

This section provides detailed information on specifications related to your pump. The safety features of your pump are individually listed and described.

Alarms and error messages

Indicators: audible tone (beep) or vibration (silent)

All alarms and errors show messages on the pump's screen and provide instructions on what to do. Unresolved alarms will escalate to siren mode for added safety.

Alarm history

Maximum records shown: 36

Backlight

LCD (Liquid Crystal Display) type

Time-out: 7 seconds (in the HOME screen);
30 seconds (after the last button press).

Basal

Delivery: 0.05 – 35 units/hour (Maximum units: 35/hour)

Factory maximum setting: 2.0 units/hour

Increments: 0.05 units

3 patterns maximum, each with 48 rates maximum

BG target

Maximum targets: 8

range: 80 – 160 mg/dL
(4.4 – 8.9 mmol/L)

warning limits: less than 90 or greater than 140 mg/dL
(less than 5.0 or greater than 7.8 mmol/L)

Bolus delivery

Insulin delivered/ stroke	Fluid delivered/ stroke	Time between delivery strokes	Delivery rate (per minute)
0.05u	0.5 uL	2 seconds	1.5u

Bolus history

Maximum records shown: 24

Bolus units

Increments: 0.1 units

Bolus Wizard

(see end of this section for information)

Carb ratios

Maximum ratio settings: 8 range: 3 – 75 grams/u warning limits: less than 5 or greater than 50 grams/u
0.2 – 5.0 u/exch less than 0.3 or greater than 3.0 u/exch

Carb units

(The food entry when using Bolus Wizard)

grams: 0 – 300 (increments: 1 gram)

exchanges: 0.0 – 20 (increments: 0.5 exch)

Daily totals

Maximum records shown: 14 days of data 999.9 units

Accuracy: +0/–0.05 units

Default screen

The HOME screen. If no buttons are pressed for 30 seconds
(60 seconds for status type screens), the pump returns to this screen.

Delivery accuracy

Delivery accuracy: ±5%. Displacement (piston) accuracy: ±2%

Drive motor

The pump motor has a unique, patented design with an integrated safety check system. The system delivers in precise increments.

Dual Wave bolus

Delivers a Normal bolus followed by a Square Wave bolus (limited by maximum bolus).

Easy bolus

Features programming using audible tones (or vibrate pulses) in user-determined increments. Beep mode range: 0 to maximum bolus; Vibrate mode range: 0 to 20 steps or maximum bolus, whichever comes first.

Default step increment: 0.1 unit

Step size < maximum bolus.

Adjustable step size: 0.1 to 2.0 units per step.

Accessible from the remote control or pump buttons.

Infusion pressure

Maximum infusion pressure and occlusion pressure: 13.7 PSI.

(insulin) sensitivity

Maximum settings: 8

Factory default: 50 mg/dL (2.8 mmol/L)

range:	10 – 250 mg/dL (0.5 – 13.9 mmol/L)	warning limits:	less than 20 or greater than 100 mg/dL (less than 1.1 or greater than 5.6 mmol/L)
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Insulin type

Pump users can select one: U100 fast acting (default) U100 regular acting

Low resv (reservoir) warning

Values are based on displayed amount, not actual amount.

time:	2 – 24-hours, and @1:00 hour before empty	08:00 hours (default when time is selected)
units:	5 – 50 units, and @ 1/2 amount remaining	20 units (factory default)

Meter value

The BG measurement received from Paradigm Link meter. Appears in the ENTER BG screen during bolus programming. Appears on the screen when the pump is idle at the HOME screen.

Expiration: 12 minutes;
Range: 20 – 600 mg/dL
maximum meter entries: 3

Normal bolus

Range 0.1 – 25.0 units of insulin (limited by maximum bolus setting).

Occlusion detection

When occlusion is detected, the “no delivery alarm” will occur. The occlusion alarm is triggered by an average of 2.35 units of “missed” insulin. This table shows occlusion detection for 3 different situations when using U100 insulin.

Rate	Minimum time before alarm	Typical time before alarm	Maximum time before alarm
bolus delivery (1.5 u/minute)	26 seconds	94 seconds	2.5 minutes
basal delivery (1.0 u/h)	40 minutes	141 minutes	4 hours
basal delivery (0.05 u/h)	13 hours	47 hours	81 hours

Percent temp basal

Default value: 100% of basal programming

Power supply

The pump is powered by a standard 1.5 V AAA alkaline battery (Energizer brand recommended for best results).

Prime function

Fixed prime: 0.1 – 25.0 units (limited by maximum bolus)
Manual prime limit: warning at 30 units, then at each 10 units thereafter.
Fill rate: 1 to 5 units/second.
Prime insulin is not counted in daily totals but is recorded separately in the prime history.

Prime history

Maximum records shown: 20 (manual and fixed)

Program safety checks

Over 50 independent safety systems are continuously monitoring all pump operations.

Maximum infusion with single fault condition: 0.0074 ml.

Pump size

The dimensions of the pump are: 2 x 3 x 0.77 inches, 0.8 inches (2.0 cm) in battery area
[5 cm x 7.6 cm x 2 cm.].

Pump weight

Less than 100 grams

Remote control

Uses radio signals to allow users to program Normal boluses or to suspend/resume their pumps.

Reservoir

The user-filled reservoir is made from impact-resistant, insulin-compatible polypropylene.

Volume: up to 176 units of insulin.

Square Wave bolus

Delivers bolus insulin over a duration of 30 minutes up to 8 hours
(limited by the max bolus setting).

Status screen

➡ Time and insulin type	(always appears)	
➡ Status of pump	(i.e., Rewind, Suspended, Low Reservoir, Set Time, etc.)	
➡ Block:	(if active)	ON
➡ BG meter value: (most recent BG value received)	(appears if BG meter is enabled)	XXXmg/dL time and date (received)
➡ Last bolus information:	type and units delivered	(‘S’-Square, ‘N’-Normal, ‘D’-Dual) delivery time and date
➡ basal pattern information	(if active)	Pattern A or B
➡ Current temp basal information: (if currently active)	(if active)	rate (units per hour) duration time remaining
➡ Standard basal delivery data:	(always appears)	current basal rate (basal 1, basal 2, etc.)
➡ Reservoir started:	(always appears)	date, time units left time left
➡ BG Reminder in:	Time remaining before BG reminder is set to go off H:MM h (if less than 1 hour, 0:XXh where XX is minutes remaining)	
➡ Remote On:	(appears if enabled)	
➡ Meter On:	(appears if enabled)	
➡ Meter Off, Low Batt:	(appears if enabled but battery is low or empty)	
➡ Battery Status:	(always appears)	Normal, Low or Off
➡ Auto-off	(X HR)	
➡ Current date:	DDD ## MMM YYYY	
➡ Serial number:	(always appears)	
➡ Pump model number:	(always appears)	
➡ Software version:	(always appears)	

Temporary (temp) basal rate

Allows you to temporarily change the current basal rate for a duration of 30 minutes up to 24-hours (limited by maximum basal setting). The temp basal rate can be set to either Percent of basal or Insulin rate.

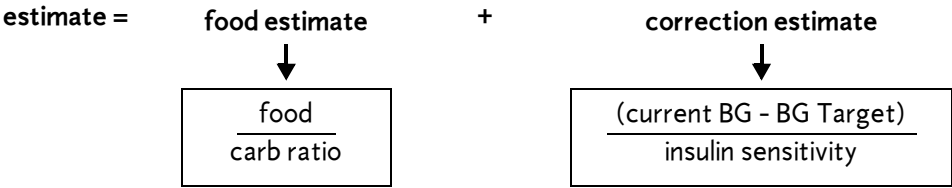
Time and date screen

Pump users have the choice of 12-hour or 24-hour formats. Pump users set the time/date, including the year, month and day. The date/time always appears in the status screen.

Water tight

With the tubing connector and battery cap securely in place, your pump can be used in water for up to 24-hours at depths of up to 8 feet (2.44 meters). Exposure for time lengths exceeding 24 hours or to depths greater than 8 feet (2.44 meters) should be avoided.

Bolus Wizard specifications

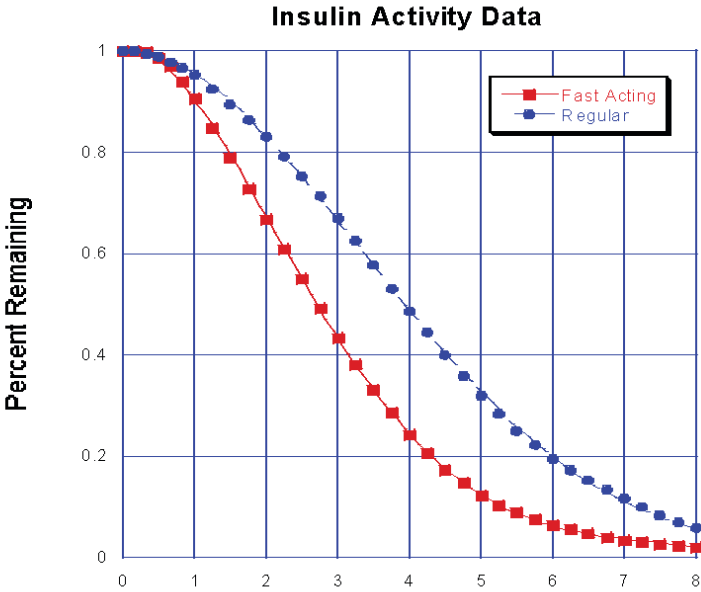


notes:

- Active insulin is based on timing of previous bolus insulin and insulin type. Four to six hours after a bolus, the majority of insulin has been absorbed, but a very small amount is active for a few more hours. The Bolus Wizard automatically calculates this and subtracts the appropriate amount. The details will appear in the ESTIMATE DETAILS screen during the bolus programming steps.

ESTIMATE DETAILS	
Est total:	4.0U
Food intake:	45gr
(Meter) BG:	160
Food:	3.0U
Correction:	2.0U
Active Ins:	1.0U
ACT to proceed,	
ESC to back up	

(values shown
are for
example only)



- Active insulin only reduces the correction portion of the estimate, not the food portion.
- If the active insulin is more than the correction estimate, the correction portion of the estimate will be changed to zero (0).
- If the current BG is lower than target, the correction portion of the estimate will reduce the total estimate.
- If a Dual Wave bolus is less than the estimate due to the max bolus limit or user change, the square (sq) portion is reduced first.

Bolus Wizard examples: (settings:) Carb ratio: 30 grams/unit
 Insulin
 sensitivity: 40 mg/dL/unit
 Target BG: 120 mg/dL

#1: No previous bolus activity for at least 10 hours. User inputs 60 grams of carbs and does not enter BG.

$$\text{(food estimate)} \quad \frac{60\text{g}}{30\text{g/u}} = 2 \text{ units}$$

estimate = 2 units

#2: No previous bolus activity for at least 10 hours. User inputs 60 grams of carbs and a BG of 200.

$$\text{(food estimate)} \quad \frac{60\text{g}}{30\text{g/u}} = 2 \text{ units} \quad + \quad \text{(correction)} \quad \frac{200\text{mg/dL} - 120\text{mg/dL}}{40\text{mg/dL/u}} = 2 \text{ units}$$

$$= 2 + 2$$

$$= 4 \text{ units}$$

estimate = 4 units

#3: No previous bolus activity for at least 10 hours. User inputs 60 grams of carbs and a BG of 80.

$$\text{(food estimate)} \quad \frac{60\text{g}}{30\text{g/u}} = 2 \text{ units} \quad + \quad \text{(correction)} \quad \frac{80\text{mg/dL} - 120\text{mg/dL}}{40\text{mg/dL/u}} = \frac{-40\text{mg}}{40\text{mg}} = -1 \text{ unit}$$

$$= 2 + (-1)$$

$$= 1 \text{ unit}$$

estimate = 1 unit

#4: Previous bolus activity results in a calculation of 1.5 units unabsorbed(active) insulin.
User inputs 60 grams of carbs and a BG of 200.

(food estimate) $\frac{60\text{g}}{30\text{g/u}} = 2 \text{ units}$	+	(correction) $\frac{200\text{mg/dL} - 120\text{mg/dL}}{40\text{mg/dL/u}} - 1.5\text{mg/dL (active insulin)} = 2 - 1.5 = 0.5 \text{ units}$
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$$= 2 + 0.5$$

$$= 2.5 \text{ units}$$

$$\text{estimate} = 2.5 \text{ units}$$

#5: Previous bolus activity results in a calculation of 3.5 units unabsorbed (active) insulin.
User inputs 60 grams of carbs and a BG of 200.

(food estimate) $\frac{60\text{g}}{30\text{g/u}} = 2 \text{ units}$	+	(correction) $\frac{200\text{mg/dL} - 120\text{mg/dL}}{40\text{mg/dL/u}} - 3.5\text{mg/dL (active insulin)} = 2 - 3.5 = -1.5 \text{ units}^*$ * This negative number indicates that active insulin is sufficient to cover the correction that is needed. Thus, correction will be 0 units. Active insulin is not allowed to reduce the food portion of the estimate.
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$$= 2 + 0$$

$$= 2.0 \text{ units}$$

$$\text{estimate} = 2.0 \text{ units}$$

Default settings

Menu	Item	Default Setting	Limits	Increments	Warning Limits
Bolus Menu:	*Bolus wizard:	Off			
	Easy bolus:	On			
	Easy bolus step:	0.1 u/h	maximum bolus setting		
	Dual/Square bolus:	Off			
	Bolus wizard:	Off			
	Maximum bolus:	10.0 u/h	0 - 25 u (per single bolus)		
	BG reminder:	Off	0:00 - 5:00	0:30 (minutes)	
Basal Menu:	Patterns:	Off			
	Maximum basal rate:	2.0 u/h	0.00 - 35.00 u/h	0.05u	
	Basal rate:	0.0 u/h		0.05u	
	Temp basal type:	(100) Percent	max basal rate setting	5% (or 0.05u/h)	(basal rate = 0.0)
Prime Menu:	Insulin type:	U100 fast acting			
Utilities Menu:	(Alarm)History:	(no defaults)			
	Alert type:	audio, beep-med			
	Auto-off:	Off			
	Low reservoir warning:	(20) insulin units	5 - 50 u; 2nd: @ 1\2 amount (2:00 - 24:00; 2nd: after 1:00)	20 u (0:30 mins)	
	(Time/Date) Time:	12 a.m. (midnight)			
	(Time/Date) Date:	1/1/03			
	(Time/Date) Time format:	12-hour			
	Block:	Off			
	Alarm clock:	Off			
	Remote option:	Off			
	Meter option:	Off			
	Language:	English			
(*Bolus Wizard settings)					
	carb units:	grams or exchanges	0 - 300 g/u or 0 - 20.0 u/exch	1 g/u or 0.5 u/exch	(none)
	ins to carb (or exch) ratio:	15 grams/u or 1 units/exch	3 - 75 g/u or 0.2 - 5.0 u/exch	1 g/u or 0.1 u/exch	5 - 50 g/u or 0.3 - 3.0 u/exch
	(insulin) sensitivity:	50 mg/dL or 2.8 mmol/L	10 - 250 mg/dL or 0.5 - 13.9 mmol/L	1 mg/dL or 0.1 mmol/L	20 - 100 mg/dL or 1.1 - 5.6 mmol/L
	BG target:	100 mg/dL or 5.6 mmol/L	80 - 160 mg/dL or 4.4 - 8.9 mmol/L	1 mg/dL or 0.1 mmol/L	90 - 140 mg/dL or 5.0 - 7.8 mmol/L

Icon table

Do not reuse:	
Attention: See Instructions for Use	
Method of sterilization using ethylene oxide:	STERILE EO
Date of manufacture (year - month):	
Batch code:	LOT
Use by: (year - month)	
Catalogue number:	REF
Device serial number:	S N
Storage temperature range:	-68°F (-20°C)  +131°F (+55°C)
Fragile product:	
Type BF equipment: (Protection from electrical shock)	
Pump: water tight Remote transmitter: splash proof	IPX8 IPX4
Country	
Language of Instructions for Use:	
Recycle:	
Radio communication:	

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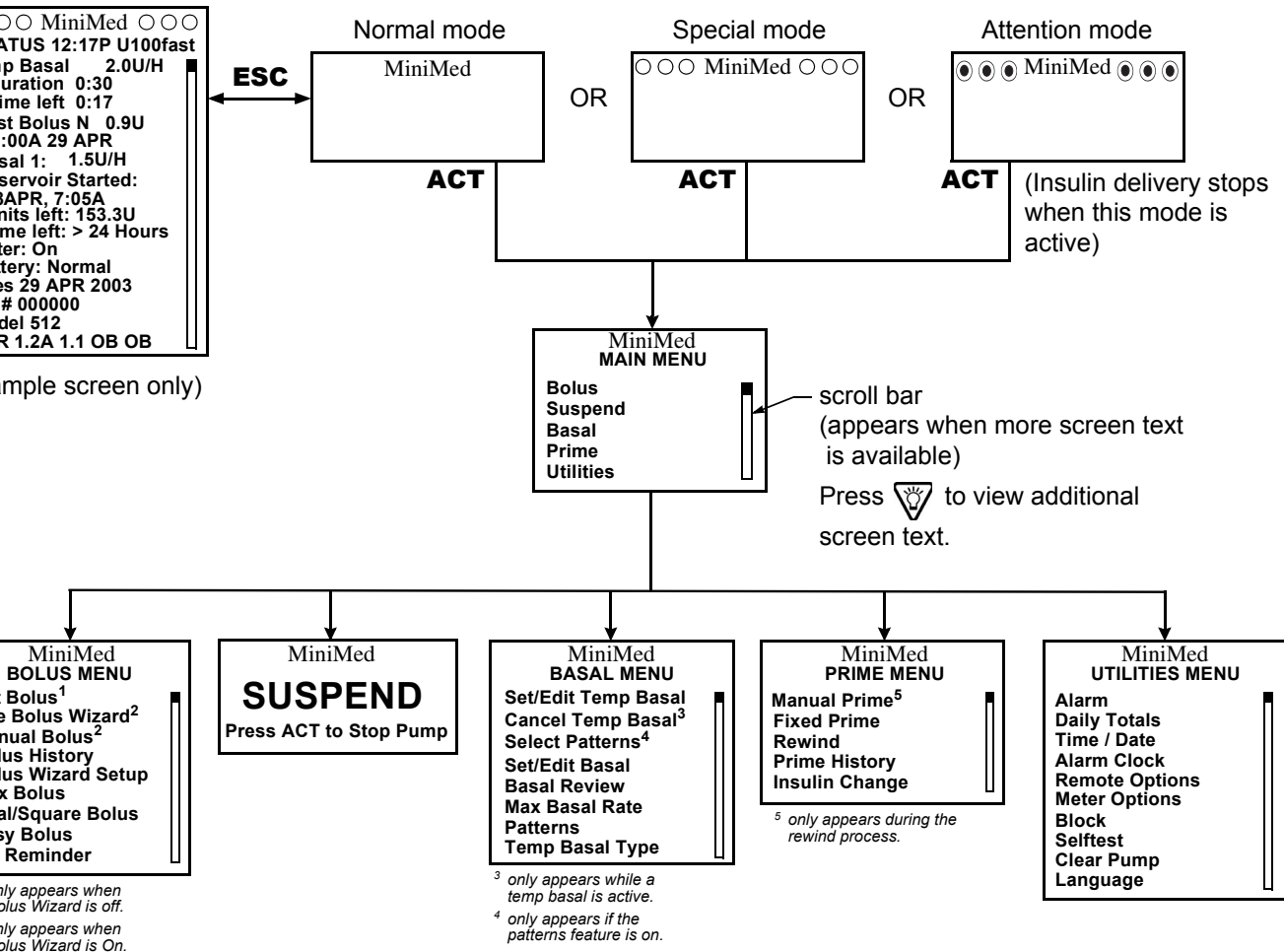
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Menu map



NOTE: All screens are samples only. Actual screens depend on the current active functions.

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- Use Bolus Wizard
- Manual Bolus
- Bolus History
- Bolus Wizard Setup
 - Edit Settings
 - Wizard Off/On
 - Carb Units (grams/exch)
 - Carb Ratios
 - BG Units
 - Sensitivity
 - BG Targets
 - Review Settings
- Max Bolus
 - Max Bolus Setup
- Dual/Square Bolus
 - Off/On
- Easy Bolus
 - Off/On
- BG Reminder
 - Off/On

SUSPEND

- Press ACT to Stop Pump

BASAL

- Set/Edit Temp Basal
 - 0:30 - 24:00
- Cancel Temp Basal
- Select Patterns
 - Standard, A, B
- Set/Edit Basal
 - Standard, A, B
- Basal Review
- Max Basal Rate
 - 0 - 35
- Patterns
 - Off/On
- Temp Basal Type
 - Insulin rate U/H, Percent of basal %

PRIME

- Manual Prime
- Fixed Prime
 - 0 - 10
- Rewind
- Prime History
- Insulin Change
 - U100 Fast Acting
 - U100 Regular Acting

UTILITIES

- Alarm
 - Alarm History
 - Alert Type
 - Beep-long
 - Beep-medium
 - Beep-short
 - Vibrate
 - Auto-Off
 - (0 - 24-hours)
 - Low Resv Warning
 - Units
 - Time
- Daily Totals
- Time/Date
 - 12-hour/ 24-hour
- Alarm Clock
 - Off
 - On
- Remote Options
 - Off
 - On/Set
 - Add, Delete, Review
- Meter Options
 - Off
 - On
 - Add, Delete, Review
- Block
 - Off/On
- Selftest
- Clear Pump
 - No/Yes
- Language