action is taken to clear the signal until the next beep and vibration cycle, the beep and vibration will reoccur.

Category	Cause	Beep Rate
Alarm: HIGH PRIORITY	Drug delivery / equipment or supply failure / general	10 beeps in 3 sec
Alert: MEDIUM PRIORITY	Drug delivery / equipment or supply failure / general	3 beeps in 4 sec
Alert: LOW PRIORITY	Any	2 beeps in 17 sec
Reminder: NO PRIORITY	NA	User defined

NOTE: The loudness of Alarms and Alerts can be changed in Sound and Vibration in the Settings menu. The type of Reminder you prefer and the ability to silence it can also be changed in this setting. (See page 107 for volume and silencing.)

For more details on the tone and alarm signals, please refer to Appendix.

6.2.1 The range of signal limits provided by manufacturers

The range of alarm limits provided by manufacturers:

Alerts	Parameters	Lower Limit	Upper Limit	Increments	Default
Auto-off advisory	Time	1hr	24hr	1hr	Off
Low reservoir	Insulin remaining	10U	50U	5U	10U
Patch expiration notification	Warranty	1hr	24hr	1hr	4hr

To ensure safe use of the device, check if the LEDs, Speaker, and Motor are properly working every time you replace the Patch.

WARNINGS:

- If you do not respond to an alert, it may be upgraded to an alarm. In some situations, this action may suspend insulin delivery and cause hyperglycemia, DKA or death.
- If the audible alarm is set too low, you may not hear it in all environments. If you do not respond to an alarm, it may lead to suspension of insulin delivery and cause hyperglycemia, DKA or death.

6.3 Alarm descriptions

6.3.1 High Risk Alarms

Alarm	Source	Priority / Repeat Interval	Recommended User Action
Auto-Off **Insulin delivery has stopped.** **Touch 'Resume' to restart the insulin delivery.**	Patch and ADM	High priority Repeats continuously	This Alarm occurs when the ADM does not receive a patch status within 15 minutes after auto-off advisory Alert. Insulin delivery has stopped. Touch 'Confirm' to interact with Patch and resume insulin delivery. Check blood glucose.
Empty Reservoir **Patch has been deactivated and insulin delivery stopped.** **Change Patch now.**	Patch and ADM	High priority Repeats continuously	This Alarm occurs when the Patch's reservoir is out of insulin. Touch 'Confirm' to clear the Alarm. Change Patch. Check blood glucose.
Patch Error **Patch has been deactivated and insulin delivery stopped.** **Change Patch now.** **Call customer care.**	Patch and ADM	High priority Repeats continuously	This Alarm occurs when the Patch detects an unexpected Error. Touch 'Confirm' to clear the Alarm. Change Patch. Check blood glucose. Customer care immediately.
Inappropriate Temperature **Insulin delivery or 'Activate Patch' process stopped.** **Avoid extreme temperature now.**	Patch and ADM	High priority Repeats continuously	Touch 'Confirm' to clear the Alarm. Bring Patch back to normal operating temperature (4.4~37℃) before filling it with insulin or using Patch.
Needle Insertion Error **Check lever position and then touch 'Retry'.**	Patch and ADM	High priority Repeats continuously	This Alarm occurs when the Patch detects an Error in inserting the cannula during Patch activation process. Touch 'Confirm' to clear the Alarm. Change Patch.
Fill Error **Patch has been deactivated and insulin delivery stopped.** **Change Patch now.**	Patch and ADM	High priority Repeats continuously	This Alarm occurs when the Patch detects an Error during filling the reservoir. Touch 'Confirm' to clear the Alarm. Change Patch. Check blood glucose.
Patch Battery Error **Patch has been deactivated and insulin delivery stopped.** **Change Patch now.**	Patch and ADM	High priority Repeats continuously	This Alarm occurs when the Patch is about to shut down. Touch 'Confirm' to clear the Alarm. Remove Patch.

Activation Error **'Activate Patch' process has expired. Touch 'Confirm' to deactivate current Patch. Change Patch now.**	**Patch and ADM**	**High priority** **Repeats continuously**	**This Alarm occurs when you do not complete 'Activate Patch' process within 60 minutes after Patch wake-up. Touch 'Confirm' to clear the Alarm. Change Patch. Check blood glucose.**
Clock Reset **Date and time have been reset. Set the date and time.**	ADM	High priority Repeats continuously	This Alarm occurs when date and time settings of ADM is reset. Touch 'Confirm' to clear the Alarm. Set the date and time.
ADM Memory Corruption **Patch has been deactivated and insulin delivery stopped. Change Patch now.** **Touch 'Confirm' to reset ADM and delete all user settings except history records.**	Patch and ADM	High priority Repeats continuously	This Alarm occurs after the ADM is reset and a memory corruption Error occurs. Touch 'Confirm' to clear the Alarm. Change Patch. Check blood glucose. Call Customer Service immediately.

Cautions:

- If you receive more than one alarm, alert or reminder at the same time, the one with the highest priority will be generated first.
- When the ADM screen is off, the alarms, alerts and reminders will signal, and the corresponding message will appear after unlocking the screen.
- Clear any active alarms, alerts and reminders in the screen in which they appear before accessing the Home screen.
- Each time you replace a Patch, check to make sure the LED, speaker and mother are working properly through the EOPATCH diag and reset in the Advanced Settings menu.

6.3.2 Medium to Low Risk Alerts

Alert	Source	Priority / Repeat Interval	Recommended of User Action

End of Insulin Suspend Touch 'Resume' to restart the insulin delivery.	Patch and ADM	Medium priority Repeats every minute until insulin delivery is resumed.	Touch 'Resume' to resume insulin delivery at programmed basal rate. (Warning) Insulin delivery will not resume until you Touch 'Resume'. If you do not Touch 'Resume' to resume insulin delivery, you could develop hyperglycemia (high blood glucose)
Auto-Off Advisory Move ADM closer to Patch. Touch 'Confirm' to interact with Patch. Auto-off advisory will escalate to an Alarm if ignored and insulin delivery will stop.	Patch and ADM	Medium priority Repeats every minute for 15 minutes. Escalates to 'Auto-off' Alarm if not cleared within 15 minutes.	This Alert occurs when the ADM does not receive a patch status within a predefined period of time. Touch 'Confirm' to interact with Patch after moving ADM close to Patch. (Warning) The Auto-off advisory will escalate to an Alarm if ignored and will stop delivering insulin. Be sure to respond to the Alert when it occurs.
Low Reservoir Replace Patch soon.	Patch and ADM	Medium priority ADM: Repeats every 3 minutes until cleared. Patch: Repeats 4 times(0, 3, 6, 9min) with 3 mins interval every 1 hr. Escalates to 'Empty reservoir' Alarm when empty.	Touch 'Confirm' to clear the Alert. (Warning) The Low reservoir Alert will escalate to an empty reservoir Alarm when insulin is depleted. Be sure to respond to the Alert when it first occurs.
Patch Expiration Notification Be ready to change Patch.	Patch and ADM	Low priority ADM: Repeats every 5 minutes until cleared. Patch: Repeats 4 times (0, 5, 10, 15min) with 5 mins interval every 1 hr.	This Alert occurs when Patch has reached the time set to be notified before it expires. Touch 'Confirm' to clear the Alert. Be ready to change Patch.
Patch Operating Life Expired Change Patch now.	Patch and ADM	Low priority ADM: Repeats every 5 minutes until cleared. Patch: Repeats 4 times (0, 5, 10, 15min) with 5 mins interval every 1 hr.	This Alert occurs when Patch has expired. Touch 'Confirm' to clear the Alert. Change Patch.
Patch will expire soon Change Patch now.	Patch and ADM	Low priority Repeats every 3 minutes during the last hour of Patch's life until cleared and is independent of 'Patch expiration' Alert set by user.	This Alert occurs one hour before Patch has reached the end of its service time. Touch 'Confirm' to clear the Alert. Change Patch.

		Escalates to 'Patch service time expired' Alarm.	
ADM Overheating Check ADM and avoid inappropriate temperature now.	ADM	Low priority Repeats every 5 minutes until cleared.	Touch 'Confirm' to clear the Alert. Bring ADM back to normal operating temperature (4.4℃ ~ 40℃).
ADM Battery Empty Charge ADM now.	ADM	Medium priority Repeats every 3 minutes until cleared.	This Alert occurs when ADM is about to shut down. Touch 'Confirm' to clear the Alert. Charge your ADM now.
ADM Battery Low Charge ADM now.	ADM	Low priority Repeats every 5 minutes until cleared.	This Alert occurs when ADM has low power. Touch 'Confirm' to clear the Alert. Charge your ADM now.
Incomplete Patch Activation Complete 'Activate Patch' process.	ADM	Medium priority Repeats every 3 minutes for 60 minutes. Escalates to 'Invalid Patch activation' Alarm if not cleared within 60 minutes.	Touch 'Confirm' to clear the Alert. Complete Patch activate process. (Warning) The Incomplete Patch activation Alert will escalate to an Alarm if ignored and will result in the deactivation of your active Patch. Be sure to respond to the Alert when it occurs.
Patch Battery Low Be ready to change Patch.	Patch and ADM	Medium priority Repeats every 3 minutes until cleared.	This Alert occurs when the Patch battery is low. Touch 'Confirm' to clear the Alert. Be ready to change Patch.

6.3.3 Reminders

Reminder	Source	Priority, repeat interval	Recommendation of User Action
BG Check blood glucose.	ADM	No priority Repeats every 15 minutes until cleared.	Touch 'Confirm' to clear the Reminder. Check blood glucose.
Missed Meal Bolus Please deliver a bolus for __:__ ~ __:__ if necessary.	ADM	No priority Repeats every 15 minutes until cleared.	Touch 'Confirm' to clear the Reminder. Check meal bolus delivery.
_____(User defined name) __:__ (time set).	ADM	No priority Repeats every 15 minutes until cleared.	Touch 'Confirm' to clear the Reminder. Check custom Reminders.

No Active Patch Activate a new Patch now?	ADM	No priority Repeats every 15 minutes until new Patch is activated or Reminder is cleared.	Touch 'Confirm' to clear the Reminder. Start a new Patch.
Previous BG Low Check blood glucose. Low BG was entered ____ min(s) ago.	ADM	No priority Repeats every 15 minutes until cleared.	Touch 'Confirm' to clear the Reminder. Check blood glucose.
Check Patch Check infusion site and ensure cannula is properly inserted. Check blood glucose.	ADM	No priority. Repeats every 15 minutes until cleared.	Touch 'Confirm' to clear the Reminder. Check blood glucose.

7 DIABETES MANAGEMENT AND TROUBLESHOOTING

This section will discuss the practical use of an insulin pump as compared to injection therapy. It will review the similarities and differences between insulin pump therapy and injection therapies and point out how an insulin pump affects diabetes management.

7.1 The Difference

Insulin pumps deliver insulin very similar to the way the human pancreas delivers insulin and uses a type of insulin that is very similar to the insulin made by the pancreas.

The pancreas delivers a basal rate of insulin based on a person's individual need for insulin and then delivers boluses for the rise of blood glucose in the carbohydrate content of ingested food. This is very similar to the way an insulin pump delivers insulin.

The goal of injection therapy is to simulate the pancreatic delivery of insulin. The only difference in taking an injection for a bolus or delivering it through an insulin pump is that the pump can accurately divide the dose smaller than with a syringe. In both insulin pump therapy and injection therapy, rapid-acting insulin is used for boluses.

The biggest difference in insulin pump therapy and injection therapy is in the basal delivery. Insulin pumps deliver rapid-acting insulin approximately every 10 minutes at various rates based on your need for insulin at that time of day. This is the way the human pancreas delivers insulin. In injection therapy, the person takes a type of insulin that is longer-acting, and the rate cannot be adjusted like it can in insulin pump therapy. This adjustable basal rate is the biggest difference in insulin pump therapy and injection therapy. Research shows that hypoglycemia occurs less with insulin pump therapy than with injection therapy because of this ability to match the pump's delivery of insulin to the user's need for insulin.[5]

Another difference between the two is flexibility. Since you are using an insulin pump, you have the advantage of decreasing your basal rate for sports or other blood-glucose-lowering activity whereas a person who has already taken an injection of long-acting insulin does not have that advantage.

Still another difference is the ability to extend a food bolus since high-fat foods often need insulin throughout a longer period of time.

Lastly, since insulin pumps use only rapid-acting insulin, if you are not receiving insulin from the pump because of an occlusion or other insulin pump delivery issue, you are more prone to hyperglycemia than with injection therapy because you have no long-acting insulin to keep your blood glucose from rising. This is one disadvantage of insulin pump therapy and is why you must be willing to monitor your blood glucose frequently when using an insulin pump.

Did you know: Adjusting your basal program for optimal blood glucose control takes time but is well worth the effort. Your healthcare provider or insulin pump trainer can help you reach this goal. (See page 20 for adjusting basal rate.)

7.2 Counting Carbohydrate and Other Nutrients

One of the advantages of insulin pump therapy is it allows flexibility in meal timing and food choices. Once your basal insulin is adjusted to keep your blood glucose steady throughout the day

and night, you'll be able to decide when and what to eat instead of your insulin dictating that for you. And, by understanding how the nutrients in the food you eat affect your body, you will be able to take boluses that keep your blood glucose within your target range.

Carbohydrate have the greatest impact on blood glucose, especially within the first few hours after eating. Eating food with a high fat content can slow down the absorption of the carbohydrate and protein has the least impact on blood glucose. In addition, food with a high fiber content can you're your blood glucose from rising as much after a meal.

Since the ADM has a Food Library, understanding the nutritional content of the food you eat is simplified, but it is still important to understand the basics of carbohydrate counting and how to read a nutritional label.

7.2.1 Food Containing Carbohydrate

- Starches: bread, rice, pasta, cereal, muffins, cookies, and other pancakes, waffles, etc.
- Starchy vegetables: potatoes, beans, peas, lentils, corn. etc.
- Fruit and Fruit Juices
- Milk and Milk Products: yogurt, ice cream, pudding, etc.
- Candies and Food with Sugar

7.2.2 Nutrition Facts Label

The most important parts of Nutrition Facts label are the Serving Size and Total Carbohydrate. The label below on shows that the Serving Size is 1 cup and the Total Carbohydrate is 15 grams. What this tells you is that every cup you eat of this food contains 15 grams of carbohydrate.

If your insulin-to-carbohydrate ratio is 1 unit of insulin for every 10 grams of carbohydrate, then you would need 1.5 units of insulin for 1 cup of this food. Of course, the bolus calculator in the ADM will do the match for you.

If you are eating a food that is not in the Food Library of the ADM, you can look at the serving size on a package and use that information in the ADM. Always remember to consider how many servings you are going to eat before entering the carbohydrate in the ADM.

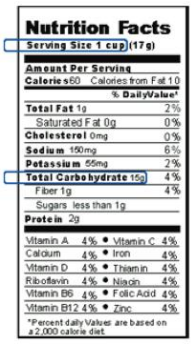


Figure 7-7-1 - Nutrition label

7.2.3 ADM Food Library

The Food Library in the ADM makes it easy to see nutritional content for 12,000 foods and to copy

the nutritional content to be saved for programming a bolus for that food. The nutrition information from the ADM Food Library for milk is displayed below. The label below on shows that the Serving Size is 1 cup and the Total Carbohydrate is 14 grams. What this tells you is that every cup you drink of milk contains 14 grams of carbohydrate. (See page 119 for instructions on using the food library.)

If your insulin-to-carbohydrate ratio is 1 unit of insulin for every 10 grams of carbohydrate, then you would need 1.4 units of insulin for 1 cup of this food. Notice that you can copy this nutrition information to Carb presets so that you can access it in the future.

7.2.4 Other Nutrients that Affect Blood Glucose

The other two nutrients that affect blood glucose are fat and fiber.

Fat
The effect of fat on blood glucose is that it may slow down the absorption of the carbohydrate in a meal. This affect is dependent on the type and amount of fat you eat. For example, many people find that fried foods slow down the absorption of the carbohydrate in the meal. Also, the fat in pizza has such a great impact on blood glucose that an extended bolus for pizza is often called a "pizza bolus".

Usually the impact of fat on blood glucose is that the reading is low after eating a meal and high 3 to 6 hours after the meal. The extended bolus feature in the ADM is perfect for blousing for high-fat meals.

Fiber
The effect of a large amount of fiber on blood glucose is that the insoluble fiber may help you better digest the carbohydrate in a meal so that you need less insulin for that meal. If you notice that your blood glucose is low after eating a high-fiber food, you'll know that you need less insulin for that food. Some people subtract the insoluble fiber content of the food from the carbohydrate for the food, Again, this takes trial and error to determine what works for you.

7.3 Exercise & Sports

Insulin pump therapy allows you to set a temporary basal rate for activity that typically lowers your blood glucose. Determining what rate to use for what activity and how much advance time is needed takes trial and error but is far superior to having to eat carbohydrate to offset exercise with injection therapy. (See page 65 for instructions on setting a temporary basal rate.)

> **WARNING:** Always have a source for fast-acting carbohydrate available during exercise and sports in the event of exercise-induced hypoglycemia.

7.4 Hypoglycemia

Low blood glucose may occur with insulin pump therapy for the same reasons as it occurs with injection therapy:

- Too much insulin
- Not enough food
- More exercise than usual
- Consumption of alcoholic beverages

7.4.1 Symptoms of Hypoglycemia

- Blood glucose result under 70 mg/dL.
- Feeling shaky
- Sweating, chills and clamminess
- Confusion
- Fast heartbeat
- Feeling lightheaded or dizzy
- Sudden Hunger
- Nausea
- Color draining from the skin (pallor)
- Feeling Sleepy
- Feeling weak or having no energy
- Blurred/impaired vision
- Tingling or numbness in the lips, tongue, or cheeks
- Anxiety Headaches
- Nightmares or crying out during sleep
- Seizures

Low blood glucose is not always avoidable. The goal of treating hypoglycemia is to bring your blood glucose into a healthy range. You need to be prepared to treat low blood glucose before it becomes a medical emergency. Since low blood glucose may occur any place and any time, it is important to always have treatment with you and treat blood glucose results under 70 mg/dL.

7.4.2 Hypoglycemia Protocol – The Rule of 15

- Eat 15 gram of fast-acting carbohydrate
- Check blood glucose in 15 minutes
- If blood glucose is not above 70 mg/dL, eat another 15 grams of fast-acting carbohydrate
- Repeat every 15 minutes until blood glucose is above 70 mg/dL.

Fast-acting carbohydrate:

- Glucose tablets (see instructions on container)
- Glucose get (see instructions on container)
- 4 ounces (1/2 cup) of juice or soda (not diet)
- 8 ounces (1 cup) milk
- Candy without chocolate. Chocolate should not be used to treat low blood glucose because it contains fat which slows down the absorption of carbohydrate.
- Glucagon emergency kit in case of severe hypoglycemia

Some people with diabetes feel when their blood glucose is low, and others do not. Not knowing when blood glucose is low is called hypoglycemia unawareness. If you are not aware of hypoglycemia, it is important to test your blood glucose more often or use a continuous glucose monitor that alerts you when your blood glucose is low or is rapidly dropping. It is also important to have a Glucagon kit and to instruct someone on its use.

WARNINGS:

- If you have hypoglycemia unawareness, consider using the ADM's Blood Glucose Reminders to check your blood glucose regularly. (See page 86 for blood glucose reminders.)
- Keep a Glucagon kit with you and teach people who are close to you how to use it in the event you become unconscious from hypoglycemia.
- If you have symptoms of hypoglycemia but can't test your blood glucose, treat the symptoms without testing.
- Test your blood glucose before driving and don't drive if your blood glucose result is not 100 mg/dL or higher.
- Untreated hypoglycemia can cause seizure, stroke, heart failure and death.

7.5 Hyperglycemia and DKA

High blood glucose may occur while using while using an insulin pump for the same reasons it occurs with injection therapy including some situations that are unique to insulin pump therapy.

Similar to injection therapy

- Too much food
- Not enough insulin
- Less activity than usual
- Loss of insulin potency
- Not receiving enough or any insulin

Unique to insulin pump therapy

- Occlusion
- Dislodged cannula

WARNINGS:

- A blockage in the Patch can occur. This is called an **occlusion.** If the occlusion causes the Patch to deliver NO insulin, you will receive an alarm; however, if a partial occlusion occurs, the Patch MAY or MAY NOT alarm. Therefore, anytime you have a high blood glucose result that does not resolve with a correction bolus, you MUST deactivate the current Patch and activate a new Patch. If you do not have a Patch, you should switch to injections until you can activate a new Patch. Be prepared for thus possibility by discussing it in advance. with your healthcare provider or insulin pump trainer.
- The cannula may become dislodged from your skin. If this occurs, the Patch will continue to deliver insulin and will NOT alarm. Therefore, anytime you have a high blood glucose result d oes not resolve with a correction bolus, you MUST deactivate the current Patch and activate a new Patch. If you do not have a Patch, you should switch to injections until you can activat e a new Patch. Be prepared for thus possibility by discussing it in advance. with your healthcare provider or insulin pump trainer.

7.5.1 Symptoms of Hyperglycemia

- Blood glucose result over 250 mg/dL
- Increased urination
- Trouble concentrating
- Blurred vision
- Fatigue

7.5.2 Symptoms of DKA (Diabetic Ketoacidosis)

- Sustained blood glucose over 250 mg/dL
- Exhaustion
- Breath smells fruity
- Nausea
- Vomiting
- Rapid pulse
- Difficulty breathing

The goal of treating hyperglycemia is to prevent Diabetic Ketoacidosis (DKA) a life-threatening condition produced by high blood glucose and ketones in the urine and blood. Since an insulin pump delvers only rapid-acting insulin, hyperglycemia and DKA can occur from not getting insulin from the pump due to the pump being dislodged from the body or not pumping insulin properly due to an occlusion.

7.5.3 Hyperglycemia & DKA Protocol

- Immediately take a correction bolus
- Test blood glucose every 2 hours or use a continuous glucose monitor
- Test ketones every 2 hours
- If the second blood glucose reading is not lower than the 1st, discard the Patch
- Take a correction injection with a syringe; not through the Patch
- Activate a new Patch
- Drink sugar-free liquid every 30 minutes
- Continue to test blood glucose every 2 hours and continue to take a correction injection with a syringe: not through the Patch, until blood glucose reaches target
- Test ketones and call healthcare provider if ketones are moderate or large, if blood glucose remains elevated or if you are unable to drink

WARNINGS:

- An occlusion (full or partial high blood glucose. (Since the Patch only delivers rapid-acting insulin, hyperglycemia can occur rapidly.)
- A dislodged cannula may be the reason for unexplained high blood glucose. Since the Patch only delivers rapid-acting insulin, hyperglycemia can occur rapidly.
- If your blood glucose remains high and you have symptoms of DKA, have someone drive you to the hospital or call 911.
- Untreated DKA can cause breathing difficulties, coma and death.

7.6 Sick-day Management

Since illness and infection place extra stress on the body and often raise blood glucose, managing diabetes during sick-days requires extra attention to detail. Insulin pump therapy allows you to make adjustments quickly without the concern of how long-acting background insulin will affect your blood glucose.

Just like in injection therapy, even if you are unable to eat, you need insulin. With insulin pump therapy, your basal insulin may be sufficient to keep your blood glucose in your target range or you made need to take boluses, set a temporary basal rate or both to cover the need for extra insulin.

7.6.1 Sick-day Protocol

- Test blood glucose and at least every 2 hours or use a continuous glucose monitor
- Test ketones at least every 2 hours
- Keep accurate records of blood glucose, ketones, fever and any other symptoms
- Take extra insulin if blood glucose is 250 mg/dL or higher
- Call your healthcare provider if ketones are moderate or large and remember that extra insulin and fluids are needed when ketones are present, even if your blood glucose is within your target range. If your blood glucose is in target range and you have moderate to large ketones, drink fluids with sugar to avoid hypoglycemia and take the necessary amount of insulin for the carbohydrates.
- Call your healthcare provider if you are vomiting

7.6.1.1 Sick-day Supplies

- Fluids containing sugar: regular soda, popsicles, etc. to replace solid food
- Sugar-free liquids: water, diet-drinks, bullion, chicken broth, for replacing lost fluids
- Thermometer
- Medications for fever, cough, congestion, nausea and vomiting
- Extra blood glucose strips
- Ketone testing supplies
- Glucagon emergency kit in case of severe hypoglycemia

WARNING: If you are unable to care for yourself, have someone drive you to the hospital or call 911.

7.7 Troubleshooting

When there is an issue with the EOPatch Insulin Management System, you will receive an alarm or alert as was discussed in the previous chapter. However still there may be times when you are questioning if your blood glucose issues could be from the system. Following are some common concerns with suggestions for troubleshooting them.

My blood glucose results are running higher than usual.

- Check the ADM to make sure your basal rate is correct.
- Check the ADM to make sure the time is correct.
- Check to make sure you do not have a reduced temporary basal rate running.
- Consider if you have recently made any changes in your settings, especially basal rates, insulin-to-carbohydrate ratios, insulin sensitivity factors and target blood glucose ranges.
- Consider if you may be getting sick or are taking medication that may raise your blood glucose.
- Check the area around the Patch to make sure it is not wet and there is no smell of insulin indicating the cannula has slipped partially or completely out. If so, remove the active Patch

and activate a new Patch.
- Consider if your insulin may be expired, may have gotten too warm or has been out of the refrigerator for over a month. If so, remove the active Patch and activate a new Patch with a new vial of insulin.
- If your blood glucose remains high, remove the active Patch and activate a new Patch.

My blood glucose results are running lower than usual.

- Test more often and be prepared to treat hypoglycemia should it occur.
- Check the ADM to make sure your basal rate is correct.
- Check the ADM to make sure the time is correct.
- Check to make sure you do not have an increased temporary basal rate running.
- Consider if you have recently made any changes in your settings, especially basal rates, insulin-to-carbohydrate ratios, insulin sensitivity factors and target blood glucose ranges.
- Consider if you have been doing more exercise than usual and, if so, if you need to set a decreased temporary basal rate.
- Consider if you have recently been drinking alcohol which can lower your blood glucose.

My blood glucose result is higher than I think it should be after a meal.

- Check the ADM to make sure you programmed a bolus for the meal.
- Check the area around the Patch to make sure it is not wet and there is no smell of insulin indicating the cannula has slipped partially or completely out.
- Check to make sure you do not have a reduced temporary basal rate running.
- Consider if the meal may have had more carbohydrates than you counted for the meal.
- Consider the amount of fat in the meal that may have kept your blood glucose elevated longer than usual.
- If your blood glucose remains high, remove the active Patch and activate a new Patch.

My blood glucose result is lower than I think it should be after a meal.

- Test more often and be prepared to treat hypoglycemia should it occur.
- Check the ADM to make sure you programmed the correct bolus for the meal.
- Check the History settings to make sure you didn't program more than one bolus for the meal.
- Check to make sure you do not have an increased temporary basal rate running.
- Consider if the meal may have had less carbohydrates than you counted for the meal.
- Consider the amount of fat in the meal that may have kept your blood glucose from rising after the meal and may cause your blood glucose to be higher much later.
- Consider if you drank alcohol with the meal which can lower your blood glucose.

8 APPENDIX

8.1 EOPatch system options and settings

Item	Unit	Option & Settings	Remarks
Basal delivery			
Delivery rate range	unit/hr	0.05~15	Max basal rate default is 3U/hr.
Basal rate default	unit/hr	0.05	
Basal pattern	ea	Max. 8	
Basal rate increase	unit/hr	Default: 0.05 U/hr User Input	
Temporary basal			
Temporary basal program	ea	Max. 8	
Temporary basal	% or U/hr	Default: Off	Adjustable from 0.5 to 12 hours in 0.5 hour increments. You may select from -100% to 100% in 5% increments if you use percent (%); if you use U/hr, you may set/adjust it to be between 0U/hr and the maximum basal rate you set.
Blood glucose(BG) target			
Set segment	ea	Max. 48	Separate 24 hours in 30-minute increments
Range	mg/dL (mmol/L)	70~200	BG input range: 10~600 mg/dL (1~33.3 mmol/L)
Target BG & correction threshold	mg/dL (mmol/L)	70~200	Target blood glucose can be adjusted in 1 mg/dL (0.1 mmol/L) increments between 70 mg/dL and 200 mg/dL (3.9 - 11.1 mmol/L); correction threshold is adjustable as well in 1 mg/dL (0.1 mmol/L) increments between the target BG and 200 mg/dL (11.1 mmol/L).
Meal bolus setup			
Carbohydrate units	gram	0~400	
Carbohydrate-insulin ratio	g carb /unit	1~150	
Insulin Sensitivity Factor, Correction Factor	mg/dL (mmol/L) per unit	1~400	
Insulin activation period	hours	Default: 5.0 Range: 2.0~8.0	In 30-minute increments
Reverse correction	ON/OFF	ON	

Minimum BG for Bolus calculator	mg/dL (mmol/L)	Default: 70 mg/dL(3.9 mmol/L) (default) Range: 50-70 mg/dL 2.8 - 3.9 mmol/L)	
Bolus delivery			
Delivery rate range	unit	0.05 ~ 25	Max bolus default is 10U.
Bolus programming increase	unit	Default: 0.05 User controllable	
Bolus presets	ea	8	
Carb presets	EA	36	Food library information
Extended bolus	hr	0.5~8	In 0.5 hour increments
Suspend	hr	0.5~2.0	
Auto-off Alert	hr	1~24	
Patch expiration Alert	hr	1~24	Can be set in 1-hour increments
Low reservoir Alert	U	10~50	Can be set in 5U increments
History saved for	Days	90	
Language		Korean or English	

8.2 Patch specifications

Items	Spec.
Number of Uses	Disposable
Waterproof and dustproof grade	IP48 (1m, 24hrs)
Size and weight	49.5 x 39 x 14.5 mm, 26g (without drug)
Network	BT Low Energy 5.0
Operating Frequency	2,402MHz ~ 2,480MHz
Modulation Type	GFSK(Bluetooth LE)
EIRP	3.5 dBm
Alarm type	Audible (buzzer)
Reservoir tolerance	200U (2ml), Need to fill at least 80U to activate the Patch
Needle	Soft cannula (FEP), insertion depth 4.75mm
Operating temperature range	4.4~37℃ (39.92~98.6℉)
Startup temperature	10℃(50℉) or higher
Storage temperature range	4.4~30℃ (39.92~86℉)
Operating humidity range	20~85 % RH, non-condensing
Storage humidity range	20~85 % RH, non-condensing

Operating atmospheric pressure	700~1,060 hPa
Storage atmospheric pressure	700~1,060 hPa
Shelf life	14 months
Warranty	84 hrs
Non-pyrogenic	fluid pathway only
BF type medical device	Protection from electric shock

8.3 ADM specifications

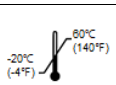
Items	Spec.
Size and weight	116.5 x 64.5 x 11.4 mm, 108g (including battery)
Communications method	BT Low Energy 4.2
Communication distance	6.1m
Operating Frequency	2,402MHz ~ 2,480MHz
Frequency modulation Type	GFSK(Bluetooth LE)
	GFSK(BT 1Mbps), π/4-DQPSK(BT 2Mbps), 8DPSK(BT 3Mbps)
EIRP	0.5 dBm
LCD	3.5 “, HVGA (320 x 480) Color TFT
Key input method	touch, capacitive
Battery	3.7 V, 1130mAh Li_Ion, rechargeable
USB	Micro USB 5pin, USB 2.0
Alarm type	Audible/visible/vibratory
Operating temperature range	4.4~40℃ (39.92~104℉)
Storage temperature range	-20~60℃ (-4~140℉)
Operating humidity range	20~90 % RH, non-condensing
Storage humidity range	20~90 % RH, non-condensing
Operating atmospheric pressure	700~1,060 hPa
Storage atmospheric pressure	700~1,060 hPa
Warranty	2 year limited, (rechargeable battery is covered by the warranty for 6 months from the date of purchase)

8.3.1 Symbols, Labels, Icons & LED Light Colors

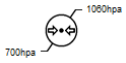
8.3.1.1 Symbols

Symbols	Meaning	Explanation
WARNING	Warning	Safety hazard indicated
Caution	Caution	Potential risk indicated
Note	Note	Comment about information
Did you know	Knowledge	Pertinent diabetes infomation

8.3.1.2 Labels

Labels	Meaning	Labels	Meaning
	Manufacturer		Date of Manufacture
	Follow instructions for use		Caution
	Prohibited	SN	Serial Number
	Do not reuse	STERILE EO	Sterilized using ethylene oxide
LOT	Lot number (Batch code)	Rx only	Prescription only
	Use by date		Magnetic Resonance (MR) unsafe
IP48	IP Code (Patch)	IP22	IP Code (ADM)
	Temperature limit (Patch)		Type body floating (BF) applied part (Patch)
	Temperature limit (ADM)		Keep dry

Field Code Changed

	Atmospheric pressure limitation		Humidity limitation
	Do not use if the package is damaged		Non-pyrogenic fluid path
	Class Ⅱ Equipment (ADM)		CE marking
	waste batteries and accumulators		WEEE
	This way up		Stack up to 4 cartons high only
	Stack up to 5 cartons high only		Mounted on cargo planes only
	Lithium-ion battery safety		Fragile, handle with care
	Hooks use no hand		

Field Code Changed

Field Code Changed

8.3.1.3 Icons

Name	Icon	Description
Advanced settings menu		See Advanced menu
Settings		Change ADM settings
ON		Turn function ON
OFF		Turn function OFF
Home		Return to Home screen
Reminder volume		Control volume

Display brightness		Control brightness
Bluetooth		Configure Bluetooth
Previous		Previous icon
Delete		Delete
Etiquette		Sound (including Mute)
Add		Add items to the menu
Alarm		Alarm
Alert		Alert
Reminder		Reminder
Patch expiration date		Patch expiration date
Drop-down		Details

8.3.2 LED Light Colors

Name	Color	Description
ALARM		Highest risk indicated by a continuous red light
Alert		Medium and Low risk indicated by a blinking yellow light
Reminder		Notification not related to risk indicated by a blinking blue light
Charging		Charging indicated by a constant green light which turns off when fully charged

8.4 EOPatch Insulin Management System Notice Regarding Occlusion

EOPatch software checks whether the intended dose is actually being injected. If over- or under-infusion is detected, insulin delivery is stopped and an alarm is generated.

8.4.1 Occlusion Detection

EOPatch generates an 'Occlusion' Alarm when a blockage is detected during insulin delivery. An occlusion requires that the current Patch be discarded, a new Patch activated and blood glucose carefully monitored due to the lack of insulin delivery for a period of time.

	Minimum	Medium	Maximum
5.00U Bolus	142 seconds	24 minutes	29 minutes
1.00U/hr Basal rate	1.5 hours	3 hours	5 hours
0.1U/hr Basal rate	9 hours	17 hours	40 hours

Figure 8-1 Occlusion Detection Times

WARNINGS

- Low Basal rate or low dose Bolus delivers can lengthen the 'Occlusion' detection time, so check your blood glucose more frequently for early detection of signs of occlusion.
- If an Occlusion Alarm occurs, it is recommended to check your blood glucose and change the new Patch.
- On average, when 2-5 U of insulin is not delivered, Occlusion Alarm is raised, and when the occlusion is resolved, an amount of insulin is delivered that does not exceed the delivery dose set by the user.

8.5 EOPatch Insulin Management System Notice Regarding Interference

The EOPatch Insulin Management System (both the ADM and the Patch) complies with Part 15 of the Federal Communications Commission (FCC) Rules. Operation is subject to the following two conditions:

- These devices may not cause harmful interference

- These devices must accept any interference received, including interference that may cause undesirable operation.

Changes or modifications not approved by EOFLOW could void the user's authority to operate the equipment.

Both the ADM and the Patch generate, use, and can radiate radio frequency energy, and may cause harmful interference to radio communications of other devices. There are no guarantees that interference will not occur in a particular installation. If the EOPatch Insulin Management System does cause harmful interference to radio and television reception, the interference may be corrected by one of the following measures:

- Move or relocate the EOPatch Insulin Management System.
- Increase the distance between the EOPatch Insulin Management System and the other device that is emitting or receiving interference.

EOFLOW asserts that the EOPatch Insulin Management System is in compliance with the critical requirements and other relevant provisions of Directive 1999/5/EC. This ISM device complies with Canadian ICES-003 and IC-RSS-210.

8.6 Electromagnetic Compatibility

The information contained in this section is specifically written with regard to the EOPatch Insulin Management System. The numbers provided will not guarantee faultless operation but should provide reasonable assurance of faultless operation. This information may not be applicable to other medical electrical equipment; older equipment may be particularly susceptible to interference.

8.6.1 General Notes

Medical electrical equipment requires special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in this document and the instructions for use. If the EOPatch Insulin Management System fails due to electromagnetic disturbances, it may need to be replaced.

Portable and mobile radio frequency (RF) communications equipment can affect the function of the EOPatch Insulin Management System.

WARNING: Cables and accessories not specified within these instructions for use are not authorized to be used with the EOPatch Insulin Management System. Using other cables or accessories may adversely impact safety, performance, and electromagnetic compatibility (increased emission and decreased immunity).

EOFLOW declares that the EOPatch Insulin Management System is in compliance with the essential requirements and other relevant provisions of Directive 1999/5/EC.

Care should be taken if the EOPatch Insulin Management System is used near adjacent to other electrical equipment; if adjacent use is inevitable, such as in work environments, observe the EOPatch Insulin Management System to verify normal operation in this setting.

The EOPatch Insulin Management System communicates by low level RF energy. As with all RF receivers, the potential for disturbance exists, even with equipment that complies with FCC and CISPR emissions requirements.

The EOPatch Insulin Management System communicates with the following characteristics:

Frequency: 433 Mhz, FSK modulation, with an effective radiated power of 13mW

The EOPatch Insulin Management System complies with the immunity requirements of the general standard for electromagnetic compatibility, IEC 60601-1-2.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 12 inches (30 cm) to any part of the EOPatch Insulin Management System. Otherwise, degradation of the performance of this equipment could result.

8.6.2 EMC test report

Guidance and manufacturer's declaration - electromagnetic emissions		
The EOPatch is intended for use in an electromagnetic environment as specified below. The customer or the user of the Product should ensure that it is used in such an environment.		
Emissions test	**Test level/requirement**	**Electromagnetic environment - guidance**
Radiated disturbance CISPR 11:2015	Group 1 Class B	***EOPatch*** uses RF energy only for its internal functions. Therefore, its RF emissions are very low and are not likely to cause any interference to nearby electronic equipment.
Mains terminal disturbance voltage CISPR 11:2015	Group 1 Class B	
Harmonics Current Emission IEC 61000-3-2:2014	Class A	***EOPatch*** 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.
Voltage change, Voltage fluctuations and Flicker Emission IEC 61000-3-3:2013	Pst:1 Plt: 0.65 Tmax: 0.5 dmax: 4% dc: 3.3%	

Guidance and Manufacturer's Declaration - Electromagnetic Immunity				
EOPatch is intended for use in the electromagnetic environment specified below. The customer or the user of the ***EOPatch*** should assure that it is used in such environment.				
Immunity Test	**Operating Mode**	**Test Voltage**	**Test level/ requirement**	**Electromagnetic environment - guidance**
Electrostatic Discharge Immunity IEC 61000-4-2:2008	Insulin injection/ Charging mode & Battery operating	230V, 50Hz 220V, 60Hz 100V, 50/60Hz 120V, 60Hz d.c.3.7V	±8kV/Contact ±2, ±4, ±8 ± 15kV/Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.

Radiated RF Electromagnetic Field immunity IEC 61000-4-3:2010	Insulin injection/ Charging mode & Battery operating	230V, 50Hz 220V, 60Hz 100V, 50/60Hz 120V, 60Hz d.c.3.7V	10 V/m 80 MHz-2.7 GHz 80% AM at 1 kHz	***EOPatch*** is suitable to use in home healthcare environment
Immunity to Proximity Fields from RF wireless Communications Equipment IEC 61000-4-3:2010	Insulin injection/ Charging mode & Battery operating	230V, 50Hz 220V, 60Hz 100V, 50/60Hz 120V, 60Hz d.c.3.7V	Table 9 in IEC 60601-1-2:2014	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the ***EOPatch***, including cables specified by EOFLOW. Otherwise, degradation of the performance of this equipment could result
Electrical Fast Transient/Burst Immunity IEC 61000-4-4:2012	Insulin injection/ Charging mode	230V, 50Hz 220V, 60Hz 100V, 50/60Hz 120V, 60Hz	± 2 kV, 100kHz repetition frequency	The quality of supplied power be suitable for heme healthcare environment.
Surge Immunity IEC 61000-4-5:2014	Insulin injection/ Charging mode	230V, 50Hz 220V, 60Hz 100V, 50/60Hz 120V, 60Hz	Line to Line ±0.5kV, ±1kV	The quality of supplied power be suitable for heme healthcare environment.
Immunity to Conducted Disturbances induced by RF fields IEC 61000-4-6:2013	Insulin injection/ Charging mode	230V, 50Hz 220V, 60Hz 100V, 50/60Hz 120V, 60Hz	3 V 0.15-80 MHz 6 V in ISM bands & Amateur radio bands between 0.15 and 80 MHz 80% AM at 1kHz	The strength of RF field in the frequency range 150 kHz~80 MHz, the strength of the RF field should be smaller than 3 V. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the EOPatch.

Power Frequency Magnetic Field Immunity IEC 61000-4-8:2009	Insulin injection/ Charging mode & Battery operating	230V, 50Hz 220V, 60Hz 100V, 50/60Hz 120V, 60Hz d.c.3.7V	30 A/m 50 Hz & 60Hz	If degradation of the essential performance occurs, it may be necessary to position the EOPatch further from sources of power frequency magnetic fields.
Voltage dips, IEC 61000-4-11:2004	Insulin injection/ Charging mode	100V, 50Hz 100V, 60Hz 240V, 50Hz 240V, 60Hz	0 % UT: 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 Cycles Single phase: at 0°	The quality of supplied power should be suitable for home healthcare environment. For the user to operate the equipment continuously even the electric power supply is interrupted, it is recommended that the uninterruptable power supply device (UPS) or battery is prepared.
Voltage interruption IEC 61000-4-11:2004	Insulin injection/ Charging mode	100V, 50Hz 100V, 60Hz 240V, 50Hz 240V, 60Hz	0% UT; 250/300 cycle	The quality of supplied power should be suitable for home healthcare environment. For the user to operate the equipment continuously even the electric power supply is interrupted, it is recommended that the uninterruptable power supply device (UPS) or battery is prepared.
Electrical Fast Transient/Burst Immunity IEC 61000-4-4:2012	Insulin injection	230V, 50Hz 220V, 60Hz 100V, 50/60Hz 120V, 60Hz	± 2 kV, 100kHz repetition frequency	The quality of supplied power be suitable for heme healthcare environment.
Surge Immunity IEC 61000-4-5:2014	Insulin injection	230V, 50Hz 220V, 60Hz 100V, 50/60Hz 120V, 60Hz	Line to Line ±0.5kV, ±1kV	The quality of supplied power be suitable for heme healthcare

				environment.
Immunity to Conducted Disturbances induced by RF fields IEC 61000-4-6:2013	Insulin injection	230V, 50Hz 220V, 60Hz 100V, 50/60Hz 120V, 60Hz	3 V 0.15-80 MHz 6 V in ISM bands & Amateur radio bands between 0.15 and 80 MHz 80% AM at 1kHz	The strength of RF field in the frequency range 150 kHz~80 MHz, the strength of the RF field should be smaller than 3 V. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the EOPatch.
Power Frequency Magnetic Field Immunity IEC 61000-4-8:2009	Insulin injection	230V, 50Hz 220V, 60Hz 100V, 50/60Hz 120V, 60Hz d.c.3.7V	30 A/m 50 Hz & 60Hz	If degradation of the essential performance occurs, it may be necessary to position the EOPatch further from sources of power frequency magnetic fields.
Voltage dips, IEC 61000-4-11:2004	Insulin injection	100V, 50Hz 100V, 60Hz 240V, 50Hz 240V, 60Hz	0 % UT: 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 Cycles Single phase: at 0°	The quality of supplied power should be suitable for home healthcare environment. For the user to operate the equipment continuously even the electric power supply is interrupted, it is recommended that the uninterruptable power supply device (UPS) or battery is prepared.

Voltage interruption IEC 61000-4-11:2004	Insulin injection	100V, 50Hz 100V, 60Hz 240V, 50Hz 240V, 60Hz	0% UT; 250/300 cycle	The quality of supplied power should be suitable for home healthcare environment. For the user to operate the equipment continuously even the electric power supply is interrupted, it is recommended that the uninterruptable power supply device (UPS) or battery is prepared.
Note U_T is the A.C. voltage supply before the test level voltage.				

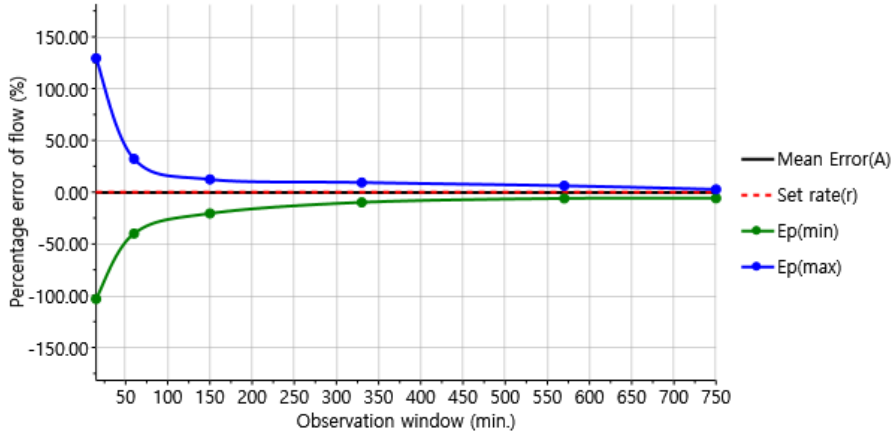
Figure 8-2 - EMC Test Report

8.7 Delivery accuracy test result

Delivery accuracy (Tested per IEC 60601-2-24)

- Basal: ± 5% at rate ≥ 0.10 U/hr
- Bolus: ± 5% for all set values ≥ 0.10 U

Accuracy test results: The following graph show the flow accuracy curve. The measurements were made using a Patch with a basal rate of 0.10U/hr. The overall mean percentage flow error was -0.38%.



8.8 Conversion Table mmol/L to mg/dL

BG (mmol/L) x 18 = BG (mg/dL)					
(mmol/L)	(mg/dL)	(mmol/L)	(mg/dL)	(mmol/L)	(mg/dL)
0.0	0	13.5	243	27.0	486
0.5	9	14.0	252	27.5	495
1.0	18	14.5	261	28.0	504
1.5	27	15.0	270	28.5	513
2.0	36	15.5	279	29.0	522
2.5	45	16.0	288	29.5	531
3.0	54	16.5	297	30.0	540
3.5	63	17.0	306	30.5	549
4.0	72	17.5	315	31.0	558
4.5	81	18.0	324	31.5	567
5.0	90	18.5	333	32.0	576
5.5	99	19.0	342	33.0	585
6.0	108	19.5	351	33.5	594
6.5	117	20.0	360	34.0	603
7.0	126	20.5	369	34.5	612
7.5	135	21.0	378	35.0	621
8.0	144	21.5	387	35.5	630
8.5	153	22.0	396	36.0	639
9.0	162	22.5	405	36.5	648
9.5	171	23.0	414	37.0	657
10.0	180	23.5	423	37.5	666
10.5	189	24.0	432	38.0	675
11.0	198	24.5	441	38.5	684

11.5	207	25.0	450	39.0	693
12.0	216	25.5	459	39.5	702
12.5	225	26.0	468	40.0	711
13.0	234	26.5	477	40.5	720

8.9 Customer Rights

8.9.1 Scope of Services

EOFLOW's scope of services is limited to providing the EOPatch Insulin Management System which consists of the Advanced Diabetes Manager (ADM) a handheld, smart, wireless, touchscreen remote controller, which programs insulin delivery instructions to the Patch: a tubeless, disposable insulin infuser.

8.9.2 Compliance

The EOPatch Insulin Management System is manufactured and distributed by EOFLOW. The company is committed to complying with all federal and state regulations. If you have any questions or concerns regarding any of our activities, please contact EOFLOW.

8.9.3 Inquiries

EOFLOW representatives are available 24 hours a day, 7 days a week to answer product-related questions.

8.9.4 CHAP Accredited

EOFLOW is accredited by the Community Health accreditation Program (CHAP). If you have concerns you are unable to resolve directly with EOFLOW, please contact CHAP at www.chapinc.org or 1-800-656-9656.

8.9.5 Rights and Responsibilities

You have the right to:

- Receive considerate and respectful customer service.
- Receive customer service without regard to race, creed, national origin, sex, age, disability, sexual orientation, illness, or religious affiliation.
- Expect confidentiality of all information pertaining to you, your medical care and service. Please review our HIPAA Privacy Notice below.
- Receive a timely response to your requests.
- Receive continued service.
- Select the medical equipment supplier of your choice.
- Make informed decisions regarding your healthcare planning.

- Understand what services will be provided to you.
- Obtain an explanation of charges, including the policy for payment.
- Agree to, or refuse, any part of the service plan or care plan.
- Voice concerns and complaints without fear of lack or service or any other reprisals.
- Have your communication needs met.

You have the responsibility to:

- Ask questions about any part of the service or plan of care that you do not understand.
- Use the EOPatch Insulin Management System for the purpose for which it was prescribed and follow the instructions for use, handling, safety and cleaning.
- Provide EOFLOW with insurance information for payment for services.
- Agree to pay charges not covered by insurance and settle account in full.
- Notify us immediately of:
  - Equipment failure or damage.
  - Need of supplies.
  - Any change in your prescription of healthcare provider.
  - Any change in insurance or loss of insurance.
  - Any change of address or telephone number, temporary or permanent.

8.10 GDPR Compliance

Since we do not collect customer information. This product does not apply to REGULATION (EU) 2016/679 General Data Protection Regulation (GDPR).

8.11 Information on disposal of electrical and electronic equipment and disposal of batteries and accumulators

The crossed out wheeled bin symbol with under bar shown on the product or accompanying documents indicates the product requires appropriate treatment, collection and recycle for waste electrical and electronic equipment (WEEE) under the Directive 2012/19/EU  , and waste batteries and accumulators under the Directive 2006/66/EC  in the European Union.

This product should not be disposed of as unsorted household waste.

Your correct disposal of WEEE, waste batteries and accumulators will contribute to reducing wasteful consumption of natural resources, and protecting human health and the environment from potential negative effects caused by hazardous substance in products.

8.12 Limited Express Warranty, Disclaimer or Implied Warranties and Limitation of Remedies

8.12.1 Limited Express Warranty Coverage

Limited Warranty Coverage for the EOPatch Insulin Management System's, Advanced Diabetes Manager (ADM)

Subject to the terms and conditions stated herein ("Limited Express Warranty"), EOFLOW warrants to you, the original purchaser of the EOPatch Insulin Management System, that, if EOFLOW determines, during the period of four (4) years from the date of purchase, that the EOPatch Insulin Management System's Advanced Diabetes Manager (ADM) included in your shipment manifests a defect in material or workmanship while utilized under normal use and conditions, EOFLOW will either repair or replace, at its sole option, the ADM.

This four-year (4) warranty period applies only to a new ADM and, in the event the ADM is repaired or replaced, the warranty period shall not be extended or reset. Thus, EOFLOW replaces a ADM under this Limited Express Warranty, the warranty coverage for the replacement ADM shall expire four (4) years from the date of purchase of the original ADM.

Limited Warranty Coverage for the EOPatch Insulin Management System's Patches

Subject to this Limited Express Warranty, EOFLOW warrants to you, the original purchaser of the EOPatch Insulin Management System, that, if EOFLOW determines, during the period of eighteen (18) months from the date of manufacture and eighty-four (84) hours from the time of activation, that an unexpired Patch included in your shipment manifests a defect in material or workmanship while utilized under normal use and conditions, EOFLOW will replace the Patch. To be eligible for replacement, the activation of the Patch must fall within both time periods (i.e. occur on or before the expiration date printed on the label with a manufacture date no more than XX (xx) months before, and, on or before a time no more than eighty-four (84) hours before you notify EOFLOW of the claim.)

This XX (xx)month and eighty-four (84) hour warranty period applies to new Patches only. In the event a Patch is replaced, the warranty period shall not be extended or reset. Thus, if EOFLOW replaces a Patch under this Limited Express Warranty, the warranty coverage for the replacement Patch shall expire either XX (xx) months from the manufacture date of the original Patch or eighty-four (84) hours form the time of activation of the original Patch, whichever occurs first.

8.12.2 Limited Express Warranty Terms and Conditions

Claim Procedure

To be eligible for this Limited Express Warranty, you must notify EOFLOW of the claimed defect with the ADM or the Patch within the applicable warranty periods by calling Customer Care.For a claim involving the ADM, you must provide the ADM serial number and a description of the claimed defect. For a claim involving a Patch, you must provide the Patch lot number and a description of the claimed defect. You may also be required to verify the date of purchase of the ADM and/or the Patch, the manufacture date of the Patch and the time of activation of the Patch. Your failure to follow any of

the above steps may result in the denial of coverage under this Limited Express Warranty. Unless EOFLOW elects to repair the ADM (which may include, but not limited to, a repair kit or replacement part(s) provided by EOFLOW, or refers you to a third party, you must obtain a prior authorization and return the ADM or Patch to EOFLOW according to the instructions provided in the Return Merchandise Authorization (RMA) Kit. With a prior authorization, EOFLOW will pay all reasonable freight and transportation charges, where applicable, incurred in shipping the ADM or Patch to EOFLOW under the Limited Express Warranty. For the avoidance of doubt, this Limited Express Warranty does not cover repairs performed or replacements provided by any person or entity other than EOFLOW, except those performed or provided by third parties to which you were explicitly referred by EOFLOW.

Proof of Purchase

In order to verify the date of purchase, the date of manufacture, or the time of activation and to determine if the claim under this Limited Express Warranty is within the applicable warranty periods, EOFLOW may require that you provide a valid proof of purchase, manufacture or activation. Failure to provide a valid proof of purchase, manufacture or activation, as determined by EOFLOW, may may result in the denial of coverage under this Limited Express Warranty.

Exclusions

This Limited Express Warranty covers only the original purchaser and cannot be transferred or assigned with the sale, rental or other transfer of the ADM or of the Patch to any other person or entity.

This Limited Express Warranty will apply only if the ADM or the Patch at issue has been used in accordance with the EOPatch Insulin Management System User Guide and/or other written instructions provided by EOFLOW. THIS LIMITED EXPRESS WARRANTY DOES NOT APPLY IF THE ADM OR THE PATCH HAVE BEEN:

- Altered, changed or modified by any person or entity other than EOFLOW;
- Opened, serviced or repaired by any person or entity other than EOFLOW;
- Damaged by an act of God or other “force majeure” life event;
- Damaged by misuse, abuse, negligence, accident, unreasonable use, or improper handling, care or storage;
- Damaged by wear and tear, causes unrelated to defective materials or workmanship or other circumstances outside of the reasonable control of EOFLOW.

This Limited Express Warranty does not apply to test strips, batteries, other accessories, or related products provided by third parties (e.g., blood glucose monitors, data management tools, CGMs).

This Limited Express Warranty does not extend to design defects (i.e. claims that the ADM or the Patch should have been designed in a different way).

DISCLAIMER OF IMPLIED WARRANTIES AND LIMITATION OF REMEDIES

REPAIR OR REPLACEMENT AS PROVIDED UNDER THE ABOVE LIMITED EXPRESS WARRANTY OF THE ADM OR THE Patch IS YOUR EXCLUSIVE REMEDY AND THE ENTIRE OBLIGATION OF EOFLOW. THIS EXCLUSIVE REMEDY SHALL NOT BE DEEMED TO HAVE FAILED ITS ESSENTIAL PURPOSE, SO LONG AS EOFLOW IS WILLING AND ABLE TO REPAIR OR REPLACE AN ADM OR A PATCH WITH DEFECTS IN MATERIALS OR WORKMANSHIP IN THE MANNER PRESCRIBED BY THE ABOVE LIMITED EXPRESS WARRANTY.

ANY IMPLIED WARRANTIES, INCLUDING WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, ARE EXPRESSLY DISCLAIMED.

IN NO EVENT SHALL EOFLOW, ITS SUPPLIERS, DISTRIBUTORS, SERVICE PROVIDERS, AND/OR AGENTS BE

LIABLE FOR INDIRECT, SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES CAUSED BY A DEFECT IN THE PDM OR A POD OR BY A BREACH OF THE ABOVE LIMITED EXPRESS WARRANTY, WHETHER SUCH CLAIM IS BASED IN WARRANTY, CONTRACT, TORT OR OTHERWISE.

Important Additional Provisions

EOFLOW DOES NOT WARRANT THE SUITABILITY OF THE ADM OR THE PATCH OR THE EOPATCH INSULIN MANAGEMENT SYSTEM FOR ANY SPECIFIC PERSON AS HEALTH CARE AND TREATMENT ARE COMPLEX SUBJECTS REQUIRING THE SERVICES OF QUALIFIED HEALTH CARE PROVIDERS.

The above Limited Express Warranty gives you specific legal rights, and you may also have other rights which vary by jurisdiction. The above Limited Express Warranty applies only to ADMs and the Patches that were originally sold for use in the United States of America.

Note that some jurisdictions do not allow the exclusion of implied warranties or the limitation of indirect, special, incidental, or consequential damages, so the above exclusions or limitations may not apply to you. EOFLOW LIABILITY IN SUCH JURISDICTIONS SHALL BE LIMITED TO THE MAXIMUM EXTENT PERMITTED BY LAW. SUCH LIMITATIONS SHALL INCLUDE BUT ARE NOT LIMITED TO THE FOLLOWING: ANY IMPLIED WARRANTIES THAT CANNOT BE DISCLAIMED UNDER THE LAW OF A PARTICULAR JURISDICTION ARE LIMITED, TO THE EXTENT ALLOWED BY LAW, TO THE TIME PERIOD COVERED BY THE ABOVE LIMITED EXPRESS WARRANTY, OR TO THE APPLICABLE TIME PERIOD PROVIDED BY LAW, WHICHEVER PERIOD IS SHORTER.

No Other Warranty or Agreement

Unless modified in writing and signed by both EOFLOW and you, the foregoing Limited Express Warranty is understood to be the complete and exclusive understanding between EOFLOW and you, superseding all prior warranties and agreements, oral or written, and all other communications relating to any defect in, failure or other malfunction in an ADM, a Patch or an EOPatch Insulin Management System. No employee, agent or other representative of EOFLOW or any other party is authorized to make any product warranty or agreement applicable to an ADM, a Patch or an EOPatch Insulin Management System in addition to those made in the foregoing.

Consent to Disclaimer of Implied Warranties and the Limitation of Remedies

If you do not consent to and instead wish to reject the Disclaimer of Implied Warranties and the Limitation of Remedies included with the EOPatch Insulin Management System, please return any EOPatch Insulin Management System products (including the ADM and Patches) to EOFLOW in exchange for a full refund. Failure to return such EOPatch Insulin Management System products shall constitute acknowledgement of and consent to the Disclaimer of Implied Warranties and the Limitation of Remedies.

8.13 HIPAA Privacy Notice

THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.

This notice of privacy practices (the “HIPAA Privacy Notice”) describes how we may use and disclose your Medical Information to carry out treatment, payment or health care operations and for other purposes that are permitted or required by law, including by the Health Insurance Portability and Accountability Act, and all regulations issued thereunder (“HIPAA”). It also describes your rights to access and control your Medical Information. As used herein, “Medical Information” is information about you, including demographic information, that may identify you and that relates to your past, present or future physical or mental health or condition and related health care services.

Uses and Disclosures of Medical Information

We will only use and disclose your Medical Information as permitted by law. Except for disclosures outlined in this HIPAA Privacy Notice and/or permitted by law, we will obtain your written authorization before using your Medical Information or disclosing it to any outside persons or organizations. Most uses or disclosures of your Medical Information constituting psychotherapy notes will be made only after receiving your written authorization. We will not use or disclose your Medical Information for purposes of marketing, except as permitted by law and/or outlined in this HIPAA Privacy Notice. We will not sell your Medical Information, without first obtaining your written authorization. You may revoke any written authorization you have provided to us at any time, except to the extent that we have made any uses or disclosures of your Medical Information in reliance on such authorization. To revoke a previously issued authorization, please send your request in writing, along with a copy of the authorization being revoked to our Privacy Officer. If a copy of the applicable authorization is not available, please provide a detailed description and date of the same to our Privacy Officer.

There are some situations where we may use or disclose your Medical Information without your prior written authorization, as described further below:

Uses and Disclosures of Your Medical Information Related to the Treatment and Services Provided by Us

Treatment, Payment and Health Care Operations: We may use your Medical Information for treatment, to obtain payment for treatment, for administrative purposes, and to evaluate the quality of care that you receive without your authorization. We may use or disclose Medical Information about you without your authorization for several other reasons.

Example of Treatment: In connection with treatment, we may use your Medical Information to provide you with one of our products.

Example of Payment: We may use your Medical Information to generate a health insurance claim and to collect payment on invoices for services and/or medical devices provided.

Example of Health Care Operations: We may use your Medical Information in order to process and fulfill your orders and to provide you with customer service.

Appointment Reminder and Other Communications: We may use or disclose your Medical Information without your prior written authorization to provide you or others with, among other things, (i) appointment reminders; (ii) product/supply reorder notifications; and/or (iii) information about treatment alternatives or other health-related products and services that we provide.

Family, Friends and Emergencies: If you require emergency treatment and we are unable to obtain your consent, we may disclose your Medical Information to a family member or relative who is involved in your care.

Marketing: We may use or disclose your Medical Information to provide you with marketing communications about the health-related products and services that we provide, and about products, services, treatment or healthcare providers that may be of interest to you.

Additional Categories of Uses and Disclosures

Required By Law: We may use or disclose your Medical Information to the extent that applicable law requires the use or disclosure of such Medical Information. Where the use and/ or disclosure of Medical Information is by law, the use or disclosure will be made in compliance with the law and will be limited to the relevant requirements of the law. You will be notified, as required by law, of any such uses or disclosures.

Public Health: We may disclose your Medical Information for public health activities and purposes to a public health authority that is permitted by law to collect or receive the information. The disclosure will be made for the purpose of preventing or controlling disease, injury

or disability. We may also disclose your Medical Information, if directed by the public health authority, to a foreign government agency that is collaborating with the public health authority.

Communicable Diseases: We may disclose your Medical Information, if authorized by law, to a person who may have been exposed to a communicable disease or may otherwise be at risk of contracting or spreading the disease or condition.

Health Oversight: We may disclose Medical Information to a health oversight agency for activities authorized by law, such as audits, investigations, and inspections. Oversight agencies seeking this information include government agencies that oversee the healthcare system, government benefit programs, other government regulatory programs and civil rights laws.

Food and Drug Administration: We may disclose your Medical Information to a person or company as directed or required by the Food and Drug Administration: (i) to collect or report adverse events (or similar activities with respect to food or dietary supplements), product defects or problems (including problems with the use or labeling of a product), or biological product deviations, (ii) to track FDA-regulated products, (iii) to enable product recalls, repairs or replacement, or look back (including locating and notifying individuals who have received products that have been recalled, withdrawn, or are the subject of look back), or (iv) to conduct post-marketing surveillance.

Legal Proceedings: We may disclose your Medical Information in the course of any judicial or administrative proceeding (i) in response to an order of a court or administrative tribunal (to the extent such disclosure is expressly authorized), and (ii) in certain conditions in response to a subpoena, discovery request or other lawful process, after we receive satisfactory assurance that the party seeking the information has reasonably attempted to notify you of the request or has reasonably attempted to secure a qualified protective order (in a court or administrative tribunal, or by stipulation) to limit disclosure of your Medical Information.

Law Enforcement: We may disclose Medical Information, as long as applicable legal requirements are met, for law enforcement purposes. These law enforcement purposes include: (i) legal processes otherwise required by law, (ii) limited information requests for identification and location purposes, (iii) pertaining to victims of a crime, (iv) suspicion that death has occurred as a result of criminal conduct, (v) in the event that a crime occurs on the premises of the practice, and (vi) medical emergency in which it is likely that a crime has occurred.

Research: We may disclose your Medical Information to researchers when their research has been approved by an institutional review board that has reviewed the research proposal and established protocols to ensure the privacy of your Medical Information.

Criminal Activity: Consistent with applicable federal and state laws, we may disclose your Medical Information, if we believe the use or disclosure is necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public. We may also disclose Medical Information if it is necessary for law enforcement authorities to identify or apprehend an individual.

Military Activity and National Security: When the appropriate conditions apply, we may use or disclose Medical Information of individuals who are Armed Forces personnel (i) for activities deemed necessary by appropriate military command authorities, or (ii) to foreign military authority if you are a member of that foreign military service. We may also disclose your Medical Information to authorized federal officials for conducting national security and intelligence activities.

Workers' Compensation: We may disclose your Medical Information as authorized to comply with workers' compensation laws and other similar legally-established programs.

Inmates: We may use or disclose your Medical Information to a correctional institution or law enforcement official if you are an inmate of a correctional facility and your physician created or received your Medical Information in the course of providing care to you, and disclosure is necessary for (i) providing you with health care; (ii) the health and safety of you, other inmates, or others at the correctional institution; or (iii) the administration and maintenance of the safety, security, and

good order of the correctional institution.

Required Uses and Disclosures: Under the law, we must make disclosures to you when required by the Secretary of the Department of Health and Human Services to investigate or determine our compliance with the requirements of HIPAA.

Non-identifiable Information: We may use or disclose your Medical Information if we have removed from it any information that is personally identifiable to you.

Your Rights

The following is a statement of your rights with respect to your Medical Information and a brief description of how you may exercise these rights.

You Have the Right to Inspect and Copy Your Medical Information: This means you may inspect and obtain a copy of Medical Information about you, provided, however, that applicable law may limit your ability to inspect or copy certain types of records. In certain circumstances, if we deny your request to review Medical Information, you may have a right to have this decision reviewed. If you would like to make a request to review your Medical Information, please download our Request Form at:

https://

and follow the directions included on that form. We will respond to your request in a reasonable amount of time. If your request is honored, we may charge a nominal fee for photocopying expenses. Please contact our Privacy Officer if you have questions about access to your Medical Information.

You May Have the Right to Amend Your Medical Information: If you believe that the Medical Information we have about you is incorrect or incomplete, you may ask us to make an amendment to your Medical Information. You may request an amendment as long as the Medical Information is still maintained in our records. If you would like to make a request to review your Medical Information, please download our Request Form at:

https://

and follow the directions included on that form. We will respond to your request in a reasonable amount of time. Please contact our Privacy Officer if you have questions about requeting an amendment to your Medical Information.

You Have the Right to Request a Restriction of Your Medical Information: You may ask us not to use or disclose any part of your Medical Information for the purposes of treatment, payment or healthcare operations. You may also request that any part of your Medical Information not be disclosed to family members or friends who may be involved in your care or for notification purposes as described in this HIPAA Privacy Notice. Your request must state the specific restriction requested and to whom you want the restriction to apply. Except as otherwise provided in this HIPAA Privacy Notice, we are not required to agree to a restriction that you may request. We are required to agree to your request to restrict disclosure of your Medical Information to a health plan if (i) the disclosure is to carry out payment or healthcare operations and is not otherwise required by law; and (ii) your Medical Information pertains solely to a healthcare item or service for which you or someone (other than the health plan) on your behalf, has paid us in full. If we agree to the requested restriction, we may not use or disclose your Medical Information in violation of that restriction unless it is needed to provide emergency treatment. If you would like to request a restriction of the use of your Medical Information, please download our Request Form at:

https://

and follow the directions included on that form. We will respond to your request in a reasonable amount of time. Please contact our Privacy Officer if you have questions about requesting a

restriction of the use of your Medical Information.

You Have the Right to Request to Receive Confidential Communications From Us By Alternative Means or at an Alternative Location: We will accommodate reasonable requests to receive confidential communications from us by alternate means or at an alternative location. We may also limit this accommodation by asking you for information as to how payment will be handled or specification of an alternative address or other method of contact. We will not request an explanation from you as to the basis for the request. Please make this request in writing to our Privacy Officer.

You Have the Right to Receive an Accounting of Certain Disclosures We Have Made, if any, of Your Medical Information: This right applies to disclosures for purposes other than treatment, payment or healthcare operations as described in this HIPAA Privacy Notice. It excludes disclosures we may have made to you, for a facility directory, to family members or friends involved in your care, for notification purposes, for national security or intelligence purposes, to correctional institutions or law enforcement officials, or as part of a limited data set. You have the right to receive specific information regarding these disclosures that occurred after April 14, 2003, or as otherwise provided for under applicable law. You may request a shorter timeframe. The right to receive this information is subject to certain exceptions, restrictions and limitations. If you would like to request an accounting of certain disclosure of your Medical Information, please download our Request Form at:

https://

and follow the directions included on that form. We will respond to your request in a reasonable amount of time. Please contact our Privacy Officer if you have questions about requesting an accounting of the disclosures of your Medical Information.

You Have The Right to Obtain a Copy of this HIPAA Privacy Notice: You have the right to obtain a paper copy of this HIPAA Privacy Notice from us, upon request, even if you have agreed to accept this notice electronically. If you would like to request a paper copy of this HIPAA Privacy Notice, please download our Request Form at:

http://www.eoflow.com/eng/main/main.html

Our Duties

Generally: We are required by law to maintain the privacy and security of your Medical Information and to provide you with notice of our legal duties and privacy practices with respect to Medical Information, and to notify you if there is a breach resulting in disclosure of your unsecured Medical Information.

Revisions and Modifications: We may change this HIPAA Privacy Notice at any time. Before we make a significant change in our policies, we will change this HIPAA Privacy Notice and post our new notice (the "Revised HIPAA Privacy Notice"). We are required to abide by the terms of this HIPAA Privacy Notice until a Revised HIPAA Privacy Notice becomes effective. The Revised HIPAA Privacy Notice will be effective for all Medical Information that we maintain as of the effective date of the Revised HIPAA Privacy Notice even if we collected or received the Medical Information prior to the effective date of the Revised HIPAA Privacy Notice. The current HIPAA Privacy Notice is posted on our Website at www.. com. If you would like to request a paper copy of this HIPAA Privacy Notice, please download our Request Form at:

http://www.eoflow.com/eng/main/main.html

What to Do If You Have a Problem or Question

If you have any further questions relating to this HIPAA Privacy Notice or if you have a problem or complaint, please contact us in writing or by phone.

Furthermore, if you believe that EOFLOW has violated your privacy rights with respect to your Medical Information, you have the right to file a complaint in writing with our Privacy Officer or with the Secretary of Health and Human Services at 200 Independence Avenue, S.W. Washington, D.C. 20201 or by calling (877) 696-6775. There will be no retaliation against you for filing such a complaint.

9 GLOSSARY

Active Insulin

Bolus insulin that has already been delivered and may still lower your blood glucose.

Active Insulin Setting

A user setting that determines the length of time bolus insulin is tracked as Active Insulin.

ADM (Advanced Diabetes Manager)

The smart remote controller in the EOPatch Insulin Management System

Alarm

An audible sound with a message. Alarms require immediate action. When an alarm sounds, you must respond to the situation.

Alarm/Alert History

A feature used to check saved information on Alarms and Alerts.

Alert

An audible sound with a message. Alerts may require you to act or prepare to act at a later time.

Basal Insulin

Background insulin that is continually delivered in insulin pump therapy to maintain blood glucose between meals and during sleep.

Basal Rate

The Units per Hour (UPH) of continuous insulin being delivered by the Patch. This is a personalized setting in the ADM that can be modified for different times of day.

Basal Program

The basal rate being delivered in 24-hours. This is a personalized setting in the ADM that can be modified for different times of day. (For example, a higher basal rate overnight for the Dawn Phenomenon.)

Blood Glucose (BG)

The level of the glucose (sugar) present in the blood at a specific time as measured by a blood glucose meter, continuous glucose monitor or in a laboratory.

Bolus

An immediate delivery of insulin for an expected rise in blood glucose from eating carbohydrate or to lower blood glucose that is above your target range.

Bolus Calculator

A feature in the ADM that calculates a bolus amount to lower blood glucose that is above your target range and/or to deliver insulin for a rise in blood glucose from eating carbohydrate. The Bolus Calculator uses previously entered personal settings for Insulin to Carbohydrate Ratio, Insulin

Sensitivity Factor, Target Blood Glucose and Insulin Duration.

Bolus Preset

An ADM feature that lets you name and save common bolus amounts for chosen food or meals.

BG Reminder

An ADM feature that allows you to set a reminder to check your blood glucose.

Calories

A unit of measurement. As it pertains to food, a calorie is the amount of energy your body can get from eating a certain food. The ADM provides calorie data for 12,000 foods.

Cannula

The tube in the Patch automatically inserted into the skin through which insulin enters the body.

Carbohydrate (Carb)

One of the three major nutrients in food necessary for health. (The other two are protein and fat). Carbohydrate raises blood glucose. Foods high in carbohydrate include fruit, fruit juice, milk, yogurt, ice cream, bread, rice, potato and other starchy vegetables. The ADM provides carbohydrate data for 12,000 foods.

Carb Preset

An ADM feature that allows you to save the name and carbohydrate content of frequently eaten foods.

Continuous Glucose Monitor (CGM)

A monitoring tool inserted below the skin that measures the amount of glucose in your interstitial fluid and converts the number to a blood glucose reading. CGM provides a measurement of blood glucose every five minutes.

Correction Bolus

A bolus to lower blood glucose that is above your personal target. To calculate a correction bolus, the ADM uses the current blood glucose and your previously entered personal settings for target blood glucose and correction factor.

Correction Factor

The ratio that expresses how many mg/dL 1 unit of insulin lowers blood glucose. For example 1U/50 mg/dL.

Continuous Subcutaneous Insulin Infusion (CSII)

CSII is a scientific name for insulin pump therapy in which insulin is delivered continuously in subcutaneous tissue. CSII allows adjustment of insulin delivery over a 24-hour period. CSII has been associated with lower and more consistent blood glucose and lower A1C results.[5]

Dawn Phenomenon

A rise in blood glucose in response to hormones that are released in the early morning hours. Insulin pump therapy is especially beneficial for this response since the basal rate can be set to offset this blood glucose rise.

Diabetic Ketoacidosis (DKA)

DKA is a life-threatening condition caused by high blood glucose with low insulin levels causing the body to use fat for energy and creating ketones in the urine and blood. In insulin pump therapy, DKA can occur from not getting insulin from the pump due to the pump being dislodged from the body or not pumping insulin properly.

Extended Bolus

A bolus that is divided so that some is delivered immediately, and some is delivered over a longer period of time. You may choose to use an extended bolus for foods that absorbs slower than most, due to the high content of fat, which slows down the absorption of carbohydrate. (A good example of this phenomenon is after eating pizza. For this reason, the extended bolus has also been labeled the “pizza bolus”.)

Fat

One of the three major nutrients in food necessary for health. (The other two are protein and carbohydrate). Fat does not raise blood glucose but may cause carbohydrate to rise slowly creating a situation in which blood glucose is lower after eating and higher several hours later. Foods high in fat include fatty meats and pizza. The ADM provides fat data for 12,000 foods.

Fiber

The part of fruits and vegetables that cannot be digested but aids in the digestion of other foods. In diabetes, the insoluble fiber content of carbohydrate-containing food does not raise blood glucose. The ADM provides fiber data for 12,000 foods.

Food Library

Data in the ADM for the carbohydrate, fat, protein, fiber and calories of 12,000 foods.

Glucagon

A hormone made by the body. Glucagon raises blood glucose. In people without diabetes, the regulation of blood glucose is achieved by the release of insulin and glucagon and other hormones. Synthetic glucagon is a product that can be injected to raise blood glucose in someone who has become unresponsive from hypoglycemia.

Glucose

An important energy source for the body. Insulin aids in the absorption of glucose. If enough insulin is not available, the glucose concentration in the blood increases, raising the blood glucose level.

Glycosylated Hemoglobin Test (HbA1c or A1C))

A blood test that can be converted to an average blood glucose number in order to estimate blood glucose control over the last 60 to 90 days. For example, an A1C result of 7.0% converts to a blood glucose average of 150 mg/DL. The lower the A1C, the lower the risk of diabetes complications.[5]

Healthcare Provider

A medical professional who specializes in disease management. Diabetes healthcare providers educate patients about the management of diabetes.

Hyperglycemia (high blood glucose)

Blood glucose above the upper limit set by your healthcare provider. Symptoms of high blood glucose include thirst, frequent urination, fatigue, headache and blurred vision. Prolonged high

blood glucose over 250 mg/dL can lead to DKA, a potentially deadly condition. In insulin pump therapy, hyperglycemia can occur from not taking any or enough insulin for the amount of carbohydrate eaten, not getting insulin from the pump due to the pump being dislodged from the body or using a lower basal rate than needed by the body, or the pump not pumping insulin properly.

Hypoglycemia (low blood glucose)
Blood glucose under the lower limit set by your healthcare provider. Symptoms of low blood glucose include shaking, sweating, dizziness, blurred vision and extreme hunger. Hypoglycemia is a potentially deadly condition that requires the immediate ingestion of glucose tablets, juice, soda (with sugar) candy (not chocolate) or any other high sugar/low fat food. Any blood glucose under 70 mg/dL can result in hypoglycemia. In insulin pump therapy, hypoglycemia can occur from taking too much insulin for the amount of carbohydrate eaten, getting too much insulin from the pump due to using a higher basal rate than needed by the body, or the pump not pumping insulin properly.

Hypoglycemia Unawareness

A condition in which a person does not feel symptoms of low blood glucose. Research shows that insulin pump therapy may reverse hypoglycemia unawareness

Infusion site

The place in the skin through which the Patch delivers insulin to the body.

Insulin-to-Carbohydrate Ratio (IC ratio)

The ratio that expresses how many grams of carbohydrate are covered by 1 unit of insulin. (For example 1U/15 grams CHO) This is a personalized setting in the ADM that can be modified for different times of day.

Insulin Duration

An estimate of the time it takes your body to use bolus insulin. This is a personalized setting in the ADM.

Insulin on Board (IOB)

The active insulin remaining from a carbohydrate or correction bolus. The bolus calculator uses the insulin duration set in the ADM and the time and amount of the last bolus to determine the IOB. IOB reduces the chance of hypoglycemia by avoiding stacking insulin from multiple boluses.

Max Basal Rate

The maximum amount of basal insulin that can be infused per hour. This is a personalized setting in the ADM.

Max Bolus

The maximum amount of bolus insulin that can be delivered per hour. This is a personalized setting in the ADM.

Meal Bolus

A bolus for an expected rise in blood glucose from eating carbohydrate. To calculate a meal bolus, the ADM uses the current blood glucose and your previously entered personal settings for target blood glucose and insulin-to-carbohydrate ratio.

Meal Bolus Reminder

A reminder that occurs when bolus delivery is not performed. This is a personalized setting in the ADM.

Multiple Daily Injections (MDI)

Injections taken throughout the day with an insulin pen or syringe, rather than insulin pump or Patch.

mg/DL

The unit of blood glucose used in the United States as a standard.

mmol/L

The unit of blood glucose used in some countries in Europe, Asia, and Canada.

Occlusion

A blockage, or partial blockage, of the cannula through which insulin is delivered from the Patch. An occlusion prevents insulin from flowing as expected.

Patch

The insulin delivery portion of the EOPatch Insulin Management System.

Pedometer

Measures the number of steps of the user walking or running.

Protein

One of the three major nutrients in food necessary for health. (The other two are carbohydrate and fat). Protein does not raise blood glucose but some foods containing protein have a high fat content which may cause carbohydrate to rise slowly creating a situation in which blood glucose is lower after eating and higher several hours later. Foods high in protein include meats, chicken, fish, tofu, eggs, and some yogurt. The ADM provides protein data for 12,000 foods.

Priming

A process that removes air bubbles from the reservoir of the Patch after it is filled with insulin.

Reminder

A feature in the ADM that delivers information.

Resume

A user-activated feature that restarts insulin delivery after it has been suspended.

Reverse Correction

A feature in the Bolus Calculator that reduces meal bolus insulin when your current blood glucose is below your target blood glucose and you still have insulin on board from a previous bolus.

Snooze

A user-activated feature in the ADM that allows you to be notified again after a Reminder, Alarm or Alert.

Subcutaneous

The tissue underneath the skin where insulin is delivered.

Suspend

A user-activated feature that allows you to stop insulin delivery for a certain period of time. When activating Suspend, all bolus and basal deliver is stopped.

Target Blood Glucose

The desired level or range. This is a personalized setting in the ADM that can be modified for different times of day. (For example, before and after meals or overnight.)

Temporary Basal
A user-activated feature to decrease or increase the basal infusion over a chosen period of time.

10 INDEX

11 References

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3. Mora M, Carreira M, Anarte M, et al. Bolus calculator reduces hypoglycemia in the short term and fear of hypoglycemia in the long term in subjects with type 1 diabetes (CBMDI Study). Diabetes Technology & Therapeutics 2017;19(7):402-409.
4. USDA National Nutrient Database for Standard Reference 28 Software v.3.5.5.1
5. Monami M, Lamanna C, Marchionni N, Mannucci E. Continous subcutaneous insulin infusion versus miltiple daily insulin injections in type 1 diabetes: a meta-analysis. Acta Diabetologica 2010;47(suppl 1):77-81.
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7. Ostrovski I, Lovblom L, Scarr D, et al. Analysis of prevalence, magnitude, and timing of the dawn phenomenon in type 1 diabetes - descriptive analysis of two insulin pump trials. Diabetes 2018;67(suppl 1)

FCC Information to User

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one of the following measures:

• Reorient or relocate the receiving antenna.
• Increase the separation between the equipment and receiver.
• Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
• Consult the dealer or an experienced radio/TV technician for help.

Caution

Modifications not expressly approved by the party responsible for compliance could void the user’s authority to operate the equipment.

FCC Compliance Information : This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment.