

CHAPTER 4:

PUMPS AND INFUSION DEVICES

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CHOICES, CHOICES, CHOICES

Since insulin pumps were introduced in 1978, the market has expanded to provide many options. There are so many options that choosing the right pump and related devices may at first seem intimidating. Several companies now offer excellent pumps, as well as choices in data management systems, infusion sets and insertion devices. This chapter should help you be more knowledgeable about some of the most popular pumps and related devices.

Beyond the information provided here, it is important to do your own research before purchasing an insulin pump. Technology is advancing rapidly and new pump features are added often. You want the right pump for you or your child. Most people use a pump for at least four years before upgrading to a newer model. Insulin pump warranties typically cover a pump for four years, and most insurance companies do not pay for a person to have a new pump before the warranty is out. Upgrading to a newer model is an option with most companies. You should know, however, that this is usually an out of pocket expense.

While doing your research, be sure to talk to other people/families to see how they like the pump they chose. In addition, it is helpful to ask these important questions:

1. Which pump has features that will best address your or your child's diabetes management needs?
2. Which pump will best fit your or your child's health and lifestyle needs for the next four years? (Most insurance providers will not cover upgrades for four years after getting a pump.)

3. Does the company provide good support and education for your region? (Your diabetes doctor or nurse should be able to help you with this question.)
4. Does the company provide a user-friendly data management system that will help you and your diabetes care providers to easily identify blood sugar patterns?

The most popular pumps in the United States today, made by Medtronic MiniMed, Deltec, Animas and Insulet, have several important features in common. We'll begin this chapter by considering some of these common features. Then we will look at features that distinguish these pumps from each other. Finally we'll discuss related devices for these pumps — data management systems, infusion sets and insertion devices.

COMMON FEATURES OF INSULIN PUMPS

“Smart” Pumps

“Smart” pumps are now the norm. The minimum requirement for a pump to be considered “smart” is that it must have a bolus calculator. Since these pumps rely on the programming of a person's insulin to carbohydrate ratio, they work best for people who are carbohydrate counting, or at a minimum, using carbohydrate exchanges to determine their mealtime insulin dosages. Bolus calculators allow a user to personalize an insulin dose using the following features:

1. Insulin to carbohydrate (I/C) ratio = the amount of carbohydrate that one unit of insulin will accommodate (e.g., 1:15)

2. Blood sugar sensitivity/correction factor (sensitivity) = the amount of blood sugar that one unit of insulin will reduce (e.g., 1 unit decreases the blood sugar by 50 mg/dl or 2.8 mmol/L)
3. Target blood sugar ranges or values = the ideal blood sugar range or value for this person (e.g., 100-180 mg/dl or 5.5 - 10 mmol/L)

These settings can vary by time of day.

Adjustable Time (Curves) for Insulin Action (Insulin on Board)

In addition to a bolus calculator, most smart pumps have an adjustable time of insulin action. This feature accounts for the amount of active insulin that remains in a person's body from a previous bolus. Active insulin is insulin that has been delivered but not yet used by the body. It is also referred to as "insulin on board" (IOB). An adjustable time curve accommodates differences in the length of time insulin acts to lower the blood sugar in different people. The active insulin curve duration is set for the average estimated time it takes for the insulin to be used by the body. We usually set this curve between three and five hours. The person or family often has the best guesstimate on how long a shot of Humalog/NovoLog/Apidra effectively works. This curve reduces the occurrence of insulin "stacking," which commonly occurs when a person gives a correction bolus too soon after a previous bolus. It also serves to improve the accuracy of the bolus. With most insulin pumps, this insulin on board adjusts for previous correction boluses as well as food boluses (Table 1).

Locking Keypads

A feature that is specifically made for young children is the "lock out" or "lock keypad" option. This feature is highly recommended for very young children who use insulin pumps. A child wearing a pump may be taught not to touch the pump's buttons; however, friends at pre-school may not be able to resist touching the pump.

With young children, buttons are there to be pushed!

Some parents are concerned about the possibility of pushing buttons during sleep and inadvertently delivering a bolus. As long as the "Audio" or "Touch" bolus features are turned off, there is no need to worry about a person accidentally programming a bolus during sleep. Either way, it is very difficult to accidentally bolus. For added protection, the keypad locking feature can be used at night.

Programmable Alarms

Each of the pumps discussed in this chapter has user programmed alerts and alarms to help the pump wearer. Alerts let the pump user know something needs attention. Alarms sound when the matter is urgent (e.g., it involves insulin delivery). Alerts and alarms are very useful; however, a balance must be achieved to prevent the pump wearer from becoming desensitized to them. For instance, a bolus reminder alert for lunchtime at work or school might be more important than a bolus reminder alert for an occasional snack after school. Blood sugar reminder alerts can remind a person to check the blood sugar. Alarm clock functions can be used to remind the child to bolus for a meal or to hand in their homework. Infusion site change reminders and low reservoir reminders can be used to avoid leaving the infusion set in too long or unexpectedly running out of insulin. It is important to choose alerts and alarms that fit the pump user's needs and no more. Programming alarms that are unnecessary can lead to the wearer being annoyed and desensitized to all alarms.

Preset Special Basal Patterns

A shared feature of these pumps is the ability to program more than one set of basal rates. An example is the use of special basal patterns for the week before the menstrual period when the blood sugar is running high. Another example is having a second set of basal rates for heavy exercise days. This could be used to provide a

reduced basal pattern for days with physical education at school.

Using different basal patterns is different from using a temporary basal rate. Basal patterns are pre-programmed basal rates that differ from the normal basal pattern and are used when needed and will remain as the basal rate until they are switched again. In contrast, a temporary basal rate would have to be set at the time and for the length of time that it is needed. The pump then automatically returns to the normal basal pattern.

Specialized (Advanced) Boluses

The two specialized (advanced) boluses available with these pumps are the Square Wave (Extended) bolus and the Dual Wave (Combination) bolus (Chapter 6). Square Wave (Extended) boluses are used for extended eating situations when the amount of carbohydrates that will be consumed is known and duration of eating can be anticipated. Munching on popcorn at the movies would be a good example. Dual Wave (Combination) boluses allow a person to deliver a portion of a bolus right away and extend the delivery of the other portion over a set amount of time. This is most often used to accommodate meals such as macaroni and cheese, pizza or chicken nuggets with french fries. Since these meals are high in fat, the absorption rate of some of the carbohydrates in the meal can be delayed, making the Dual Wave (Combination) bolus a good fit.

Upgrade Programs

In 1993 Medtronic MiniMed began an upgrade program that gives people the option to take advantage of the newest technology available from the company. Most companies now offer similar programs. A company may charge a significant fee or none at all to upgrade a pump to one with the latest technology.

SPECIFIC INSULIN PUMPS AND THEIR FEATURES

Currently, the three most popular pumps in the United States are the Medtronic MiniMed Paradigm®, the Deltec Cozmo® and the Animas® 2020. A new pump introduced in 2005 is the Insulet OmniPod®. This section reviews these companies and the unique features of their pumps. The websites of the pump companies are provided for further information. Table 1 summarizes some of the similarities and differences of these pumps.

Medtronic MiniMed Paradigm (www.minimed.com)



MiniMed (acquired by Medtronic in 2001) has manufactured ten models of insulin pumps over the past 20 years. MiniMed

pioneered many of the features we find in pumps today (e.g., the Square and Dual Wave boluses, Temporary Basal Rate, “On-Screen Dose Analyzer” and a “Save Settings” feature). The On-Screen Dose Analyzer provides a breakdown of insulin received each day in the past month. This can be used for diabetes clinic appointments or to simply determine if the insulin dose needs adjusting. The Save Settings feature allows one to make a back up file of the pump settings in case the settings are lost.

MiniMed designed the Smart Pump Bolus Calculator called the “Bolus Wizard®.” The company also pioneered the first infusion set with a quick release that allows the pump wearer to disconnect from their pump, as well as the first automatic insertion device for the infusion set.

In 2006, MiniMed launched the first insulin pump that not only delivers insulin but acts as a receiver of the glucose levels from their real-time Continuous Glucose Monitor (CGM). This is called the Paradigm REAL-Time System. This communication system eliminates the need to wear a separate device to receive the glucose

data that is transmitted from the CGM. The system sends a glucose value to the pump every five minutes using radio frequency technology. The glucose levels are only displayed on the face of the pump and are NOT used to control the pump's insulin delivery or any other pump features.

Deltec Cozmo (www.cozmore.com)

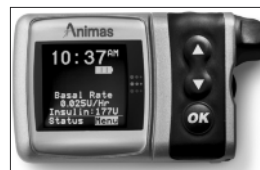
Smiths Medical acquired Deltec, manufacturer of the Cozmo insulin pump, in 1994.



The first Cozmo insulin pump entered the market in 2003. Deltec has offered two upgrades since 2003, some without cost to the user. In 2004 Smiths Medical partnered with Abbott Diabetes Care to launch the CoZmore®

Insulin Technology System. With this system, a CoZmonitor® blood sugar module (using FreeStyle™ technology) attaches to the back of the Cozmo pump and uses infrared technology to send the sugar reading to the pump. The results of the blood sugar check are displayed on the screen of the insulin pump. This pump also has a “Missed Meal Bolus” alert that will sound if the pump user does not bolus within a window of time that is pre-programmed into the pump. The Cozmo pump has many other unique features, such as a Disconnect Feature that calculates the insulin missed (or to be missed when disconnected) and a Weekly Schedule. The Weekly Schedule allows settings to be programmed for different days. An example of when this would be helpful is when lunch is at 11a.m. on Mondays and Wednesdays, but at 12:30p.m. on all other days. In this situation, the missed meal bolus alert can be programmed for different times according to the time of the meal. Another new feature is the “Hypo Manager™.” This feature suggests a carbohydrate amount to correct a current low blood sugar. It also warns of possible hypoglycemia based on the blood sugar level and the “insulin on board.” The Cozmo pump includes a food database to help with carbohydrate counting. The insulin pump is waterproof; however, the CoZmonitor is not.

Animas 2020 (www.animacorp.com)



Animas, acquired by Johnson and Johnson in 2005, has been in business since 1996. Animas launched its first insulin pump, the R1000®, in 2000, followed by the 1200 series, and their newest pump, the Animas 2020. Animas pumps were the first to have “menu driven operation” (i.e., all pump functions can be found under the corresponding menu on the pump screen) and allow multiple pre-programmed basal patterns. The new Animas 2020 model is the first insulin pump to provide a flat panel, wide angle, color display screen. This display screen is a great feature to help pump users with visual impairment. The Animas is also the first pump to offer “mini” basal rate programming, allowing increments as small as 0.025 units/hour. For insulin pump users with very small insulin requirements, such as very young children, this is a helpful feature. Another helpful feature of the Animas pump is the high occlusion sensitivity setting. Unlike other pumps that detect occlusions between two to five units of undelivered insulin, the regular occlusion sensitivity setting on the Animas detects under two units and the high sensitivity setting detects under one unit. This is especially helpful in avoiding DKA for young children or anyone using very little insulin. Animas was the first to have a food database to help with carbohydrate counting. Their new 2020 model is stated to be “water tight” at 12 feet for 24 hours.

Insulet OmniPod (www.myomnipod.com)



In 2005, a new insulin pump called the OmniPod was launched. The OmniPod shares most features of the conventional pumps but is unique in two major ways.

First, the OmniPod is a disposable insulin pod, which measures 1.6 inches wide, 2.4 inches long,

and 0.7 inches tall. The insulin pod is designed to last up to 72 hours (unless the insulin has run out) before being replaced. It is attached to the body with adhesive. It has a 9 mm cannula that is automatically inserted to a 6½ mm depth using a handheld device called the Personal Diabetes Manager (PDM). The user simply has to fill the pod with insulin, adhere it to the skin and use the PDM to prompt the insulin pod to insert the cannula and retract the needle. A new pod is used each time more insulin is needed or it has reached 72 hours of wear. The PDM is necessary for all functions and if lost, the current basal rate will still be delivered; however, the other functions of an insulin pump (e.g., meal or correction boluses) cannot be used. A person uses the PDM to program the insulin pod, deliver boluses, change basal rates and program alarms.

Second, the OmniPod does not require tubing. Since the pod (which holds the insulin) is attached directly to the skin, there is no tubing outside of the system. The OmniPod is waterproof and can be worn while swimming, whereas other insulin pumps would normally be disconnected at the insertion site. The OmniPod, however, cannot be disconnected. OmniPod users must remember this when using a hot tub, as the hot water will damage the insulin and it will be necessary to replace the pod.

The OmniPod holds only 200 units of insulin compared to the option of 300 units for most other pumps. This may last only two days for a teenager who is relatively insulin resistant. Insulet has partnered with Abbott and uses the FreeStyle blood sugar meter, which is built into the PDM. As of this writing, the OmniPod is only available in approximately half of the United States, but the company is rapidly expanding the market.

Roche Accu-Chek™ Spirit (www.disetronic-usa.com)



At the time of this writing (2007), the Spirit insulin pump is being introduced into the U.S. The Spirit was previously the Disetronic pump (prior to the Roche acquisition). However, to date, we have no experience with the Spirit.

The Accu-Chek Spirit Insulin Pump System comes with a PDA that contains the Accu-Chek Pocket Compass software with bolus calculator. There is also the option to purchase a palmOne™ Treo 650™ smartphone and have the software loaded onto that device. The software on the PDA allows for calculation of meal or correction insulin boluses with the ability to personalize the settings as with the other pumps mentioned previously. The software also includes the ability to display reports such as blood sugar trends and a blood sugar logbook. HbA1c values and ketones (when entered manually into the PDA), and pump information such as basal rates can also be tracked on the PDA. The Accu-Chek meter and pump have the ability to wirelessly transfer data to the PDA to maintain an electronic diary. The PDA does not communicate with the insulin pump using wireless technology, so that bolus insulin dosages calculated by the PDA must be manually entered into the pump. One special feature of the Spirit pump is that the tubing and cartridges (but not the insertion site) last for six days instead of three days like the other pumps. In addition, the screen can be flipped to be read from either the top or the bottom.

Unlike the other pumps, the Spirit itself does not calculate meal or correction insulin boluses. The PDA is necessary for the calculation. The recommended bolus is then manually entered into the pump by the user. If the PDA is lost, misplaced or forgotten, all bolus calculations must be done without the aid of an electronic bolus calculator.

Other Insulin Pumps

There are several other pumps with which we have very little experience. These include the Nipro Diabetes Systems Amigo® pump and Sooil's DANA Diabecare IISG® pump. The DANA Diabecare IISG is a “smart” pump with an integrated BG meter.

DATA MANAGEMENT SYSTEMS

The ability for pump users to download their pump data has many advantages:

- First, it enables the pump user to have a copy of everything programmed in the insulin pump. It's not fun to be on vacation and have a pump “die.” Pump manufacturers are usually very good about replacing a pump that is still under warranty. However, having a replacement pump overnighted to the hotel helps very little if the pump user does not have a record of the programs to enter in the new pump.
- Second, downloading insulin pump information onto a personal computer allows the user to make changes on the computer and “beam them back” to the insulin pump.
- Third, anyone can gain access to a history of all pump activity. This can be especially important with teenagers who may feel like their parents are constantly nagging them for blood sugar and bolus information. Doing a quick download can help bring some peace back into the household.

- Fourth, data management systems can display blood sugar and insulin dosing data in a way that allows for easy detection of blood sugar patterns that may need attention.

Medtronic MiniMed has two data management systems — the CareLink™ and Paradigm PAL™ software. CareLink is a secure Web-based system. People can download data from their insulin pump as well as most blood sugar meters to CareLink. If the person is using the Paradigm REAL-Time Continuous Glucose Monitor, the use of the CareLink data management system is essential. CareLink is designed so that pump users can give their healthcare providers their usernames and passwords. This allows the healthcare provider to access the person's pump and/or sugar information, choose the reports they need and print them. The Paradigm PAL software is designed to allow people to download their insulin pump data, make changes to the settings and upload those changes back into their pumps.

Deltec Cozmo uses management software called CoZmanager2®. CoZmanager2 enables pump users to download their pumps using an infrared adapter, change pump settings on the computer and beam the information back into the pump. CoZmanager2 allows many of the settings in the pump to be personalized by pre-programming them and/or attaching names to them. Pump users can also print hard copies of the information from the pump. CoZmanager2 also has history reports that can be printed and sent to the healthcare providers.

The management software for Animas is called ezManager®. This system is similar to the CoZmanager software in allowing the settings to be personalized on the computer and sent back into the pump, also via an infrared adaptor.

At the time of this writing, the management software for the OmniPod is in its first phase and currently being upgraded.

The software for the Accu-Chek Spirit pump is in the PDA that comes with the pump. The data from both the pump and the Accu-Chek meter can be transmitted using an infrared adaptor into the PDA. At this time the ability to download the information from the PDA to a computer is being finalized.

INFUSION SETS AND INSERTION DEVICES

An infusion set is the tubing apparatus that connects the reservoir of insulin, which is inside the insulin pump, to the pump wearer. The end of the infusion tube is called a cannula. The cannula is a soft, flexible tube that is inserted into the body using an “introducer needle” which is removed after the insertion. Insulin enters the body through the cannula. At the other end of the infusion tube is the connection point where the tube connects to the reservoir or cartridge that holds the insulin. These connections can be one of two types – a Standard Luer Lock connection or a proprietary connection specific to that insulin pump. Tables 2 and 3 detail the specifications of a select group of Medtronic Paradigm Insulin Pump compatible infusion sets and Standard Luer Lock infusion sets.

Two insulin pumps, the Paradigm and the DANA Diabecare II, require a special, proprietary connection. The Paradigm pump has a special “cap-type” end that connects only to a Paradigm reservoir. This allows the use of a convenience device, called the “transfer guard,” that is attached to a new reservoir and eases the filling of the reservoir, especially for small hands. The “transfer guard” also serves the purpose of keeping the pressure equalized inside the insulin bottle.

Medtronic/MiniMed provides their Paradigm pump users with five different infusion sets (see Table 2 for the more commonly used sets). Three of Medtronic’s infusion sets work with an insertion device that helps people with needle phobia overcome the obstacle of inserting infusion sets. These insertion devices also help ensure straight, smooth insertions and help

minimize any associated discomfort. Medtronic’s insertion devices are not disposable. When available, their use is recommended.

Unomedical and Smiths Medical both have an infusion set that includes a disposable insertion. Unomedical’s combined infusion set/insertion device is called the Inset™. Smiths Medical’s Cleo™ Infusion Set includes a disposable retraction device. The cannula is manually inserted as the button is pressed. At full depression, the needle is automatically retracted. The cannulas of most other infusion sets must be inserted under the skin by hand. Examples are the Sure T™ and Comfort™ infusion sets (see Tables 2 and 3).

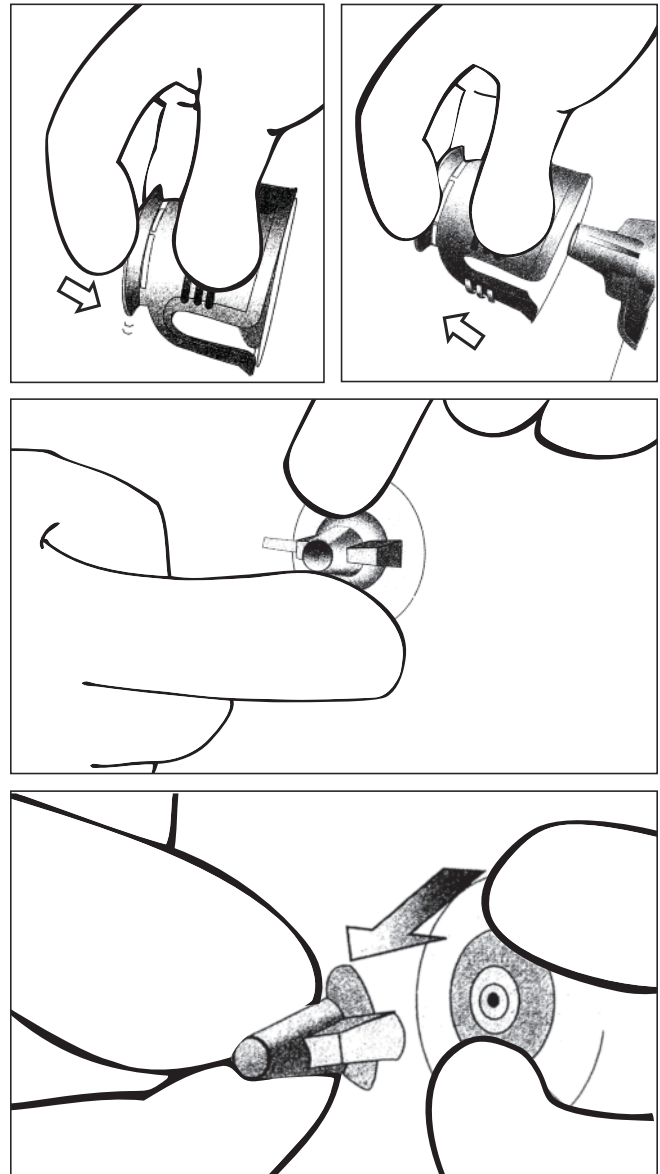


TABLE 13: FEATURES OF INSULIN PUMPS

Insulin pump	Bolus calculator	Basal rate increment (u/hr)	Smallest bolus increment (units)	Time to deliver a one-unit bolus	Bolus reminder alarm	Adjusts for active insulin on board from previous corrections	Bolus types	Food database bolusing	Water-proof	Integrated blood sugar meter	Cartridge size
Medtronic Paradigm 22 series	Yes	0.05	0.10	40 seconds	4; occur daily	Yes, and carb bolus as well	Normal, Square, Dual	No	No	Yes	176 or 300 units
Deltec Cozmo	Yes	0.05	0.05	1-5 minutes	4; occur daily or as one-time event	Yes, and carb bolus as well	Normal, Extended, Combo	Yes	Yes	Yes	300 units
Animas 2020	Yes	0.025	0.05	1 or 4 seconds	2 generic alarms	Yes, and carb bolus as well	Normal Extended, Combo	Yes	Yes	No	200 units
OmniPod	Yes	0.05	0.05	40 seconds	Many generic on PDA	Yes	Normal, Extended, Combo	Yes	Yes	Yes	200 units
Accu-Chek Spirit	Yes (on PDA only)	0.10	0.10	5 seconds	Many generic on PDA, 2 generic on pump	Yes	Normal, Extended, Combo, and "no look" bolus	Yes	Yes	Yes	315 units

TABLE 2:**MEDTRONIC PARADIGM PUMP COMPATIBLE INFUSION SETS***

	Quick-set®	Sure T™	Silhouette®	Sof-set QR®
Insertion device	Yes	No	Yes	Yes
Teflon cannula length	6 & 9 mm	N/A	13 & 17 mm	6 & 9 mm
Metal cannula length	N/A	6 mm	N/A	N/A
Disconnect feature	Yes, at site	Yes, 4 inch tail	Yes, at site	Yes, 4 inch tail
Manufacturer	Medtronic	Medtronic	Medtronic	Medtronic
Insertion angle	90°	90°	30°	90°

*These sets can also be ordered with the Standard Luer Lock and used with other pumps.

Standard Luer Lock infusion sets can be used with all insulin pumps except the Paradigm or the DANA Diabecare II pumps. Table 3 shows the Standard Luer Lock infusion sets and their specifications.

TABLE 3:**STANDARD LUER LOCK INFUSION SETS**

	Cleo 90™	Comfort™	Inset™	Inset 30™	ACCU-CHEK™ Rapid-D
Insertion device	Yes, and retracts	No	Yes	Yes	No
Teflon cannula length	6 mm	13 & 17 mm	6 & 9 mm	13 mm	N/A
Metal cannula length	N/A	N/A	N/A	N/A	6, 8 & 10 mm
Disconnect feature	Yes	Yes	Yes	Yes	Yes, 4 inch tail
Manufacturer	Smiths Medical MD	Unomedical	Unomedical	Unomedical	Roche
Insertion angle	90°	30°	90°	30°	90°

SUMMARY

The range of choices in insulin pumps and related devices is a little intimidating. These choices, however, help identify a combination of pump and related devices that are just right for each person. It is ideal to study and see all of the options prior to making choices. Qualified doctors, certified diabetes educators, pump trainers and other people who use the insulin pump are all great resources for the novice pump user.

DEFINITIONS

Cannula: The small flexible tube inserted under the skin to infuse the insulin. Metal cannulas are also available.

Infusion set: The tubing that connects the pump (insulin reservoir) to the cannula.

Insertion device: A device to automatically place the cannula under the skin to infuse the insulin.

Insulin on Board (IOB): The amount of insulin activity still present from previous insulin boluses.

Retraction device: A device that automatically pulls the needle out after insertion.

Smart pump: Most all pumps are now smart pumps in that they help to calculate bolus dosages. They allow programming of insulin/carb ratios for different times of the day. The user then just enters the grams of carbs to be eaten and the pump will suggest an insulin bolus dose. The user can accept or change the dose prior to giving the insulin. Similarly, a correction factor is programmed into the pump. Then, when a blood sugar is entered, a suggested bolus dose will be provided. The “insulin on board” from previous boluses is usually subtracted prior to advising a dose.

Specialized (Advanced) boluses: The Square Wave (or Extended) bolus and the Dual Wave (or Combination) bolus are defined in Chapter 6.

“Stacking” of insulin: Giving too many insulin boluses in a short period of time so they are working simultaneously.

Time (Curve) of insulin action: The estimated time that a bolus or shot of insulin lasts for a given individual.

