for you.

Work with your health care professional to put together a plan for managing your diabetes that includes when to use the sensor information for making treatment decisions.

Helpful Tips

- Confirm your sensor glucose readings with a blood glucose meter until you understand:
  - Sensor accuracy may vary between sensors.
  - Sensor accuracy may vary during a sensor wear session.
  - Sensor accuracy may vary in different situations (meals, exercise, first day of use, etc.).
- Check your glucose often to see how carbs, medication, exercise, illness, or stress levels impact your sensor glucose readings. The information you get can help you figure out why your glucose sometimes goes too high or too low, and how to prevent it from doing so in the future.
- Talk to your health care professional about how your insulin works. The more you understand about your insulin, including how long it takes to start working and how long it lasts in your body, the more likely you will be to make better treatment decisions.
- Making a treatment decision doesn't just mean taking insulin. Treatment decisions can also include things like taking fast-acting carbs, eating, or even doing nothing and checking again later.
- Your health care professional can also help you to understand when doing nothing and checking again later is the right treatment decision. For example, if your glucose is high and going up, your first instinct may be to take more insulin to lower your glucose, however depending on when you last took insulin or your recent activity, the right treatment decision may be to do nothing and check again later. Avoid "insulin stacking".
- Sensor glucose values, which are based on interstitial fluid glucose levels, can be different from blood glucose levels (fingersticks), particularly during times when your blood glucose is changing quickly. If your glucose readings and alarms from the sensor do not match your symptoms or expectations, use a fingerstick blood glucose value from a blood glucose meter to make diabetes treatment decisions

Removing Your Sensor

Step	Action
1	Pull up the edge of the adhesive that keeps your sensor attached to your skin. Slowly peel away from your skin in one motion. **Note:** Any remaining adhesive residue on the skin can be removed with warm soapy water or isopropyl alcohol.
2	Discard the used sensor following directions from your health care professional.

Replacing Your Sensor

Your sensor automatically stops working after the wear duration and must be replaced. You should also replace your sensor if you notice any irritation or discomfort at the application site or if your device reports a problem with the sensor currently in use. Taking action early can keep small problems from turning into larger ones.

CAUTION: If the sensor is becoming loose or if the sensor tip is coming out of your skin, you may get no readings or unreliable readings, which may not match how you feel. Check to make sure your sensor has not come loose. If it has come loose, remove it, apply a new one, and contact Customer Service.

Living With Your Sensor

Activity	What You Need To Know
Bathing, Showering, and Swimming	Your sensor is water-resistant and can be worn while bathing, showering, or swimming. **Note:** Do NOT take your sensor deeper than 3 feet (1 meter) or immerse it longer than 30 minutes in water. Bluetooth®* performance may be impacted if using the sensor while underwater.
Sleeping	Your sensor should not interfere with your sleep. Place your device nearby so you will receive alarms and any reminders you have set.
Traveling by Air	You may use your sensor while on an aircraft, following any requests from the flight crew. **IMPORTANT:** You will not receive alarms or glucose readings while your phone is in airplane mode unless you enable Bluetooth. • Some airport full-body scanners include millimeter radio-wave, which you cannot expose your sensor to. The effect of these scanners has not been evaluated and the exposure may damage the sensor or cause inaccurate results. To avoid removing your sensor, you may request another type of screening. If you do choose to go through a full-body scanner, you must remove your sensor. • The sensor can be exposed to common electrostatic (ESD) and electromagnetic interference (EMI), including airport metal detectors.

Maintenance and Disposal

Maintenance

The sensor has no serviceable parts.

Disposal

This product should be disposed of in accordance with all applicable local regulations related to the disposal of electronic equipment, batteries, sharps, and materials potentially exposed to body fluids.

Contact Customer Service for further information on the appropriate disposal of sensor components.

Problems at the Sensor Application Site

Problem	What It May Mean	What To Do
The sensor is not sticking to your skin.	The site is not free of dirt, oil, hair, or sweat.	1. Remove the sensor. 2. Clean the site with a plain soap and water and then clean with an alcohol wipe.

Problem	What It May Mean	What To Do
		3. Follow the instructions in the Applying Your Sensor section. Consider shaving the site, avoiding use of lotions prior to insertion, and applying the sensor to your non-dominant arm.
Skin irritation at the sensor application site.	Seams or other constrictive clothing or accessories causing friction at the site.	Ensure that nothing rubs on the site.
	You may be sensitive to the adhesive material.	If the irritation is where the adhesive touches skin, contact your health care professional to identify the best solution.

Instinct specifications and performance

Sensor Specifications

Sensor glucose assay method	Amperometric electrochemical sensor
Sensor glucose reading range	40 to 400 mg/dL
Sensor size	2.9 mm height and 21 mm diameter
Sensor weight	1 g
Sensor power source	One silver oxide battery
Sensor data	Up to 15 days
Sensor memory	Up to 15 days (glucose readings stored every 5 minutes)
Sensor transmission range	33 feet (10 m) unobstructed
Operating temperature	50°F to 113°F
Sensor applicator storage temperature	36°F to 82°F
Operating and storage relative humidity	10-90%, non-condensing
Sensor water resistance and ingress protection	IP27: Can withstand immersion into 3 feet (one m) of water for up to 30 min. Protected against insertion of objects > 12 mm diameter.
Operating and storage altitude	-1,250 ft (-381 m) to 10,000 ft (3,048 m)
Radio Frequency	2.402-2.480 GHz BLE; GFSK; 4.6 dBm EIRP

Security Measures and Quality of Service

A receiver is a compatible device, such as an insulin pump or app, that receives data from the sensor.

Security Measures:

The communication between the receiver and sensor during an activation scan is a short range Near Field Communication (NFC) method which makes it difficult to interfere with or intercept during transmission. The communication between the receiver and sensor for glucose data is a standard Bluetooth Low Energy (BLE) connection. Mutual authentication is performed between the receiver and sensor during the pairing process using application certificates, preventing unauthorized devices from connecting to the sensor. The transmitted data is protected by encryption. This prevents unauthorized devices from accessing the data if they are within range and intercept the transmission. Under normal operation, the industry standard BLE protocols allow for many users to be in the same vicinity. In the case where the connection is lost due to

out-of-range or interference, only the authenticated receiver that is paired with the sensor will be able to reconnect and receive glucose data.

Quality of Service (QoS):

QoS for the receiver and sensor wireless communications using NFC (for sensor activation) is assured when the receiver is brought near the sensor. The communication for activation is specified to occur within 15 seconds.

QoS for the app and sensor wireless communication using NFC (for sensor activation) is assured when the phone is touched to the sensor. The communication for activation takes place within 1 second. If the expected response is not received, the phone will continue to retry.

QoS for the receiver and sensor wireless communications using BLE for normal operation (receiving glucose reading and alarms) is assured at regular 5-minute intervals for the pump and 1-minute intervals for the app. If connection is lost between the receiver and sensor for more than 7 minutes for the pump or 12 minutes for the app, the receiver will display dashes "---" on the Home Screen. If connection is lost for 30 minutes, the receiver alerts the user. Lost glucose data will be automatically retrieved when the connection is restored. The receiver is designed to only accept BLE data from recognized and paired sensors. The transmission range for BLE communication is 20 feet for the pump and 33 feet for the app, unobstructed. For the pump, if the pump and sensor are seeing frequent signal loss, ensure they are both on the same side of the body, and try a new position on the body.

SBOM Inquiries

The Sensor Software Bill of Materials (SBOM) is available on request. Please visit www.cybersecurity.abbott for more information.

Instinct Sensor Performance

Overview of Clinical Study

A clinical study was conducted in the United States (US) to evaluate the performance, safety, effectiveness, and precision of the Instinct sensor (sensor). The study enrolled a total of 285 evaluable participants in 7 centers across the United States and included adult (18 years and older) and pediatric (2 to 17 years) participants. There were 149 adult participants, 124 pediatric participants ages 6-17, and 12 pediatric participants ages 2-5. 264 participants had Type 1 diabetes mellitus and 21 participants had Type 2 diabetes mellitus. All subjects required insulin to manage their diabetes.

To measure the precision of the sensor, each subject wore two sensors, one on the back of each upper arm, for a period of up to 15 days. Participants ages 6 and older had their venous blood glucose analyzed using a laboratory reference method, the Yellow Springs Instrument Life Sciences 2300 STAT Plus™ Glucose & Lactate Analyzer (YSI) over up to three separate visits to the clinical center. Sensor glucose readings were then compared to the YSI glucose results to evaluate the sensor's performance.

Clinic sessions took place at the beginning (days 1, 2, and 3), early middle (days 5, 6, and 7), late middle (days 9, 10 and 11) and end (days 13, 14, and 15) of sensor wear. Each visit lasted up to ten hours. During each visit, subjects age 11 and older had their glucose levels deliberately manipulated per the study protocol to raise or lower glucose. This was done to assess sensor performance over the range that the sensor measures glucose (40 – 400 mg/dL). Glucose was not manipulated for participants 10 years and younger. For participants ages 2-5, sensor performance was compared against a self-monitoring blood glucose meter during a 4-hour clinic visit. All participants tested their blood glucose using fingerstick capillary samples at least four times during each day of the study.

Accuracy

Accuracy of the sensor was measured by comparing paired sensor Glucose Measurement (CGM) and YSI blood glucose values. The percentage of total sensor readings that were within 20 mg/dL for YSI blood glucose values < 70 mg/dL or 20% of YSI for blood glucose values ≥ 70 mg/dL is displayed in *Table 1*. The Mean Absolute Relative Difference (MARD) gives an indication of the average percent disagreement between the CGM and the reference. For example, for adult participants, 93.7% of the readings fell within ± 20 mg/dL of YSI blood glucose values < 70 mg/dL and within ± 20% of YSI blood glucose values ≥ 70 mg/dL. For both adult and pediatric participants, the Mean Absolute Relative Difference was 8.2% for the comparison with YSI reference.

Table 1. Overall Accuracy to YSI

Subject Group	Number of CGM-Reference Pairs	Number of Subjects	Percent Within ±20% / ±20 mg/dL	Percent Within ±20% / ±20 mg/dL on Day 1	Percent Within ±20% / ±20 mg/dL in first 12 hours	MARD (%)
Adults	20497	149	93.7	82.9	79.2	8.2
Children (age 6-17)	7025	124	93.5	89.8	90.5	8.2
Children (age 2-5)*	135	10	86.7	78.9	88.9	9.7

* No YSI measurements were obtained for children ages 2-5; results displayed are from CGM-SMBG matched paired measurements obtained during clinic visits from 10 of the 12 subjects. 2 of the 12 subjects did not have CGM-SMBG matched paired measurements obtained from clinic visits.

The accuracy of different CGM glucose ranges versus YSI reference was assessed by calculating the percentage of sensor readings that were within 15%, 20%, and 40% for reference values ≥ 70 mg/dL, and within 15 mg/dL, 20 mg/dL, and 40 mg/dL for values < 70 mg/dL. For blood glucose values < 70 mg/dL, the difference in mg/dL between the CGM and YSI blood glucose values was calculated. For values ≥ 70 mg/dL, the relative difference (%) to the YSI blood glucose values was calculated. The results categorized within CGM glucose ranges are presented in *Table 2* and *Table 3*. The results categorized within YSI glucose ranges are presented in *Table 4* and *Table 5*.

Table 2. Accuracy to YSI within CGM Glucose Ranges (Adult; n=149)

CGM Glucose Level (mg/dL)	Number of CGM-Reference Pairs	Percent Within ±15 mg/dL	Percent Within ±20 mg/dL	Percent Within ±40 mg/dL	Percent Within ±15%	Percent Within ±20%	Percent Within ±40%	Mean bias (mg/dL)	MARD (%)
<54	555	84.3	91.0	98.4				-5.9	14.1
54-69	3157	91.5	95.2	99.1				-3.8	10.0
70-180	8258				82.3	90.2	99.1	-6.0	9.5
181-250	2976				89.9	94.5	99.9	-9.1	7.4
>250	5551				96.5	98.7	100.0	-3.1	5.1

Table 3. Accuracy to YSI within CGM Glucose Ranges (Pediatric*; n=124)

CGM Glucose Level (mg/dL)	Number of CGM-Reference Pairs	Percent Within ±15 mg/dL	Percent Within ±20 mg/dL	Percent Within ±40 mg/dL	Percent Within ±15%	Percent Within ±20%	Percent Within ±40%	Mean bias (mg/dL)	MARD (%)
<54	175	75.4	86.3	97.7				-8.9	15.7
54-69	755	84.5	88.6	97.5				-6.9	11.2
70-180	3074				82.6	90.9	99.6	-8.1	9.2
181-250	1176				92.0	97.4	100.0	-11.2	7.5
>250	1845				98.3	99.8	100.0	-3.5	4.8

* Includes children 6-17 years of age. No YSI measurements were obtained for children 2-5 years of age.

Table 4. Accuracy to YSI within YSI Glucose Ranges (Adult; n=149)

CGM Glucose Level (mg/dL)	Number of CGM-Reference Pairs	Percent Within ±15 mg/dL	Percent Within ±20 mg/dL	Percent Within ±40 mg/dL	Percent Within ±15%	Percent Within ±20%	Percent Within ±40%	Mean bias (mg/dL)	MARD (%)
<54	460	93.9	98.3	100.0				6.7	14.4
54-69	2799	97.6	99.0	99.6				-0.1	8.4
70-180	8386				80.6	89.2	98.9	-5.8	9.8
181-250	2792				89.9	94.6	99.7	-6.3	7.3
>250	6060				94.2	96.8	99.9	-7.5	5.8

Table 5. Accuracy to YSI within YSI Glucose Ranges (Pediatric*; n=124)

CGM Glucose Level (mg/dL)	Number of CGM-Reference Pairs	Percent Within ±15 mg/dL	Percent Within ±20 mg/dL	Percent Within ±40 mg/dL	Percent Within ±15%	Percent Within ±20%	Percent Within ±40%	Mean bias (mg/dL)	MARD (%)
<54	94	100.0	100.0	100.0				4.1	9.7
54-69	599	97.7	99.8	100.0				-2.1	7.6
70-180	3178				79.4	87.9	99.0	-7.8	10.1
181-250	1080				89.8	96.2	99.8	-8.7	7.6
>250	2074				96.5	98.7	99.9	-8.0	5.6

* Includes children 6-17 years of age. No YSI measurements were obtained for children 2-5 years of age.

Agreement with 'LO' and 'HI' CGM Reading against YSI Reference

The sensor reports glucose concentrations between 40 and 400 mg/dL. When the sensor determines that glucose level is below 40 mg/dL, it will report as 'LO'. When the sensor determines that glucose level is above 400 mg/dL, it will report as 'HI'. *Table 6* and *Table 7* display the concurrence between the CGM and YSI reference glucose when CGM reads 'LO'. For example, for adult participants, when CGM reading was 'LO', YSI glucose values were less than 50 mg/dL 100.0% of the time.

Table 6. Concurrence Analysis with 'LO' CGM Reading (Adult; n=149)

CGM-Reference Pairs	YSI (mg/dL)					N
	<50	<60	<70	<80	≥80	
n	1	1	1	1	0	1
Cumulative %	100.0	100.0	100.0	100.0	0.0	

Table 7. Concurrence Analysis with 'LO' CGM Reading (Pediatric*; n=124)

CGM-Reference Pairs	YSI (mg/dL)					N
	<50	<60	<70	<80	≥80	
n	0	3	4	4	0	4
Cumulative %	0	75.0	100.0	100.0	0.0	

* Includes children 6-17 years of age. No YSI measurements were obtained for children 2-5 years of age.

Table 8 and *Table 9* display the concurrence between the CGM and YSI reference glucose when CGM reads 'HI'. For example, for adult participants, when CGM reading was 'HI', YSI glucose values were above 350 mg/dL 98.3% of the time and above 300 mg/dL 100.0% of the time.

Table 8. Concurrence Analysis with 'HI' CGM Reading (Adult; n=149)

CGM-Reference Pairs	YSI (mg/dL)				N
	>350	>300	>250	≤250	
n	119	121	121	0	**121**
Cumulative %	98.3	100.0	100.0	0.0	

Table 9. Concurrence Analysis with 'HI' CGM Reading (Pediatric*; n=124)

CGM-Reference Pairs	YSI (mg/dL)				N
	>350	>300	>250	≤250	
n	49	49	49	0	49
Cumulative %	100.0	100.0	100.0	0.0	

* Includes children 6-17 years of age. No YSI measurements were obtained for children 2-5 years of age.

Concurrence of Sensor and Reference (CGM vs. YSI)

The percentage of concurring glucose values (CGM vs. YSI) in each glucose reference range is presented for each CGM range in *Table 10* and *Table 11* and for each YSI range in *Table 12* and *Table 13*. For example, for adult participants, when the sensor glucose readings were within the 81 to 120 mg/dL range, actual blood glucose values were between 40 and 60 mg/dL 0.2% of the time, between 61 and 80 mg/dL 6.6% of the time, between 81 and 120 mg/dL 71.5% of the time, between 121 and 160 mg/dL 20.4% of the time, between 161 and 200 mg/dL 1.2% of the time, and between 201 and 250 mg/dL 0.1% of the time.

Table 10. Concurrence Analysis by CGM Glucose Level (Adult; n=149)

CGM Glucose Level (mg/dL)	YSI Glucose Level (mg/dL)											N
	<40	40–60	61–80	81–120	121–160	161–200	201–250	251–300	301–350	351–400	>400	
<40†	.	100.0	.	.	.	.	.	.	.	.	.	1
40–60	0.7	53.1	42.1	4.0	0.1	0.1	.	.	.	.	.	1929
61–80	0.0	12.2	68.0	19.0	0.7	.	.	.	.	.	.	3112
81–120	.	0.2	6.6	71.5	20.4	1.2	0.1	.	.	.	.	3338
121–160	.	.	0.1	6.8	72.5	19.2	1.2	0.2	.	.	.	2568
161–200	.	.	.	0.1	9.7	68.2	18.9	3.0	0.1	.	.	1897
201–250	.	.	.	.	0.2	8.6	61.7	27.2	2.4	.	.	2102
251–300	.	.	.	.	.	0.0	6.1	71.5	21.5	0.8	0.1	2818
301–350	.	.	.	.	.	.	0.1	16.4	74.6	8.7	0.3	2100
351–400	.	.	.	.	.	.	0.2	1.3	22.7	70.6	5.2	633
>400	.	.	.	.	.	.	.	.	1.7	60.3	38.0	121

Table 11. Concurrence Analysis by CGM Glucose Level (Pediatric*; n=124)

CGM Glucose Level (mg/dL)	YSI Glucose Level (mg/dL)											N
	<40	40–60	61–80	81–120	121–160	161–200	201–250	251–300	301–350	351–400	>400	
<40†	.	75.0	25.0	.	.	.	.	.	.	.	.	4
40–60	.	46.5	44.5	8.0	1.0	.	.	.	.	.	.	499
61–80	.	6.2	62.4	30.5	1.0	.	.	.	.	.	.	840
81–120	.	0.1	4.1	71.0	24.1	0.7	.	.	.	.	.	1321
121–160	.	.	.	7.2	71.6	21.0	0.2	.	.	.	.	975
161–200	.	.	.	.	9.0	65.1	25.0	0.7	0.1	.	.	680
201–250	.	.	.	.	.	6.1	61.0	31.3	0.6	0.9	.	865
251–300	.	.	.	.	.	.	6.1	75.7	18.1	0.1	.	995
301–350	.	.	.	.	.	.	.	11.2	79.4	9.4	.	607
351–400	.	.	.	.	.	.	.	0.4	24.3	67.1	8.2	243
>400†	.	.	.	.	.	.	.	.	.	34.7	65.3	49

*Includes children 6-17 years of age. No YSI measurements were obtained for children 2-5 years of age.

†Levels out of sensor dynamic range.

Table 12. Concurrence Analysis by YSI Glucose Level (Adult*; n=149)

YSI Glucose Level (mg/dL)	CGM Glucose Level (mg/dL)											N
	<40†	40–60	61–80	81–120	121–160	161–200	201–250	251–300	301–350	351–400	>400†	
<40†	.	92.9	7.1	.	.	.	.	.	.	.	.	14
40–60	0.1	72.5	26.9	0.5	.	.	.	.	.	.	.	1412
61–80	.	25.8	67.2	7.0	0.1	.	.	.	.	.	.	3151
81–120	.	2.4	18.3	73.8	5.4	0.1	.	.	.	.	.	3233
121–160	.	0.0	0.8	24.7	67.6	6.7	0.1	.	.	.	.	2754
161–200	.	0.0	.	2.0	24.6	64.3	9.0	0.0	.	.	.	2011
201–250	.	.	.	0.1	1.7	19.3	69.6	9.2	0.1	0.1	.	1863
251–300	.	.	.	.	0.2	1.9	19.0	67.1	11.5	0.3	.	3001
301–350	.	.	.	.	.	0.0	2.1	25.5	66.1	6.1	0.1	2368
351–400	.	.	.	.	.	.	.	3.2	25.1	61.7	10.1	725
>400	.	.	.	.	.	.	.	2.3	6.9	37.9	52.9	87

†Levels out of sensor dynamic range.

Table 13. Concurrence Analysis by YSI Glucose Level (Pediatric*; n=124)

YSI Glucose Level (mg/dL)	CGM Glucose Level (mg/dL)											N
	<40†	40–60	61–80	81–120	121–160	161–200	201–250	251–300	301–350	351–400	>400†	
<40	.	.	.	.	.	.	.	.	.	.	.	0
40–60	1.0	80.6	18.1	0.3	.	.	.	.	.	.	.	288
61–80	0.1	27.7	65.4	6.7	.	.	.	.	.	.	.	801
81–120	.	3.1	19.6	71.9	5.4	.	.	.	.	.	.	1304
121–160	.	0.5	0.7	29.2	64.0	5.6	.	.	.	.	.	1091
161–200	.	.	.	1.3	28.9	62.4	7.5	.	.	.	.	710
201–250	.	.	.	.	0.3	22.3	69.4	8.0	.	.	.	761
251–300	.	.	.	.	.	0.5	24.7	68.6	6.2	0.1	.	1098
301–350	.	.	.	.	.	0.1	0.7	24.8	66.3	8.1	.	727
351–400	.	.	.	.	.	.	3.3	0.4	23.2	66.3	6.9	246
>400†	.	.	.	.	.	.	.	.	.	38.5	61.5	52

*Includes children 6-17 years of age. No YSI measurements were obtained for children 2-5 years of age.

†Levels out of sensor dynamic range.

Glucose Rate of Change Accuracy

The sensor's glucose rate of change accuracy, as assessed by concurrence analysis, is presented in *Table 14* and *Table 15*. For example, for adult participants, when the sensor glucose trend arrow indicated that glucose was changing slowly downward (-1 to 0 mg/dL/min), actual glucose levels in the body were falling quickly (<-2 mg/dL/min) 1.5% of the time, falling (-2 to -1 mg/dL/min) 7.8% of the time, changing slowly downward (-1 to 0 mg/dL/min) 65.8% of the time, changing slowly upward (0 to 1 mg/dL/min) 21.1% of the time, rising (1 to 2 mg/dL/min) 2.6% of the time, and were rising quickly (>2 mg/dL/min) 1.2% of the time. Digitally connected systems which do not utilize the sensor's trend arrow calculations may see different glucose rate of change accuracy.

Table 14. Concurrence Analysis by Glucose Rate of Change (Adult; n=149)

CGM (mg/dL/min)	YSI (mg/dL/min)						N
	<-2	[-2, -1)	[-1, 0)	[0, 1]	(1, 2]	>2	
<-2 (↓)	31.5	43.1	20.0	3.4	1.0	1.0	295
-2 to -1 ()	11.1	44.5	37.8	5.5	0.8	0.4	841
-1 to 0 (→)	1.5	7.8	65.8	21.1	2.6	1.2	9254
0 to 1 (→)	1.1	4.2	25.5	47.2	15.2	6.7	6905
1 to 2 ()	0.1	2.9	9.9	29.9	36.7	20.6	1577
>2 (↑)	.	1.2	4.8	17.5	32.2	44.3	1038

Table 15. Concurrence Analysis by Glucose Rate of Change (Pediatric*; n=124)

CGM (mg/dL/min)	YSI (mg/dL/min)						N
	<-2	[-2, -1)	[-1, 0)	[0, 1]	(1, 2]	>2	
<-2 (↓)	27.7	53.5	16.8	1.0	1.0	.	101
-2 to -1 ()	8.2	46.8	39.9	3.5	1.1	0.5	376
-1 to 0 (→)	1.1	8.8	66.5	20.5	2.0	1.1	2969
0 to 1 (→)	1.2	3.3	24.6	51.7	13.1	6.2	2344
1 to 2 ()	.	3.2	8.8	30.8	39.9	17.3	571
>2 (↑)	.	2.0	5.4	15.2	32.4	45.1	408

*Includes children 6-17 years of age. No YSI measurements were obtained for children 2-5 years of age.

Alarm Performance

The tables in this section show the accuracy of the sensor's Low and High Glucose Alarms. The Alarm Rate tells you how often the alarm is right or wrong. The Detection Rate tells you how often the sensor is able to recognize and notify you about a low or high glucose event.

Low Glucose Alarm Performance

Table 16 and *Table 17* display the percentages for these parameters:

True Alarm Rate Tells you: When you got a low glucose alarm, were you actually low? Definition: Percentage of time the alarm issued and blood glucose was below the alarm level within 15 minutes before or after the alarm.
False Alarm Rate Tells you: Did you get a low glucose alarm that you shouldn't have? Definition: Percentage of time the alarm issued and blood glucose was not below the alarm level within 15 minutes before or after the alarm.
Detection Rate Tells you: When you were low, did you get a low glucose alarm? Definition: Percentage of time blood glucose was below the alarm level and the alarm issued within 15 minutes before or after the glucose event.
Missed Detection Rate Tells you: When you were low, did you miss a low glucose alarm? Definition: Percentage of time blood glucose was below the alarm level and the alarm didn't issue within 15 minutes before or after the glucose event.

For example, for a Low Glucose alarm level set to 70 mg/dL in the adult population: 84.6% of the time a low glucose alarm was received when blood glucose was indeed below the alarm level but 15.4% of the time a low glucose alarm was received when blood glucose wasn't actually below the alarm level.

95.5% of the time blood glucose was below the alarm level and a low glucose alarm was appropriately issued but 4.5% of the time the glucose event was missed and no alarm was issued.

Table 16. Low Glucose Alarm Performance (Adult; n=149)

Low Glucose Alarm level (mg/dL)	Alarm Rate			Detection Rate		
	Number of Events (n)	True Alarm Rate (%)	False Alarm Rate (%)	Number of Events (n)	Correct Detection Rate (%)	Missed Detection Rate (%)
60	9756	71.1	28.9	1376	84.5	15.5
70	23078	84.6	15.4	3451	95.5	4.5

Table 16. Low Glucose Alarm Performance (Adult; n=149) (continued)

80	33676	90.8	9.2	4655	98.0	2.0
90	42322	92.2	7.8	5525	98.8	1.2

Table 17. Low Glucose Alarm Performance (Pediatric*; n=124)

Low Glucose Alarm level (mg/dL)	Alarm Rate			Detection Rate		
	Number of Events (n)	True Alarm Rate (%)	False Alarm Rate (%)	Number of Events (n)	Correct Detection Rate (%)	Missed Detection Rate (%)
60	2760	58.9	41.1	275	87.6	12.4
70	6138	74.2	25.8	735	98.6	1.4
80	9664	82.8	17.2	1104	98.6	1.4
90	13113	88.3	11.7	1434	99.7	0.3

High Glucose Alarm Performance

Tables 5c and 5d display the percentages for these parameters:

True Alarm Rate Tells you: When you got a high glucose alarm, were you actually high? Definition: Percentage of time the alarm issued and blood glucose was above the alarm level within 15 minutes before or after the alarm.
False Alarm Rate Tells you: Did you get a high glucose alarm that you shouldn't have? Definition: Percentage of time the alarm issued and blood glucose was not above the alarm level within 15 minutes before or after the alarm.
Detection Rate Tells you: When you were high, did you get a high glucose alarm? Definition: Percentage of time blood glucose was above the alarm level and the alarm issued within 15 minutes before or after the glucose event.
Missed Detection Rate Tells you: When you were high, did you miss a high glucose alarm? Definition: Percentage of time blood glucose was above the alarm level and the alarm didn't issue within 15 minutes before or after the glucose event.

For example, for a High Glucose alarm level set to 200 mg/dL in the adult population: 98.5% of the time a high glucose alarm was received when blood glucose was indeed above the alarm level but 1.5% of the time a high glucose alarm was received when blood glucose wasn't actually above the alarm level.

98.0% of the time blood glucose was above the alarm level and a high glucose alarm was appropriately issued but 2.0% of the time the glucose event was missed and no alarm was issued.

Table 18. High Glucose Alarm Performance (Adult; n=149)

High Glucose Alarm level (mg/dL)	Alarm Rate			Detection Rate		
	Number of Events (n)	True Alarm Rate (%)	False Alarm Rate (%)	Number of Events (n)	Correct Detection Rate (%)	Missed Detection Rate (%)
120	96119	99.3	0.7	13212	97.8	2.2
140	83016	99.2	0.8	11728	98.0	2.0
180	61513	98.8	1.2	9337	98.0	2.0
200	53287	98.5	1.5	8388	98.0	2.0
220	45745	98.4	1.6	7615	97.8	2.2
240	38393	98.9	1.1	6902	97.2	2.8
300	16594	94.8	5.2	3369	91.2	8.8

Table 19. High Glucose Alarm Performance (Pediatric*; n=124)

High Glucose Alarm level (mg/dL)	Alarm Rate			Detection Rate		
	Number of Events (n)	True Alarm Rate (%)	False Alarm Rate (%)	Number of Events (n)	Correct Detection Rate (%)	Missed Detection Rate (%)
120	34730	99.4	0.6	4845	97.2	2.8
140	29844	99.2	0.8	4268	97.2	2.8
180	21855	99.0	1.0	3352	97.9	2.1
200	18820	99.2	0.8	3030	97.9	2.1
220	15886	98.8	1.2	2753	96.9	3.1
240	12743	98.4	1.6	2449	96.0	4.0
300	5140	97.5	2.5	1098	92.2	7.8

*Includes children 6-17 years of age. No YSI measurements were obtained for children 2-5 years of age.

Sensor Accuracy Over Time

The Instinct sensor can be worn for up to 15 days. The percentage of sensor readings within YSI values and the Mean Absolute Relative Difference (MARD) is presented for the following different wear periods in *Table 20* and *Table 21*: Beginning (Adult: 105 Subjects, Day 1, 2, or 3; Pediatric: 57 Subjects, Day 1, 2, or 3), Early Middle (Adult: 94 Subjects, Day 5, 6, or 7; Pediatric: 51 Subjects, Day 5, 6, or 7), Late Middle (Adult: 90 Subjects, Day 9, 10, or 11; Pediatric: 35 Subjects, Day 9, 10, or 11), and End (Adult: 95 Subjects, Day 13, 14, or 15; Pediatric: 33 Subjects, Day 13, 14, or 15). For values 70 mg/dL and above, the percentage of readings within 15%, 20%, and 40% of the YSI value was calculated. For values below 70 mg/dL, the percentage of readings within 15 mg/dL, 20 mg/dL, and 40 mg/dL of the YSI value was calculated.

Table 20. Sensor Accuracy Relative to YSI over the wear duration (Adult; n=149)

Wear Period	Number of CGM-reference pairs	MARD (%)	Within ±15% / ±15 mg/dL	Within ±20% / ±120	Within ±40% / ±140
Beginning (days 1-3)	5410	10.0	83.0	89.7	99.1
Early Middle (days 5-7)	5043	7.2	91.6	96.1	99.8
Late Middle (days 9-11)	5142	7.7	89.9	94.8	99.3
End (days 13-15)	4902	7.8	90.0	94.5	99.6

Table 21. Sensor Accuracy Relative to YSI over the wear duration (Pediatric*; n=124)

Wear Period	Number of CGM-reference pairs	MARD (%)	Within ±15% / ±15 mg/dL	Within ±20% / ±120	Within ±40% / ±140
Beginning (days 1-3)	2634	9.0	84.0	91.0	99.5
Early Middle (days 5-7)	2277	6.9	92.3	97.3	99.9
Late Middle (days 9-11)	1209	6.9	92.3	96.9	99.8
End (days 13-15)	905	10.4	82.1	87.0	97.9

*Includes children 6-17 years of age. No YSI measurements were obtained for children 2-5 years of age.

Sensor Wear Duration

The Instinct sensor can be worn for up to 15 days. To estimate how long a sensor will work over the wear duration, 151 sensors were evaluated in the adult population and 142 sensors were evaluated in the pediatric population to determine how many days of readings each sensor provided. Subjects wore two sensors simultaneously. Some sensors were excluded from the survival analysis due to reasons not related to the device (e.g., subject dropped out of study or physical factors such as accidental knocking off the sensor etc.). Of the 151 sensors in the adult population, 83.1% lasted until the final day of use. 4 sensors (2.6%) had "early sensor shut-off" where the sensor algorithm detected that the sensors did not function as intended and presented the user with a Replace Sensor message. In the pediatric population, 76.8% of the sensors lasted until the final day of use. 3 sensors (2.1%) had "early sensor shut-off" where the sensor algorithm detected that the sensors did not function as intended and presented the user with a Replace Sensor message. *Table 22* and *Table 23* display the data for each day in the wear duration for the adult and pediatric populations.

Another clinical study was also conducted to further evaluate wear duration in subjects who wore only a single sensor. Of the 39 sensors evaluated in this study, 94.9% lasted until the final day of use.

Table 22. Sensor Survival Rate Over Wear Duration (Adult; n=151)

Day of Wear	Number of Sensors	Survival Rate (%)
1	150	100.0
2	150	100.0
3	149	99.3
4	147	98.7
5	142	96.0
6	139	95.3
7	138	95.3
8	131	92.5
9	129	91.1
10	127	90.4
11	125	88.9
12	122	87.5
13	118	85.3
14	111	83.1
15	105	83.1

Table 23. Sensor Survival Rate Over Wear Duration (Pediatric; n=142)

Day of Wear	Number of Sensors	Survival Rate (%)
1	141	100.0
2	140	99.3
3	140	99.3
4	136	96.5
5	134	95.0
6	131	93.6
7	129	92.9
8	126	90.7
9	123	90.0
10	119	89.3

Table 23. Sensor Survival Rate Over Wear Duration (Pediatric; n=142) (continued)

Day of Wear	Number of Sensors	Survival Rate (%)
11	115	87.7
12	111	85.4
13	102	79.3
14	97	77.7
15	85	76.8

Glucose Reading Availability

The sensor is designed to log a glucose reading every minute throughout the wear period after the start-up time. *Table 24* and *Table 25* show the glucose reading capture rate for each day of the wear duration.

Table 24. Glucose Reading Capture Rate Over Wear Duration (Adult; n=150)

Day of Wear	Number of Sensors	Capture Rate (%)
1	146	96.4
2	146	97.4
3	146	97.7
4	142	97.8
5	143	97.9
6	141	97.9
7	136	98.1
8	135	98.1
9	130	98.2
10	127	98.3
11	125	98.2
12	123	98.2
13	118	98.2
14	116	98.2
15	111	98.3

Table 25. Glucose Reading Capture Rate Over Wear Duration (Pediatric; n=142)

Day of Wear	Number of Sensors	Capture Rate (%)
1	141	96.9
2	138	96.5
3	135	97.1
4	137	96.6
5	137	96.9
6	129	96.9
7	127	97.0
8	122	96.8
9	118	96.6
10	118	96.6
11	112	96.5
12	111	96.4
13	109	96.3

Table 25. Glucose Reading Capture Rate Over Wear Duration (Pediatric; n=142) (continued)

Day of Wear	Number of Sensors	Capture Rate (%)
14	101	96.3
15	101	96.1

Precision

Precision of the sensor was evaluated by comparing the results from two separate sensors worn on the same subject at the same time. *Table 26* provides data from 148 adult participants and 136 pediatric participants. For adults, the paired absolute relative difference (PARD) between the two sensors was 8.0% with coefficient of variation (CV) of 5.6%. For children ages 6-17, PARD was 8.6% with CV of 6.1%. For children ages 2-5, PARD was 6.5% with CV of 4.6%. Paired absolute difference (PAD) is a measurement of absolute difference (in mg/dL) between paired CGM readings, while PARD is the absolute relative difference (in %) between paired CGM readings.

Table 26. Overall between Sensor Precision

	Coefficient of Variation (%)	Paired Absolute Difference (mg/dL)	Paired Absolute Relative Difference (%)	Number of Paired Readings
Adults ages 18+	5.6	12.3	8.0	25029
Children ages 6-17	6.1	13.8	8.6	10945
Children ages 2-5	4.6	10.5	6.5	428

Adverse Events

No device related serious adverse events occurred during the study. Mild skin irritations, such as erythema (16 instances), bruising (3 instances), and rash (3 instances) were reported around the insertion site and adhesive area by a small number of subjects (14 out of 293 or 4.8%).

Vitamin C Interference

Taking more than 1000 mg of vitamin C per day may falsely raise your sensor readings, which could cause you to miss a severe low glucose event. Vitamin C can be found in supplements including multivitamins and cold remedies such as Airborne® and Emergen-C®. See your health care professional to understand how long vitamin C is active in your body.

Additional notes for health care professionals

While using the Instinct sensor, ascorbic acid (vitamin C) doses of larger than 500 mg per day can affect the sensor readings, making them look higher than they really are. While using the Instinct sensor, users can take up to 1000 mg of ascorbic acid per day and can still use the sensor readings to make treatment decisions.

A clinical study was conducted to evaluate the effect of ascorbic acid on the performance of the Instinct sensor. Data from 60 adult subjects with diabetes was collected over a 13-hour period. Each subject had a one-hour baseline phase where venous blood was collected every 10 minutes. After this first hour, a dose of 1000 mg ascorbic acid was given with a meal and venous samples were collected every 15 minutes for the next 12 hours. A maximum average sensor bias of +5.1 mg/dL was observed around 2 hours after the 1000 mg ascorbic acid dose. Subjects then received a second dose of 1000 mg ascorbic acid with a meal and the same process was continued for another 4 hours. A third dose of 1000 mg ascorbic acid was then given, and study subjects were followed for 4 more hours. After the second dose of ascorbic acid the maximum average sensor bias increased, with minimal change in sensor bias after the third dose, suggesting that saturation had occurred by the second 1000 mg dose of ascorbic acid. The maximum average sensor bias after the three 1000 mg doses of ascorbic acid was +9.2 mg/dL.

Safety

Device related adverse events were limited to pain or bruising at the sensor insertion site.

Electromagnetic Compatibility (EMC)

Instinct Sensor - FCC ID: QX5-LIB03S

- The sensor needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual.
- Portable and mobile RF communications equipment can affect the sensor.
- Use of accessories, transducers, and cables other than those specified or provided by Medtronic could result in increased electromagnetic emissions or decreased electromagnetic immunity of the sensor and result in improper operation.
- The sensor should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the sensor should be observed to verify normal operation in the configuration in which it will be used.
- The device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) The device may not cause harmful interference, and (2) the device must accept any interference received, including interference that may cause undesired operation.
- Changes or modifications not approved by Medtronic could void the user's authority to operate the equipment.

Guidance and manufacturer's declaration - electromagnetic emissions

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The sensor uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The sensor is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.

Guidance and manufacturer's declaration - electromagnetic immunity

The sensor is intended for use in the electromagnetic environment specified below. The customer or the user of the sensor should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthet-

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
			ic material, the relative humidity should be at least 30%.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical domestic, commercial, or hospital environment.
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 in) to any part of the sensor, including cables specified by Medtronic. Otherwise degradation of the performance of the sensor could result.
Proximity fields from RF wireless communications equipment IEC 61000-4-3	See table on next page	Compliance to the tested levels	

The table below lists the immunity levels at specific test frequencies for testing the effects of some wireless communications equipment. The frequencies and services listed in the table are representative examples in various locations where the sensor may be used.

Test frequency (MHz)	Band[a] (MHz)	Service[a]	Modulation[b]	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380-390	TETRA 400	Pulse modulation[b] 18 Hz	1.8	0.3	27
450	430-470	GMRS 460, FRS 460	FM[c] ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704-787	LTE Band 13, 17	Pulse modulation[b] 217 Hz	0.2	0.3	9
745						
780						

Test frequency (MHz)	Band[a] (MHz)	Service[a]	Modulation[b]	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation[b] 18 Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation[b] 217 Hz	2	0.3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation[b] 217 Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation[b] 217 Hz	0.2	0.3	9
5500						
5785						

[a] For some services, only the uplink frequencies are included.

[b] The carrier is modulated using a 50% duty cycle square wave signal.

[c] As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

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