

Insulin Pump Therapy Management Guideline



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An Introduction to Insulin Pump Therapy

Purpose of this document

The intention of this document is to provide basic information regarding safe management of diabetes patients using an insulin pump. It is principally directed at hospital outpatient and inpatient management, but those using an insulin pump should also find many details of use.

It is important to recognise that an insulin pump is simply one of several methods for delivering insulin, albeit a highly sophisticated one. The simplest way to deal with any concerns about a patient on insulin pump therapy will always be to:

1. *stop the pump*
2. *remove the cannula, and*
3. *commence subcutaneous injections or an intravenous infusion of insulin,*

depending on circumstances (see Insulin Pump Calculation Sheet, page 29). However, greater familiarity with the principles of pump therapy may allow a more tailored response.

Increased numbers of patients using insulin pumps

Although the GGC Children's Diabetes Service has had a number of patients on insulin pump therapy for over 10 years, the situation has changed in October 2011 with the release of a Scottish Health Department directive requiring all Health Boards to establish a minimum of 25% of diabetes patients under the age of 18 years on insulin pump therapy by March 2013.

The GGC Children's Diabetes Service currently cares for over 200 patients using insulin pumps. Exposure to patients using an insulin pump will therefore also naturally increase, and hence the need for a clinical guideline. However, it must be emphasised that clinicians will generally only be expected to make decisions on whether pump therapy should or should not continue, and they will *not* be expected to make any changes to insulin pump settings. This is, and will remain, the responsibility of members of the Diabetes Service.

Why use insulin pumps?

Intensification of insulin therapy has been shown to deliver improved glycaemic control, lowered complications' risks, and improve quality of life. This may either be delivered by a **multiple dose injection** ("MDI" or "basal-bolus") **regimen** or by **insulin pump therapy**. Both methods have their advantages and disadvantages.

While both methods require significant knowledge and experience to optimise effectiveness, insulin pump therapy offers a number of advantages over injections:

1. No injections!
2. Allows multiple bolus doses to be given as and when required.
3. Allows fractional doses (e.g. 7.35 units), rather than full or half unit pen doses.
4. Allows very small doses (e.g. 0.025 units) of insulin to be given (e.g. babies & toddlers).
5. Allows variable programmed background (basal) insulin to be given.
6. Management if highly insulin sensitive (e.g. very young, or following exercise).
7. Management of hypoglycaemia (through immediate reduction in active insulin).
8. Management of hyperglycaemia (especially "Dawn Phenomenon" in adolescents).

An insulin pump is a complex device, and should only be managed by someone appropriately trained in its use. However, a basic understanding of a few principles will help any clinician make sensible and appropriate decisions on the care of a patient wearing an insulin pump.

Principles of intensifying insulin management

There are 2 recognised methods of intensifying insulin management:

1. Multiple Dose Injection (“MDI” or “Basal-Bolus”) regimen
2. Insulin pump therapy

Both methods attempt to provide as near to normal physiological insulin delivery as possible.

Multiple Dose Injection therapy

Multiple dose injection therapy relies on the use of two different insulin types, with different absorptions, onsets and durations of action.

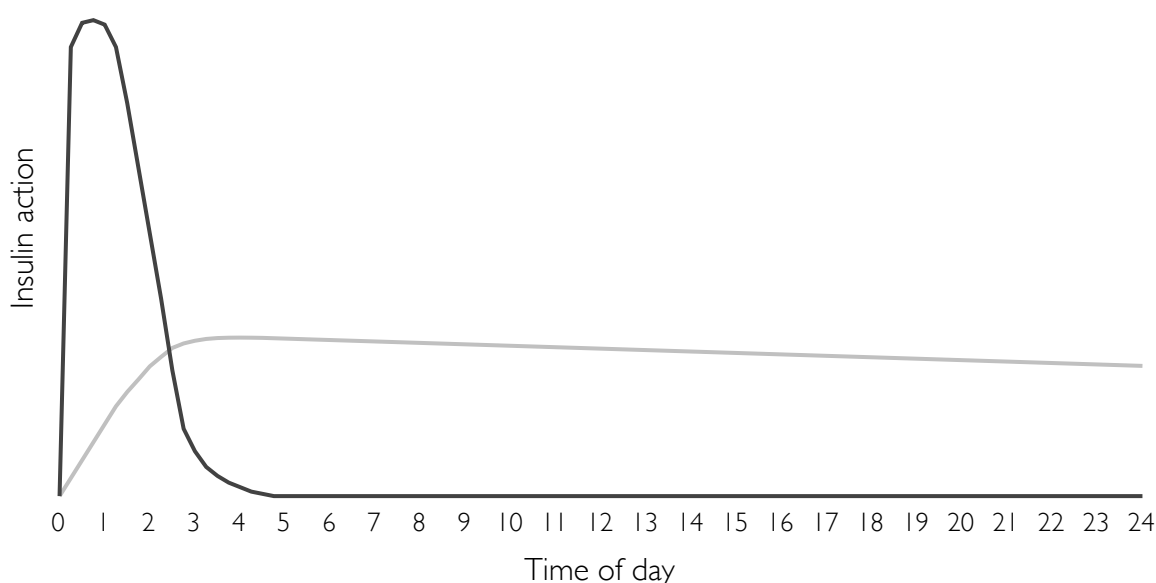


Figure 1: Action profiles of analogue insulins

The main types of insulin used are:

- | 1. Slow-acting analogue insulin | <i>Brand Name</i> | <i>Duration of Action</i> |
|----------------------------------|-------------------|---------------------------|
| 1. Insulin Detemir | (Levemir) | 18-24 hours |
| 2. Insulin Glargine | (Lantus) | 18-24 hours |
| 3. Insulin Degludec | (Tresiba) | 8-42+ hours |
| 2. Rapid-acting analogue insulin | | |
| 1. Insulin Aspart | (Novorapid) | 2-3 hours |
| 2. Insulin Lispro | (Humalog) | 2-3 hours |
| 3. Insulin Glulisine | (Apidra) | 2-3 hours |

When planning a multiple dose injection regimen, one or two daily doses of slow-acting analogue insulins provide background or “basal” insulin cover. In contrast, rapid-acting analogue insulins are given at mealtimes to mimic normal insulin release when eating.

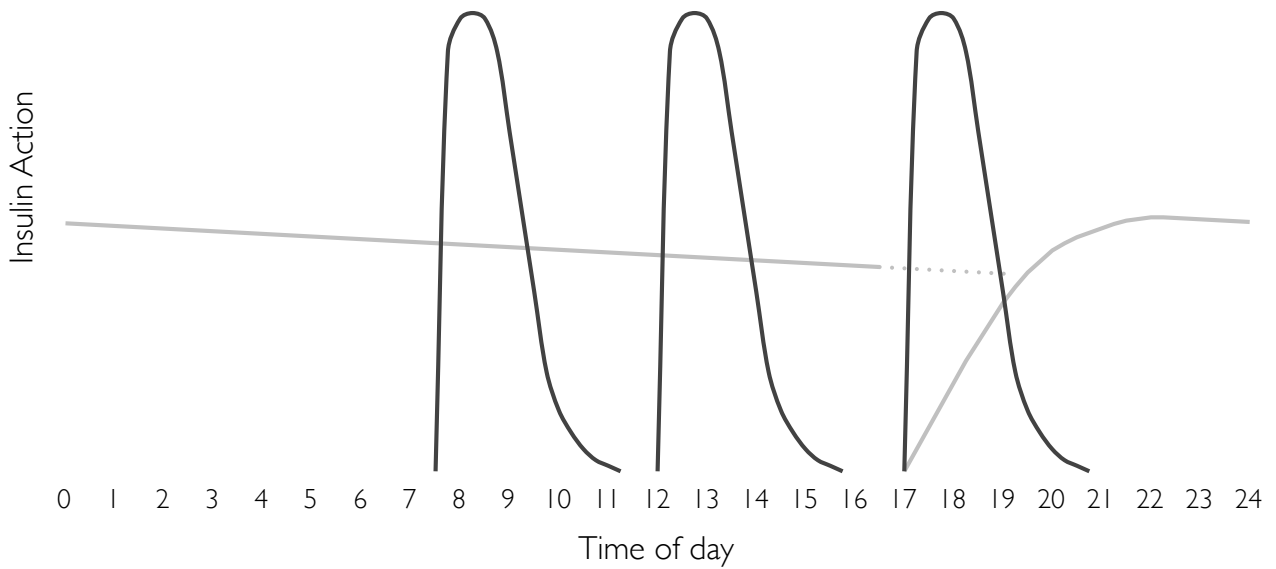


Figure 2: Typical multiple dose injection ("basal-bolus") regimen using slow-acting and rapid-acting analogue insulins

Insulin pump therapy

More formally known as "Continuous Subcutaneous Infusion of Insulin" (CSII), insulin pump therapy attempts to replicate normal insulin physiology in a way similar to that of an MDI regimen, but is capable of doing so in an even more refined and flexible fashion.

In contrast to multiple dose injection regimens, **only rapid-acting analogue insulin is used**, with the pump set to deliver either a very slow rate of background insulin (equivalent to the action of Levemir or Lantus), or a much faster insulin "burst" when eating or hyperglycaemic (equivalent to the action of injected Novorapid or Humalog). This allows multiple boluses daily, a variable rate of basal insulin delivery, and ready correction of hyperglycaemia.

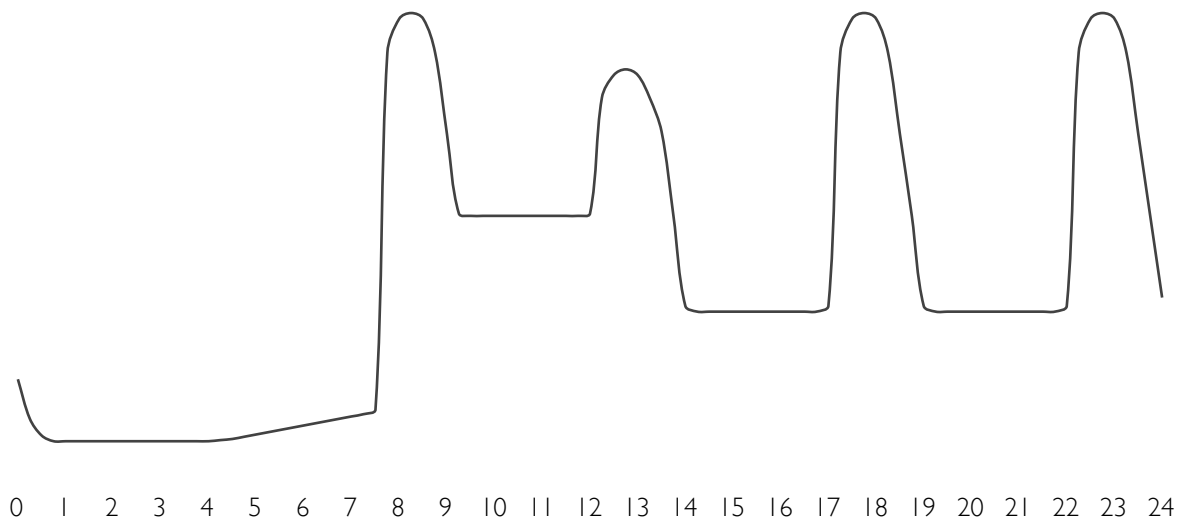


Figure 3: Continuous Subcutaneous Infusion of (Rapid-Acting Analogue) Insulin (CSII)

Insulin Pumps Settings

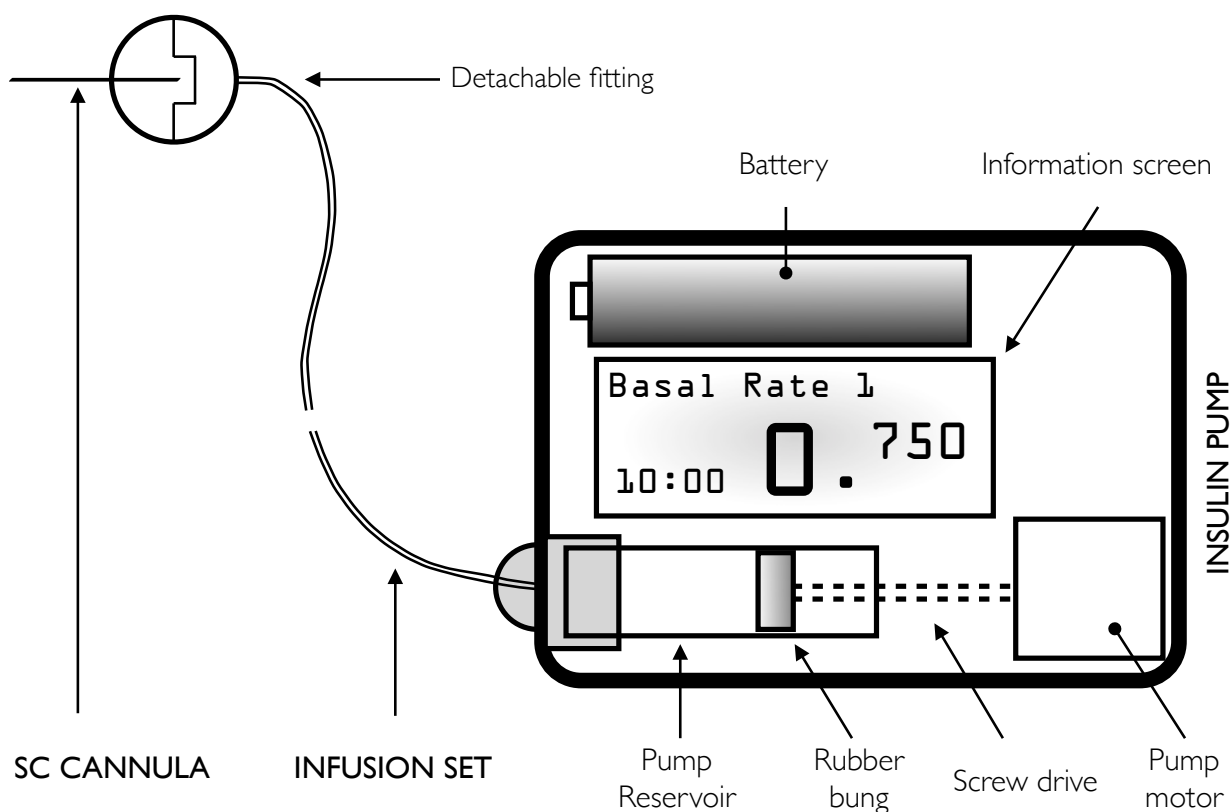


Figure 4: Typical insulin pump and equipment

The **cannula** is inserted using an integrated 27- or 28-gauge needle, and usually sited in the subcutaneous fat of the anterior abdominal wall, the upper outer quadrant of the buttocks, and occasionally into the anterior thigh. Some cannulae are inserted at a 90° angle to the skin (e.g. “Quick Set” or “Mio”), while others are placed at a 20-30° angle (e.g. “Silhouette” or “Inset II”), and insertion may be done either manually or with an inserter device. A cannula is usually resited every 2-3 days, or more frequently if there are concerns regarding patency or inflammation at the insertion point.

The **infusion set** links the cannula to the insulin pump. This fine-bore flexible tube is connected to the cannula via a detachable clip, and at the other end to the insulin reservoir using a twist-lock fitting. The **reservoir** or **cartridge** is a modified syringe, allowing it to be filled directly from an insulin cartridge or ampoule. The plunger detaches to allow the rubber bung of the filled reservoir to be fitted next to the screw drive inside the pump.

While cannulae and infusion sets may be similar, there are a number of different makes and models of **insulin pump**. All pumps share basic design principles, with a display screen, operation buttons, a motor and electronic components, and compartments for both reservoir and battery.

Principles of insulin delivery via insulin pumps

While an injection provides a subcutaneous depot of insulin, a pump delivers very small volumes as a steady infusion. Consequently, there is no insulin depot at the infusion site, and so little reserve of insulin should there be a problem with delivery. This **increases the risk of ketosis and ketoacidosis significantly**, as well as the speed at which this may develop. Constant vigilance through frequent testing of blood glucose and, if indicated, of ketonaemia is needed. Generally 4-6 tests daily are advised, including occasional overnight results.

The parameters that determine insulin delivery by a pump are:

1. **Basal Rate** (including **Temporary Basal Rate**).
2. **Carbohydrate Ratio**
3. **Insulin Sensitivity**
4. Blood glucose target range
5. Duration of active insulin
6. Bolus wave form

All these parameters are common to insulin pumps, but different manufacturers may use different terminology for each setting. The first three highlighted parameters are adjusted most frequently, and so will be dealt with individually below. Other parameters are mentioned for completeness.

All families undergo extensive training in entering and adjusting these parameters. While hospital staff may make suggestions regarding pump settings, it would usually be the pump user and/or their parents who would make any direct changes. Hospital staff would **not** usually be expected to make direct pump adjustments. However, it is useful to have a working understanding of basic principles.

Basal Rate

The **Basal Rate** is a continuous infusion of insulin throughout the 24-hour period a pump is worn. This “basal” or “background” insulin maintains normal metabolic processes, and may be considered the **insulin needed for all purposes other than matching glucose rise after carbohydrate consumption or correction of high blood glucose**. Its action is similar to that of the basal insulins Insulin Glargine (“Lantus”) and Insulin Detemir (“Levemir”), or to a constant intravenous infusion of insulin.

Although termed a basal “rate”, several differing rates are typically set throughout a single day. These reflect the normal circadian variability in beta-cell insulin release, allowing response to variable insulin requirements at different times of day. For example, pre-dawn steroid release makes the body relatively insulin resistant, and so an increasing insulin infusion rate is usually required in the hours prior to waking. Afternoon basal insulin requirements are typically low.

Basal Rate is measured in “Units per Hour”. The current rate settings are accessed via the pump’s display. Volumes delivered may be incredibly small, with most pumps able to deliver just 0.025 units per hour. As the insulin used contains 100 units per ml (“U 100 insulin”), this means a pump can infuse as little as **0.00025 ml per hour!** A very small dose such as this is usually delivered over a few seconds, several times each hour. As such small volumes are used it is easy to see how disruption of insulin delivery may result in rapid development of ketosis.

Adjusting the following parameters sets each basal rate:

1. **Start Time** (24 hour clock)
2. **Hourly dose** of insulin to be infused (Units per hour)

The **Stop Time** is usually the start time for the *following* rate, and so is not usually set directly. There may be as many as 24 individual rates set during a 24-hour period, but this number may vary from pump to pump.

A typical basal rate profile is shown below, with varying amounts of insulin delivered at different times throughout the day.

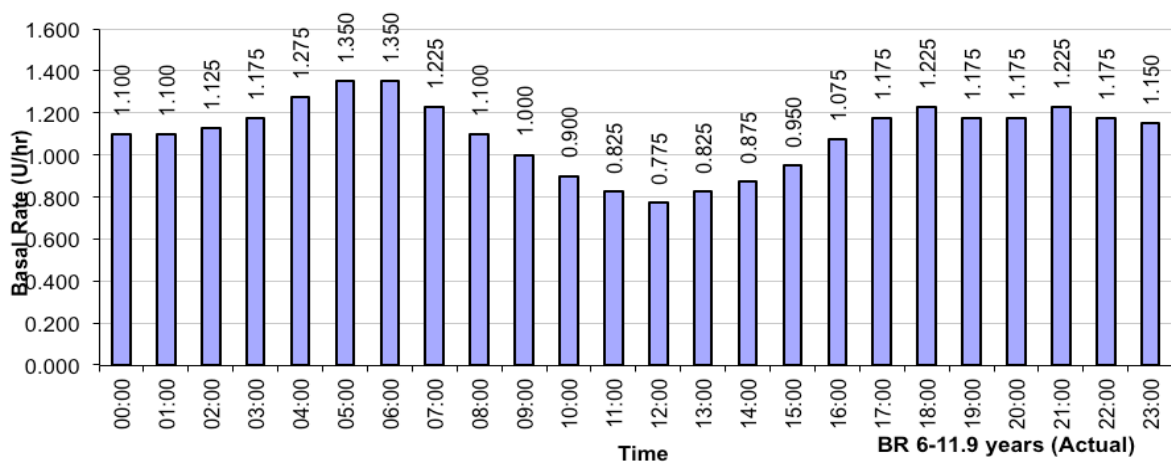


Figure 5: Typical Basal rate insulin profile for patients aged 6-11.9 years of age.

As discussed above, the pump displays and delivers **Units per hour**, and *not* a particular *volume*. It is essential that any change of basal rate is reviewed and confirmed by the family, as setting Start Time and dose decimal points are critical. Families are always taught to review any changes to basal rate by checking the “Basal Review” menu. **Beware! Errors do occur!**

Temporary Basal Rate

A “Temporary Basal Rate” (TBR) is a basal rate set for a limited period of time, usually to deal with issues such as prolonged or vigorous exercise, illness, or during times of inactivity. A percentage increase or decrease to the usual basal rate can be set for a particular duration, and the usual basal rate resumes automatically at the end of this period. The family should be able to set a TBR, but may need clinical guidance on when this is required. Examples of how a TBR might be used are included in the section, “Managing diabetes patients on insulin pumps.”

Carbohydrate Ratio

The pancreas releases insulin in response to a rise in blood glucose, such as after a meal. For someone with diabetes, this rise in blood glucose must be anticipated by measuring the carbohydrate amount to be eaten, and then matching this amount with a particular dose of insulin. This dose is calculated using a Carbohydrate: Insulin ratio, more commonly referred to as a “Carbohydrate Ratio”, or more simply, a “Carb Ratio”. Manufacturers may use different terminology for the same principle (e.g. “ICR”, “Carb Ratio”, “I:C Ratio”, etc.).

A carbohydrate ratio is usually expressed as **Grams** (of carbohydrate eaten) **per Unit** (of insulin administered). The **correct carbohydrate ratio** is one that delivers sufficient insulin to maintain a pre-meal blood glucose 90-120 minutes following that meal. In the examples below, different doses of insulin have been given for a set amount of carbohydrate (e.g. 60 grams). 6 units has maintained the pre-meal blood glucose, while 10 units has caused post-meal hypoglycaemia, and 4 units has seen a significant rise in blood glucose. As 60 grams were eaten, and 6 units the appropriate dose, a “Carbohydrate Ratio” of 10 grams per unit is set.

Carbohydrate ratio may not vary significantly through the day, but equally there may be differences with each meal and snack. A particular difference between a multiple injection insulin regimen and an insulin pump is that while for injections only main meals are treated with bolus insulin, *all* carbohydrate (main meals *and* snacks) is managed with bolused insulin. This causes a different proportions of basal to bolus insulin, as well, with those on injections typically using a 50:50 ratio, while pump patients may only need 30-40% as basal insulin.

As with basal rate, carbohydrate ratio is established by entering a Start Time and then the ratio itself. The Stop Time is automatically entered as the Start Time for the next Carbohydrate Ratio. The patient then enters the amount of carbohydrate due to be eaten. The pump will

calculate the amount of insulin due, and display this as the recommended dose to be given. Although usually appropriate, the patient can choose to override this recommendation.

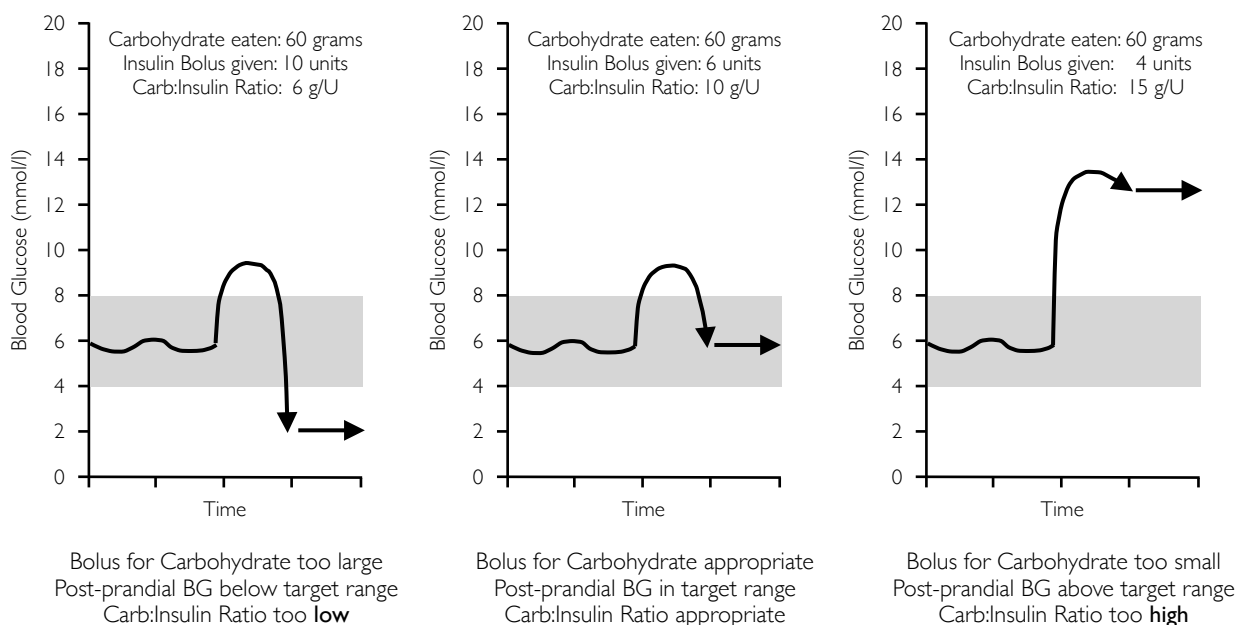


Figure 6: Varying Carbohydrate: Insulin Ratios (“Carb Ratios”) for set 60 grams carbohydrate meal.

An example of variable Carb Ratios might include the following:

Start Time	Carbohydrate Ratio	Units
00:00	20	grams per unit
07:00	8	grams per unit
20:00	15	grams per unit

In our earlier example, a 60 gram meal of carbohydrate was eaten, and 6 units found to maintain the BG before and after meal. The Carb Ratio is “10 grams of carbohydrate per 1 unit of insulin”. If using the same Carbohydrate Ratio (10 grams per unit) different amounts of carbohydrate will require different amounts of insulin to be delivered, as follows.

10 grams	matches	1 unit of insulin
30 grams	matches	3 units of insulin
70 grams	matches	7 units of insulin

This information can be used to work out the ICR, as follows:

1. Measure the amount of carbohydrate to be consumed
2. Compare blood glucose results before and 90 minutes after carbohydrate
3. Note the insulin dose resulting in *similar* before and after meal BG results
4. Divide this insulin dose by the carbohydrate consumed to give a ratio

Insulin Sensitivity

The blood glucose “target” is a result or range within which the majority of BG readings should fall. Those on pump therapy often have a narrow target range set (e.g. 5-6 mmol/l).

A blood glucose *outside* the target range is corrected by either giving extra carbohydrate (if low) or extra insulin (if high). The dose of insulin required to return a high BG result to the target range is called a **Correction Dose**. This is simply an extra amount of insulin given, either as part of a meal-time bolus or separately if high when not eating.

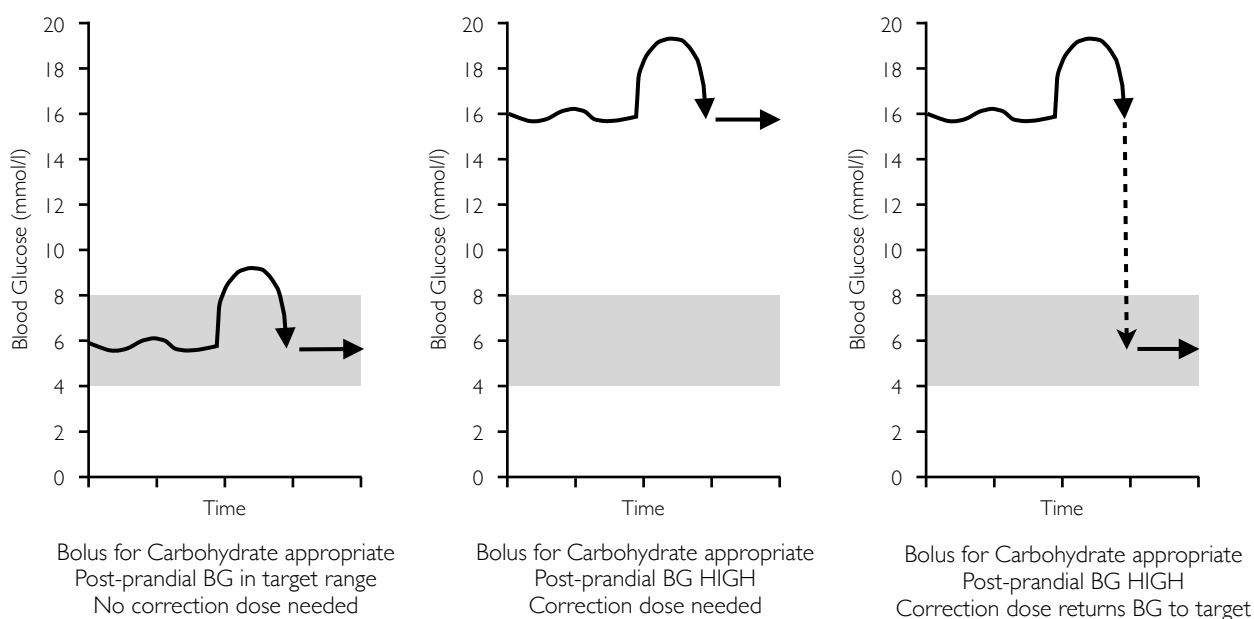


Figure 7: Correction Dose of insulin calculated using Insulin Sensitivity

A **Correction Dose** is calculated according to how sensitive a person is to insulin; if they are very sensitive, they will need *less* insulin to cause the BG to return to the target range. If they are *not* as sensitive, they will need proportionately *more*. A Correction Dose is calculated according to a person's "Insulin Sensitivity" (IS).

Insulin Sensitivity is the measure of how responsive an individual is to insulin. Measured in "**mmol/l per unit**", this represents the expected fall in blood glucose for every extra unit of insulin delivered. As with Basal Rate and Carbohydrate Ratio, Insulin Sensitivity may vary according to the hour of the day. Pubertal adolescents typically have a *low* Insulin Sensitivity in the morning, while toddlers are less sensitive late evening. Both require setting of a *lower* Insulin Sensitivity, resulting in delivery of a *larger* insulin dose to correct hyperglycaemia.

Other pump settings

Insulin pumps usually have a number of other settings. However, these particular settings do not usually require adjustment, often remaining unchanged once entered into the pump.

Blood glucose target range

Ordinarily, the body's homeostatic mechanisms maintain the blood glucose in a fairly narrow range of approximately 4 to 7 mmol/l. Insulin pumps estimate the degree of fall in blood glucose required to return a high result to the "target". The set range is often fairly narrow (e.g. 5-6 mmol/l), and a pump will aim to either return a high BG to the mid-point of the target range (e.g. 5.5 mmol/l), or to the upper limit set (e.g. 6 units, in this case). Subtracting target BG from current BG gives the blood glucose fall required to calculate a Correction Dose.

Duration of active insulin

Once delivered, insulin is metabolised at a fairly steady rate. Rapid-acting analogues, such as Novorapid, have an activity profile that sees a rapid rise in action, with a slow dissipation over several hours (see Figure 1). If an insulin bolus is delivered *before* a previous bolus has been fully cleared from the body (e.g. within 3-4 hours of the previous bolus having been given), then the blood glucose-lowering action may summate. This could result in unanticipated hypoglycaemia. The duration over which a bolus is active may be set in the pump. The effect of any such insulin will be estimated and subtracted from a later bolus suggested by the pump's internal computer, should this bolus be timed for delivery in the "active insulin" time.

Bolus wave form

Different bolus “wave forms” are available. These include:

1. **Standard wave** is delivered immediately, and used for most carbohydrate meals and the correction of hyperglycaemia.
2. **Square wave** (also known as an **extended wave**) delivers insulin evenly over an extended period (e.g. 1-2 hours), and is used when taking small carbohydrate amounts over this time.
3. **Dual wave** (also known as a “**multiwave**”) combines both standard and square wave forms, with a rapid bolus followed by a slower, steady release. It is used for meals high in fat and carbohydrate, where absorption may be delayed for several hours.

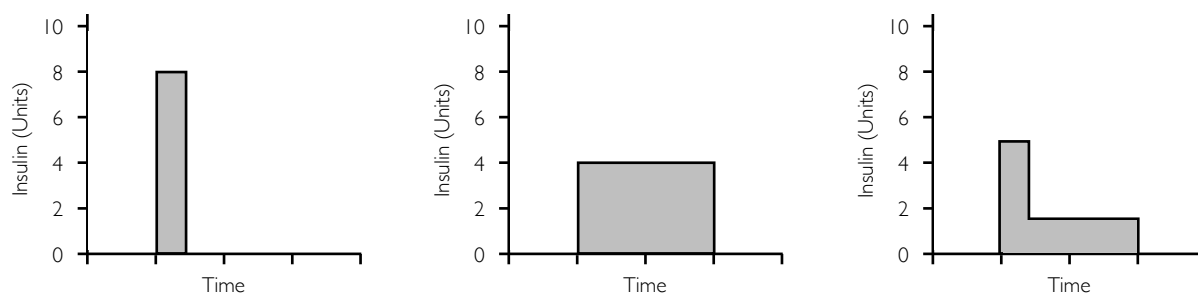


Figure 8: Insulin dose of 8 units, given as (1) a standard bolus, (2) a “square” wave, or (3) a “dual” wave.

Diluted insulin and the risk of severe hypoglycaemia

All insulin commercially available in the United Kingdom is provided in a concentration of 100 units per millilitre. This solution is known as “U100” insulin. Some countries use different concentrations, such as “U40” insulin (40 units per ml). It is possible to *dilute* standard U100 insulins further, using special diluents, to give lower concentrations in larger volumes.

Although current insulin pumps are able to accurately deliver incredibly small volumes of insulin, down to as little as 0.025 units, or 0.00025 millilitres per hour, this amount may still be too great a dose for some small children. In addition, due to the method of pump insulin delivery, where such a dose may be infused over just a few seconds each hour, on the hour, there is actually a chance that a patient may become hypoglycaemic minutes after this small dose is given, but then may develop *ketosis* over the following hour! Typically this occurs when a child’s insulin requirement is less than about 10-12 units per day.

The problems associated with very low insulin requirement can be addressed by using diluted insulin. This is uncommon, but concentration of insulin used should be queried in all infants and young children using an insulin pump. Failure to do so could cause a significantly higher dose of U100 insulin to be prescribed, with attendant serious risk of severe hypoglycaemia. All parents with children on Diluted Insulin are instructed to alert medical staff, but it remains important to always make enquiries regarding insulin concentration, especially in the very young child.

Adjustment to standard “Off Pump” insulin doses for those using Diluted Insulin

- **U10 Insulin** 10 Units per ml Divide calculated U100 dose by **10** to equate U10 dose
- **U20 Insulin** 20 Units per ml Divide calculated U100 dose by **5** to equate U20 dose
- **U50 Insulin** 50 Units per ml Divide calculated U100 dose by **2** to equate U50 dose
- **U100 Insulin** 100 Units per ml No adjustment required

Managing diabetes patients on insulin pumps

The easiest way to deal with any insulin pump problem is simply to stop the pump and give insulin another way; either resume injected insulin or start intravenous insulin, depending on the circumstances. This advice is most simply expressed as:

If in doubt, pull it out!

Clearly this is not the most considered approach, and a little knowledge about how to assess situations will allow management to be more carefully tailored to the situation. There are three particular situations where patients with diabetes on insulin pumps are likely to present for medical care:

1. Patient clinically well, with an insulin pump technical problem
2. Patient clinically unwell, with a diabetes-related problem
3. Patient clinically unwell, with a non-diabetes related problem

1. Patient clinically well, with an insulin pump technical problem

When a patient using an insulin pump presents to the Emergency Department, they may do so seeking advice on pump management. Although all such patients are well-trained how to deal with a problem of insulin delivery while using a pump, they may well seek further direct guidance. This is especially so after hours, when no Diabetes Staff are available, and the family may present for medical advice.

If the family are unable to resolve any technical problem regarding the cannula, infusion set or reservoir they should **resume injection therapy**. Please see **Calculating "Off Pump" SCI & IV Insulin Doses** and the **Insulin Pump Calculation Sheet**, both of which include information on required types and doses of injected insulin. All families are supplied with insulin, pen devices and needles for this purpose, and these should be available at home or in hospital.

The most common technical problem occurs following the **dislodging of the subcutaneous cannula**, and is usually readily resolved by replacing this with a newly-inserted cannula. It is useful to inspect the cannula to see if any fault or kink can be seen. If the problem involves **failure of the pump itself**, the family should contact the Technical Department of their particular insulin pump manufacturer. The family should have ready access to this information, but it is also included in the Insulin Pump Calculation Sheet in the Appendices.

2. Patient clinically unwell, with a diabetes related problem

The two situations where an insulin pump patient may have specific problems due to their diabetes involve:

1. Low blood glucose results
2. High blood glucose results

These should be managed according to the underlying problem. Once again, all patients using pumps may be managed *off the pump* with either subcutaneous injection or intravenous infusion. However, continuing use of the insulin pump may be beneficial in some situations.

Blood glucose results too low

Treatment of hypoglycaemia for insulin pump patients is little different from that required for those taking injected insulin. 10 grams of rapid-acting carbohydrate should be given immediately, and the blood glucose rechecked after 10 minutes. Repeat rapid-acting

carbohydrate every 10 minutes while the blood glucose remains less than 4 mmol/l, but then give some complex carbohydrate once above this level (e.g. digestive biscuit or slice of bread).

Specific management for patients on insulin pumps includes:

1. **Continue current insulin pump basal rates.** There is a 1-2 hour lag between the insulin delivered by a pump and its effect on blood glucose, usually making immediate adjustment of pump basal rate unnecessary.
2. **Set a Temporary Basal Rate.** If hypoglycaemia is profound or prolonged it may be sensible to start a lower Temporary Basal Rate. A 20% reduction from typical basal rate is a reasonable initial change. The TBR may be cut further if borderline or more marked hypoglycaemia occurs, but remember to **check for ketonaemia**, especially if the child is unwell (ketosis can occur in the absence of normal or high blood glucose results when oral intake is poor or during a vomiting illness). A correctly set TBR should result in normoglycaemia. Once the risk of hypoglycaemia has diminished, (e.g. vomiting has settled and/or oral intake improved), stop the TBR and resume the usual basal rate once again. All families should know how to set temporary rates.
3. **Omit insulin bolus for any carbohydrate used to treat hypoglycaemia.** No insulin should be delivered to counteract the rise in blood glucose expected from rapid-acting carbohydrate given as hypoglycaemia treatment, or rebound hypoglycaemia may occur. Bolusing for the next regular carbohydrate meal or snack *is* appropriate, however.

If the patient is unable to tolerate oral carbohydrate it is necessary to follow the “**Hospital Treatment of Hypoglycaemia**” protocol, as for all other diabetes patients, and available at:

http://www.diabetes-scotland.org/ggc/documents/pdf%20files/hospital_hypo.pdf

Blood glucose results too high

Hyperglycaemia may develop for a number of reasons, and correction of hyperglycaemia should be directed towards addressing the underlying cause. This may include:

1. Increased carbohydrate intake
2. Decreased activity levels
3. Illness
4. Technical failure
 1. Cannula kinked or dislodged
 2. Infusion set tubing disconnected from either cannula or reservoir
 3. Pump mechanical failure or other alarm
 4. Battery failure

High blood glucose results in diabetes patients *always* require assessment of ketone status to direct further action. Generally, hyperglycaemia *with* ketosis is due to insulin deficiency (relative or absolute), while hyperglycaemia *without* ketosis is due to carbohydrate excess. All patients on insulin pumps are issued with ketonaemia meters. These provide an accurate and immediate assessment of ketosis.

Due to the small depot of insulin available at any one time to a pump patient, ketosis may develop more easily and more rapidly than for those taking insulin by injection. While an upper limit for ketonaemia of 1.0 mmol/l is appropriate for those injecting insulin, more caution is required for pump patients. This threshold for additional insulin is therefore lowered to 0.6 mmol/l in all insulin pump patients. Any ketonaemia of 0.6 mmol/l or higher in an insulin pump patient requires immediate treatment according to the guidelines attached.

If ketonaemia *less than 0.6 mmol/l*

If there is no obvious pump technical problem, the patient should be advised to:

1. **Give a Correction Dose via the insulin pump.** Calculate according to the currently set Insulin Sensitivity. This dose may either be given separately or with a mealtime bolus (calculated using Carbohydrate Ratio).
2. **Consider a Temporary Basal Rate.** This may be required with *hyperglycaemia* and illness, just as during *hypoglycaemia*. Although regular Correction Dose boluses are usually more effective than an increase in basal rate, if hyperglycaemia persists consider a TBR initially 20% above typical basal rate. Reassess *at least* every 3-4 hours, testing both blood glucose and blood ketones, and adjust the TBR as necessary.

If ketonaemia *greater than or equal to 0.6 mmol/l*,

In this case a problem with insulin delivery must be assumed. Any additional insulin required must therefore **not** be given via the patient's pump but **by injection**, at least until normal insulin pump function can be confirmed.

1. **Give a Ketone Dose via SC injection.** This extra dose of rapid-acting analogue insulin (Novorapid) differs from a Correction Dose in that it is **given by injection**, not pump, and does *not* vary according to blood glucose.
2. **Remove and replace the currently inserted SC cannula.** It is difficult to determine if a patient's raised blood glucose and ketonaemia is due to an intercurrent illness, or whether their symptoms are due to insulin deficiency **secondary to pump technical failure**. It is therefore useful to remove and replace the currently used cannula to reduce the risk of this being the cause of the problem. Cannulae may be dislodged after prolonged use, but may also be poorly inserted, and so inspection of the cannula, and a further repeat insertion may be required. Other pump technical problems should also be considered, and if necessary advice sought from the manufacturer (see Appendix).
3. **Consider a Temporary Basal Rate.** Hyperglycaemia with significant ketonaemia indicates insulin deficiency. An injected dose of rapid-acting analogue insulin (e.g. Novorapid) should be calculated and given while attempting to establish the cause of the problem. A cannula change is usually indicated, but if hyperglycaemia with significant ketosis persists an increased TBR may be useful. As above, running the TBR for 3-4 hours while reassessing blood glucose and ketone status may be useful. It is not uncommon for TBR's of 40-60%, and higher, to be necessary for lengthy periods.
4. **Do not persist with SC insulin pump therapy if clinical response is poor.** The danger of ketosis developing into ketoacidosis mandates cessation of CSII if clinical or biochemical response is poor. Changing a patient to "off pump" SC injected insulin or starting an intravenous insulin infusion removes many of the uncertainties found when using an SC insulin pump during significant ketosis. As always, "*If in doubt, pull it out!*".

Please see "Calculating Off Pump SCI & IV Insulin Doses" Guideline below.

Further notes on using Temporary Basal Rates during intercurrent illness

Gastroenteritis with poor oral intake or recurrent vomiting may make it difficult to maintain normoglycaemia. Illness increases insulin requirements, irrespective of blood glucose. Ketosis may develop from this *relative* insulin deficiency, and be very difficult to manage at home, with admission required for intravenous fluids to maintain adequate blood glucose. Increased TBR *may* be of use, especially if blood glucose over 5-6 mmol/l, when typical Ketone or Correction bolus doses may cause hypoglycaemia. Consider a TBR 20% above standard rates, and assess regularly as outlined above, but a variable rate of intravenous insulin may be preferable.

3. Patient clinically unwell, with a non-diabetes related problem

A patient using an insulin pump may, of course, seek medical attention for a condition *not* directly related to their diabetes. However, their diabetes will continue to require appropriate management. The form of diabetes management will be dictated by the reason for presentation, the care required, and whether the parents of that child are available and willing to manage their child's diabetes on the insulin pump.

A decision should be made on whether **outpatient or inpatient care** is necessary. For example, a child with gastroenteritis requiring intravenous fluids may be easily maintained on their subcutaneous insulin infusion (pump) for the duration of their admission. The parents are responsible for managing their child's glycaemic control, just as if at home. **If the parents are *not* available** or not willing to manage the child's pump therapy, then **the insulin pump should be discontinued and insulin delivered by injection or intravenous infusion**.

Those fasting for emergency surgery may either remain on their insulin pump or have their insulin pump discontinued. If discontinued, insulin will usually be delivered by intravenous infusion, and should be decided by the attending anaesthetist and surgeon in consultation with the on-call paediatric medical team.

This situation may be managed in one of three ways:

1. Patient remains on insulin pump, managed by family
2. Patient stops pump but continues insulin via subcutaneous injections
3. Patients stops pump but continues insulin via intravenous infusion

Further information on how to manage such inpatients is included in the following section, "**Calculating Off Pump SCI & IV Insulin Doses**", and in the Appendix section entitled "**Insulin Pump Management According to Blood Glucose & Ketonemia**". Further guidance is also provided in the Insulin Pump Calculation Sheet, the final section in the Guideline's Appendix.

Medical management of pump patients during hospital admission

If a patient on CSII is to be admitted to hospital, they **must be accompanied at all times by a responsible adult, usually a parent, trained in the management of diabetes using an insulin pump**. If there is no such responsible adult available, or they are unable to remain with the patient for the duration of the admission, then an alternative insulin delivery route (such as subcutaneous injections via insulin pen devices, or an intravenous infusion of insulin) should be used. Other medical requirements (see above) may also require suspension of CSII therapy.

Any suggested changes to insulin pump settings should only be made by someone adequately trained and confident to do so, and usually in consultation with the child's or adolescent's parents, or a member of the Diabetes Team, if available.

Calculating “Off Pump” SCI & IV Insulin Doses

Calculating Regular “Off Pump” Insulin Subcutaneous Injection Doses

Use Insulin **Average Total Daily Dose** (ATDD) to calculate regular daily OFF PUMP DOSES.

Determining ATDD varies with different pumps, and the method for doing this using the most commonly used insulin pumps is illustrated in the Appendix.

- **Basal Dose** = $ATDD \div 4$ 12 hourly SCI. Start NOW (Levemir SCI)
- **Bolus Dose** = $ATDD \div 6$ with main meals (i.e. x 3 daily)* (Novorapid SCI)

* Meal-time Carbohydrate Ratios (as set in the insulin pump) can be used to calculate meal-time insulin boluses. Usually expressed as “grams per unit”, they may need conversion to an Insulin: Carbohydrate Ratio expressed as “Units per 10 gram portion”, due to the difficulty in giving fractions of a unit with a pen device. Further, while pump boluses are typically given at snack times as well as at main meals, to reduce number of injections required a person on an MDI regimen usually only boluses at main meals, and sometimes with large bed-time snacks, relying on basal insulin to deal with BG rises from mid-meal snacks. Regular and Correction Doses should usually be sufficient until insulin pump therapy can resume.

Calculating Insulin Sensitivity (IS) using the 100 Rule

- **Insulin Sensitivity** = BG Fall (mmol/l) per Unit of insulin 4 hourly.
= $100 \div ATDD$ (mmol/l per Unit).

Calculating Correction Dose (CD) using Insulin Sensitivity

A Correction Dose is an additional Novorapid bolus (by injection *or* by pump if operational) to lower BG to target range if above target & Ketonaemia less than 0.6 mmol/l.

- **Correction Dose** = BG Fall Required (mmol/l) \div Insulin Sensitivity (mmol/l per U).
= $(Current\ BG - Target\ BG) \div IS$
= *Extra Units of Novorapid required to lower BG to Target Range.*

Calculating Ketone Dose (KD)

A Ketone Dose is an additional Novorapid bolus (by injection **only**) to treat ketosis if BG greater than 14 mmol/l **and** Ketonaemia greater than or equal to 0.6 mmol/l.

- **Ketone Dose** = $ATDD \div 6$ 4 hourly
= *Extra Units of Novorapid required to reduce Ketosis.*

Ketone doses should be given regularly, **in addition** to all basal and meal-time insulin doses.

Calculating “Off Pump” SCI Insulin Doses with Target BG of 6 mmol/l

If Day 2 TDD = 42 Units, Day 3 TDD = 46 Units and Day 4 TDD = 62 Units, and BG 16 mmol/l:

- **ATDD** = $(42 + 46 + 62) = 150 \div 3$ Units = 50 Units per day
- **Basal Insulin Dose** = $50 \div 4$ Units = 12.5 Units Levemir 12 hourly
- **Carb Bolus Dose** = $50 \div 6$ Units = 8.5 Units Novorapid with main meals
- **Insulin Sensitivity** = $100 \div 50$ Units = 2 mmol/l fall in BG per Extra NOV Unit
- **Correction Dose** = $(16 - 6) \div 2$ Units = 5 Units Novorapid (\pm Carb Bolus)
- **Ketone Dose** = $50 \div 6$ Units = 8.5 Units 4 hourly (\pm Carb Bolus)

Calculating Intravenous “Sliding Scale” Insulin Variable Rate Infusions

Pump settings and ATDD can also be used to calculate a Variable Rate Infusion (VRI) of insulin. This may be required during an emergency admission or while a patient is fasted for surgery, where marked ketosis or ketoacidosis have not yet occurred but must be prevented. One method is estimated from a patient’s weight for use if pump data are not accessible, while the second is based on current pump settings. Either are effective.

ACTRAPID Insulin Variable Rate Infusion based on weight and insulin dose

As a rule of thumb, non-pubertal diabetes patients taking insulin via injection have a

Total Daily Dose requirement of 1 unit of insulin per kg body weight per day.

That is, a 40 kg patient requires about 40 units of insulin daily, with 50% as basal insulin (as one or two daily doses of basal insulin) and 50% as bolus insulin (with main meals, and possibly supper). If very young, or in the Remission Phase (“honeymoon” period), the TDD may be less (e.g. 0.5-0.8 units per kg per day), and if pubertal the requirement may be very much higher (e.g. 1.5-2.0 units per kg per day). However, the following calculations are a reasonable starting point, with the VRI prescription being adjusted in light of BG results.

- Insulin Total Daily Dose = 1 unit per kg per day
- Insulin Hourly Dose = TDD/24 per kg per hour
= 1 unit/24 per kg per hour
≈ 0.04 units per kg per hour

Use this rate as the mid-point of the VRI, with a 1 unit per ml insulin infusion, and a maintenance rate of intravenous fluids (e.g. NaCl 0.45% + Dextrose 5%) as follows:

BLOOD GLUCOSE RANGE (mmol/l)	ACTRAPID INFUSION RATE (ml/hr of 1 U/ml solution)	EQUIVALENT TO INSULIN/kg (Units/kg/hr)
> 22	Wt (kg) x 0.1	0.1
14 - 22	Wt (kg) x 0.07	0.07
8 - 13.9	Wt (kg) x 0.04	0.04
4 - 7.9	Wt (kg) x 0.02	0.02
< 4 *	Wt (kg) x 0.01 *	0.01

- If hypoglycaemic*, increase infused dextrose concentration while continuing current VRI (e.g. increase from NaCl 0.45% + Dextrose 5% to NaCl 0.45% + Dextrose 10%).
- If further hypoglycaemia, despite doubling infused concentration of Dextrose and, if ketosis negative or minimal, re-prescribe VRI using same 1 unit per ml Actrapid Infusion Rates (ml/hr) for each immediately *higher* BG range in table (e.g. use Wt x 0.01 ml/hr for 4-7.9 mmol/l range, Wt x 0.02 ml/hr for 8-13.9 mmol/l range, etc.). The lowest Insulin Infusion Rate should be halved (e.g. from Wt x 0.01 ml/hr to Wt x 0.005 ml/hr).
- If BG results persistently high (> 14 mmol/l), check for ketosis and consider re-prescribing VRI, using same Actrapid Infusion Rates (ml/hr) for each immediately *lower* BG range in table (e.g. use Wt x 0.04 ml/hr for 4-7.9 mmol/l range, Wt x 0.07 ml/hr for 8-13.9 mmol/l range, etc.). Increase highest Actrapid Infusion Rate (e.g. from Wt x 0.08 ml/hr to Wt x 0.1 ml/hr or higher).

Insulin Variable Rate Infusion based on insulin pump settings

The principles of calculating an insulin Variable Rate Infusion are the same as for prescribing SC injections of insulin, and are based on establishing the ATDD from pump settings (see Appendix). The VRI mid-point will generally be the ATDD ÷ 24, to give a “per hour” rate, and the rest of the scale will be calculated accordingly.

The following table shows some recommended Insulin Infusion Rates based on the typical average basal rate:

BLOOD GLUCOSE RANGE (mmol/l)	ACTRAPID INFUSION RATE (ml/hr of 1 U/ml solution)	EQUIVALENT TO INSULIN/kg (Units/kg/hr)
> 22	ATDD x 0.10	ATDD x 0.10 / kg
14 - 22	ATDD x 0.07	ATDD x 0.07 / kg
8 - 13.9	ATDD x 0.04	ATDD x 0.04 / kg
4 - 7.9	ATDD x 0.02	ATDD x 0.02 / kg
< 4 *	ATDD x 0.01 *	ATDD x 0.01 / kg

- As with the VRI calculated by weight, a BG less than 4 mmol/l mandates an increase in the concentration of infused Dextrose delivered, and persistent hypoglycaemia would require an adjustment to the VRI prescription itself, with lower rates infused for the same BG range.
- Persistent hyperglycaemia, with a BG constantly above 14 mmol/l, requires testing for ketosis and a prescription adjustment, with higher rates infused for the same BG range.

The VRI prescription shown below is for a patient with an Average Total Daily Dose of Insulin of 50 units, and weight of 60 kg. Assuming delivery of maintenance rates of intravenous fluids (NaCl 0.45% + Dextrose 5%) the following infusion rates and insulin doses would apply:

BLOOD GLUCOSE RANGE (mmol/l)	ACTRAPID INFUSION RATE (ml/hr of 1 U/ml solution)	EQUIVALENT TO INSULIN/kg (Units/kg/hr)
> 22	50 x 0.10 = 5.0	50 x 0.10 / 60 ≈ 0.08
14 - 22	50 x 0.07 = 3.5	50 x 0.07 / 60 ≈ 0.06
8 - 13.9	50 x 0.04 = 2.0	50 x 0.04 / 60 ≈ 0.03
4 - 7.9	50 x 0.02 = 1.0	50 x 0.02 / 60 = 0.015
< 4 *	50 x 0.01 = 0.5 *	50 x 0.01 / 60 ≈ 0.01

Calculating Intravenous Insulin Fixed Rate Infusion for Ketoacidosis

As has been stated previously, insulin pump patients are theoretically more prone to developing ketoacidosis. All such patients have a prime requirement for insulin replacement, and as such a Variable Rate Infusion is **not** appropriate. Instead, a Fixed Rate Infusion must be used, generally starting with an Actrapid dose of 0.1 Units/kg/hr (although for the very young, and depending on the degree of acidosis, a lower fixed rate of 0.05 Units/kg/hr may be more appropriate).

The **DKA Protocol** should be used for all patients with such metabolic decompensation.

Appendix

Determining Average Total Daily Doses of Insulin

1. Displaying Total Daily Dose on MEDTRONIC Insulin Pumps

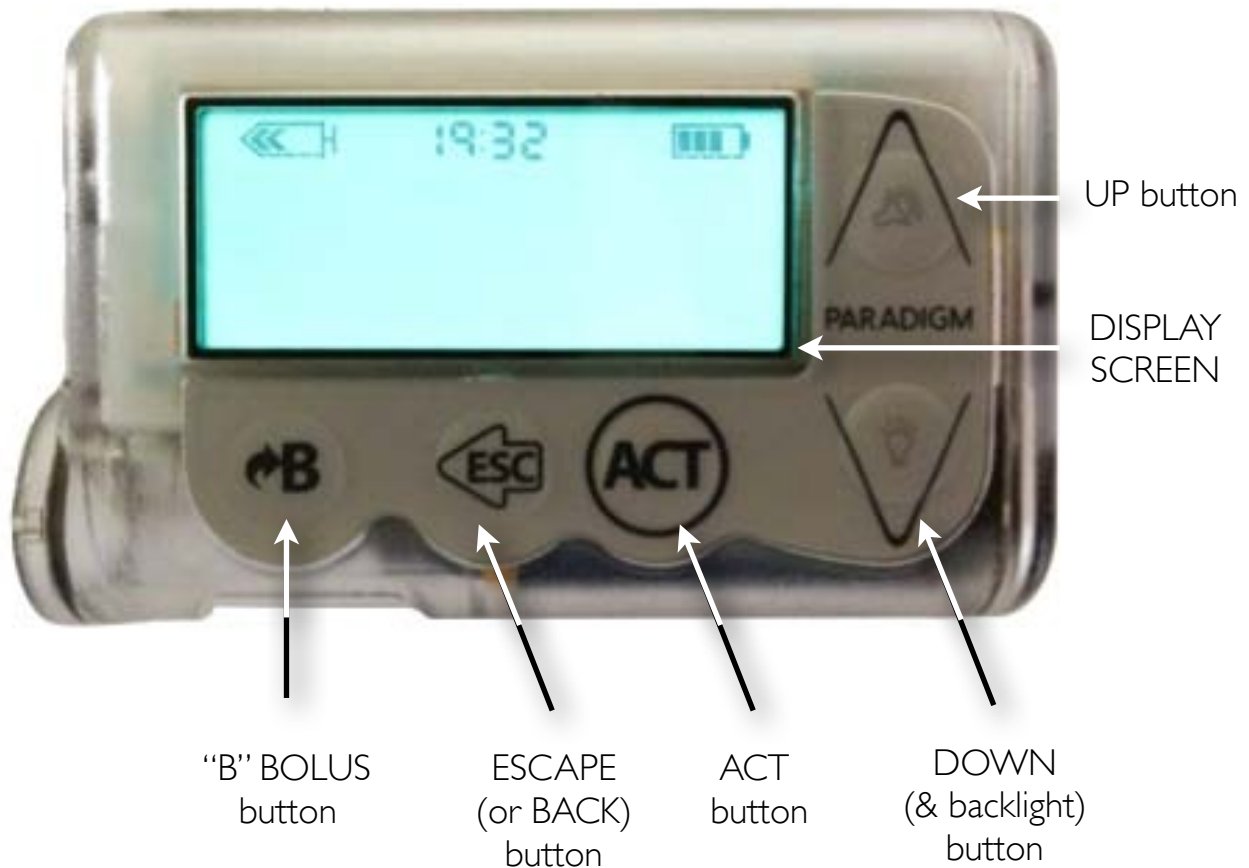


Figure 9: Medtronic insulin pump

The insulin pump normally displays the above screen until activated. However, the pump may be locked to prevent a child from accessing settings. In this case, the Display Screen will show the message "KEYPAD LOCKED. To unlock, press B and UP keys at the same time".

To unlock the pump:

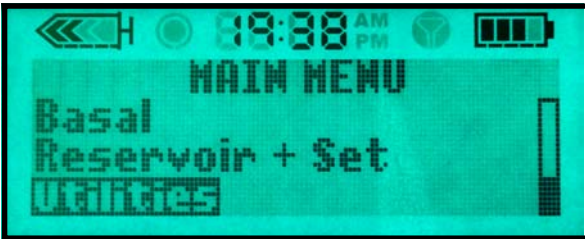
1. Press and hold the "B" BOLUS button
2. Press the UP button once



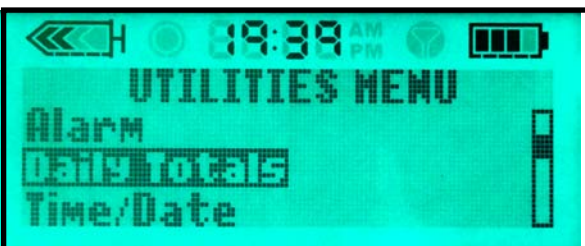
Display will show the message "KEYPAD UNLOCKED", and then revert to the screen shown in Figure 9.



1. Press ACT to access MAIN MENU. This shows menu items “Bolus”, “Suspend” and “Sensor”.
2. Press DOWN arrow to scroll to UTILITIES menu.

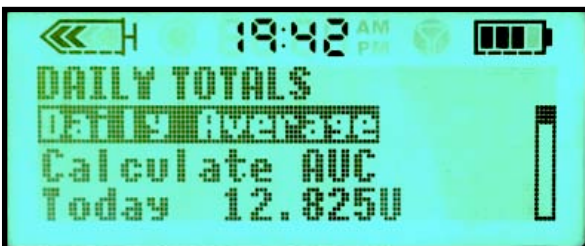


3. Press ACT button to enter UTILITIES menu.



UTILITIES MENU appears as shown to left.

4. Press DOWN to scroll to DAILY TOTALS menu.
5. Press ACT to enter DAILY TOTALS menu.



DAILY TOTALS menu appears as shown.

DAILY AVERAGE is the first menu option, and will already be highlighted in screen.

6. Press ACT button to access DAILY AVERAGE..



DAYS TO AVERAGE screen appears as shown. Select the number of days from which average TDD is calculated. “3” Days is used here.

7. Press UP or DOWN buttons to enter number of days from which to calculate Total Daily Dose
8. Press ACT button.



From the DELIVERY STATS screen observe TOT INSULIN amount. This is the **average** Total Daily Dose calculated from the number of most recent full calendar days chosen in Step 7.

This is the amount to be used for calculating doses to be given by subcutaneous injections.

The Average TDD is calculated and displayed (here it is 15.875 units *per day*), and does not need to be further divided by the number of days assessed, as is the case with other pumps.

2. Displaying Total Daily Dose on ANIMAS Insulin Pumps



Figure 10: Animas insulin pump

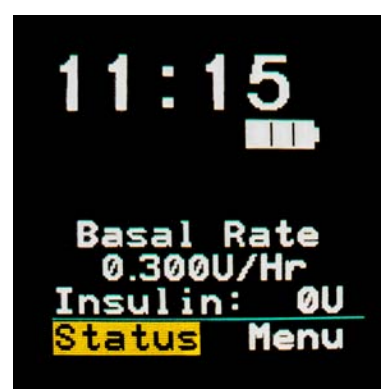
When first accessing an Animas insulin pump, the display screen may appear to be turned off. Touching any button will activate the Display Screen, as seen above. This shows the display screen details, and the MENU selection is generally highlighted by default.



The Animas insulin pump may be locked to prevent a child from accessing settings, and the Display Screen will show the word "(LOCKED)".

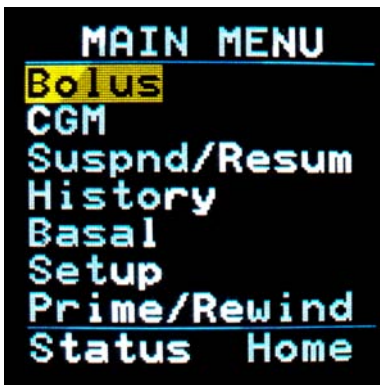
The pump may be unlocked by:

- Pressing and holding both the UP and DOWN buttons simultaneously.

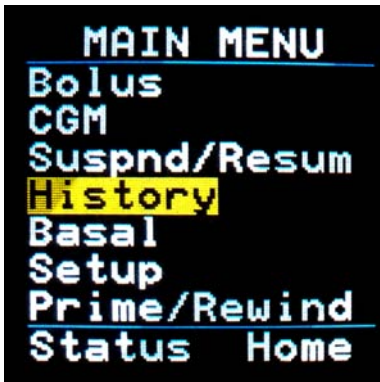


The Display Screen usually appears as shown above Left, with "MENU" highlighted by default. If "STATUS" is highlighted (as shown above Right) reselect "MENU" using Down arrow. The Up arrow may be used to reselect "STATUS".

Select MENU by pressing OK button once, which will then open the MAIN MENU.



1. Scroll down MAIN MENU, using DOWN button, to access HISTORY selection.



2. Select HISTORY from MAIN MENU by pressing OK once.



3. Scroll down HISTORY menu to access TOTAL DAILY DOSE (TDD) setting.



4. Select TOTAL DAILY DOSE (TDD) by pressing OK once.



Arrow at bottom left of screen will be highlighted.

NOTE: Pressing OK at this point will take you back to the HISTORY menu. Rather, we need to select the Day of Record 1 noted in top right of screen.

5. Press UP Arrow to select Record 1, as shown in next image.



6. Press OK once Record 1 highlighted. The number will flash. This allows the UP and DOWN buttons to then scroll through to other Days.



NB: Do **NOT** use TDD data from RECORD 1 (Current Day) as this will only have recorded insulin delivered for a partial day. **Instead:** Scroll through TDD's from DAY 2, 3 and 4, as shown below.



Day 2 TDD shown at left.



Day 3 TDD shown at left.



Day 4 TDD shown at left.

7. Add the TOTAL DAILY DOSES from Days 2, 3 and 4, and average the total.

Day 2 Total Daily Dose:	2.28 Units
Day 3 Total Daily Dose:	1.92 Units
Day 4 Total Daily Dose:	<u>6.44 Units</u>
D2+D3+D4 Basal Dose:	10.64 Units
Average Total Daily Dose:	$10.64 \div 3 \approx 3.5$ Units

3. Displaying Total Daily Dose on ROCHE ACCU-CHEK Insulin Pumps



Figure 11: Roche Accu-Chek insulin pump

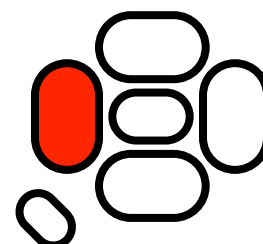
Roche Accu-Chek insulin delivery devices use a Handset to control the pump. The two units are linked and synchronised using Bluetooth wireless connectivity. Unlike other devices, most Accu-Chek pump settings are entered on the Handset, rather than using the Pump itself.

The following instructions include screen shots of the Roche Handset.

There are 9 buttons on the handset face. Of these, the four ARROW buttons, the central SELECT buttons, and the lower left POWER OFF button are those needed to set and access the required pump data.

For clarity, a **schematic** for selection of the appropriate buttons is shown at Right. The schematic shows selection of the **Left Arrow**.

The procedure for accessing the Total Daily Dose for the 3 previous days is unfortunately complex, but the guide below shows step-by-step actions using the Handset



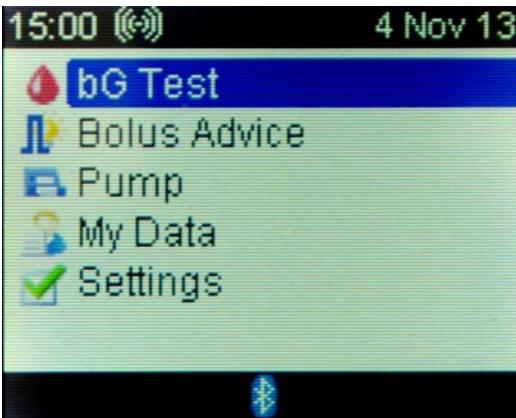
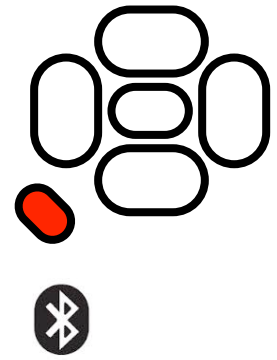


1. Hold ON/OFF BUTTON till **Accu-Chek** display shown:

- activates Handset
- connects Handset to Pump

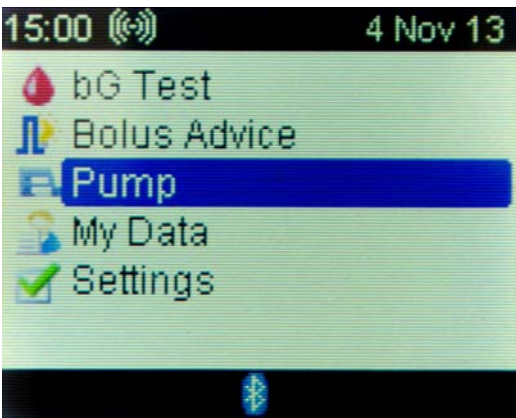
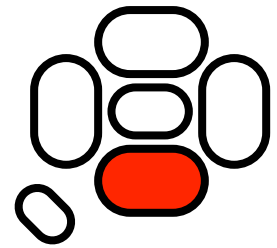
Handset shows ACCU-CHEK screen, then MAIN MENU.

Pump shows Bluetooth symbol.

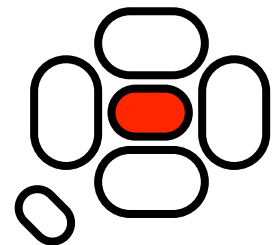


MAIN MENU selects **bG Test** as default.

2. Scroll down to **Pump** using **DOWN** arrow.



3. Select **PUMP** from Main Menu to show **PUMP Status** screen.



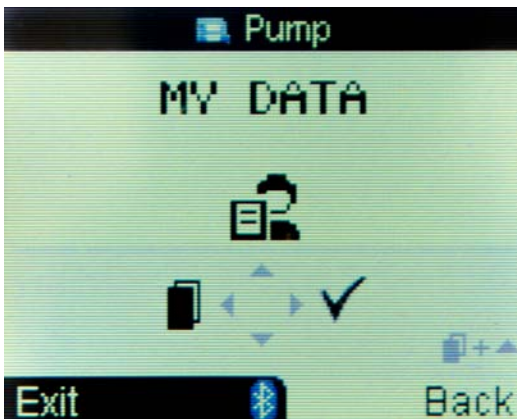
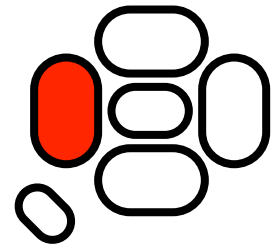
Pump Status screen shows

- Time
- Basal Rate program
- Basal Rate



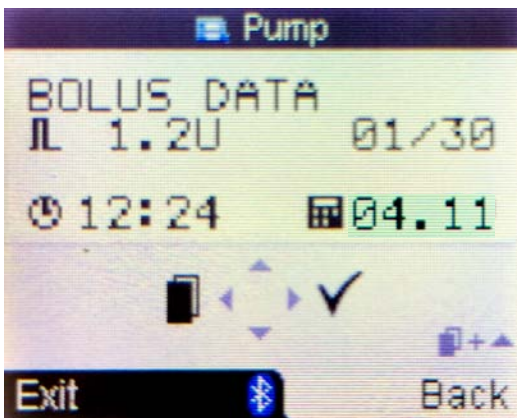
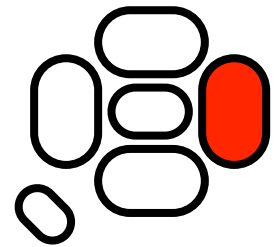
4. Press LEFT Arrow x 6 to Cycle through following screens:

- Pump Status
- Stop Your Pump
- Standard Bolus
- Extended Bolus
- Multiwave Bolus
- Temp. Basal Rate until **My Data** screen accessed.



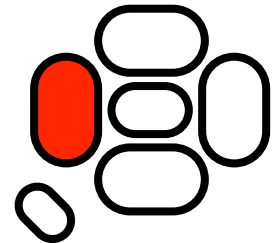
On accessing **My Data** screen

5. Press RIGHT Arrow to display **Bolus Data** screen



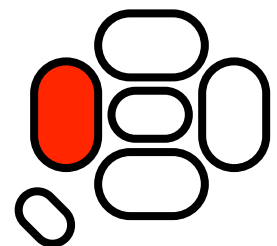
On showing **Bolus Data** screen

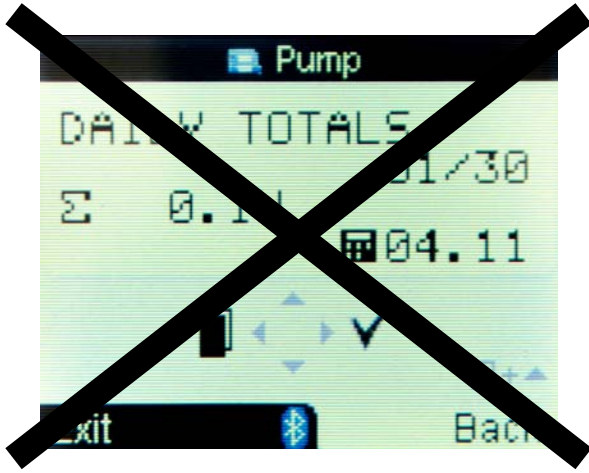
6. Press LEFT Arrow to display **Error Data** screen



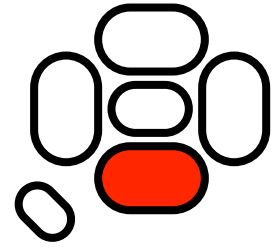
On showing **Error Data** screen

7. Press LEFT Arrow to display **Daily Totals** screen.





Daily Totals screen shows Total Daily Dose for date accessed. e.g. 4.11 (i.e. 4th November).

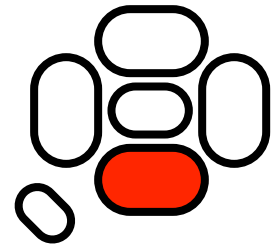


Do NOT use TDD for the first date displayed (4.11), as this total will be **not for a completed day**.

Day 2 (of 30)



8. Scroll back through **Daily Totals** (TDD's) of previous 3 complete days via DOWN Arrow.



In this example, Total Daily Doses are shown for:

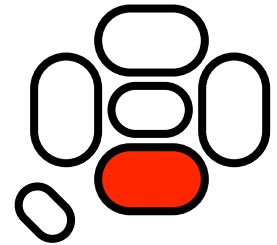
- 3.11 (12.8 units)
- 2.11 (4.0 units)
- 1.11 (12.8 units),

the first 3 complete days before today's date (4.11).

Day 3



9. Press DOWN Arrow to access Daily Totals (TDD's) for each of last 3 completed days.



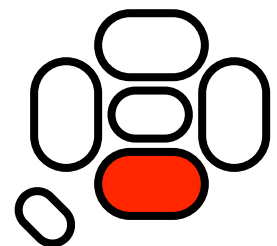
Day 4



10. Average these 3 completed days' Total Daily Doses to find the Average Total Daily Dose.

- D2 TDD: 12.8 Units
- D3 TDD: 4.0 Units
- D4 TDD: 12.8 Units
- D2+D3+D4 Dose: 29.6 Units

Average Total Daily Dose: $29.6 \div 3 \approx 9.9$ Units / day

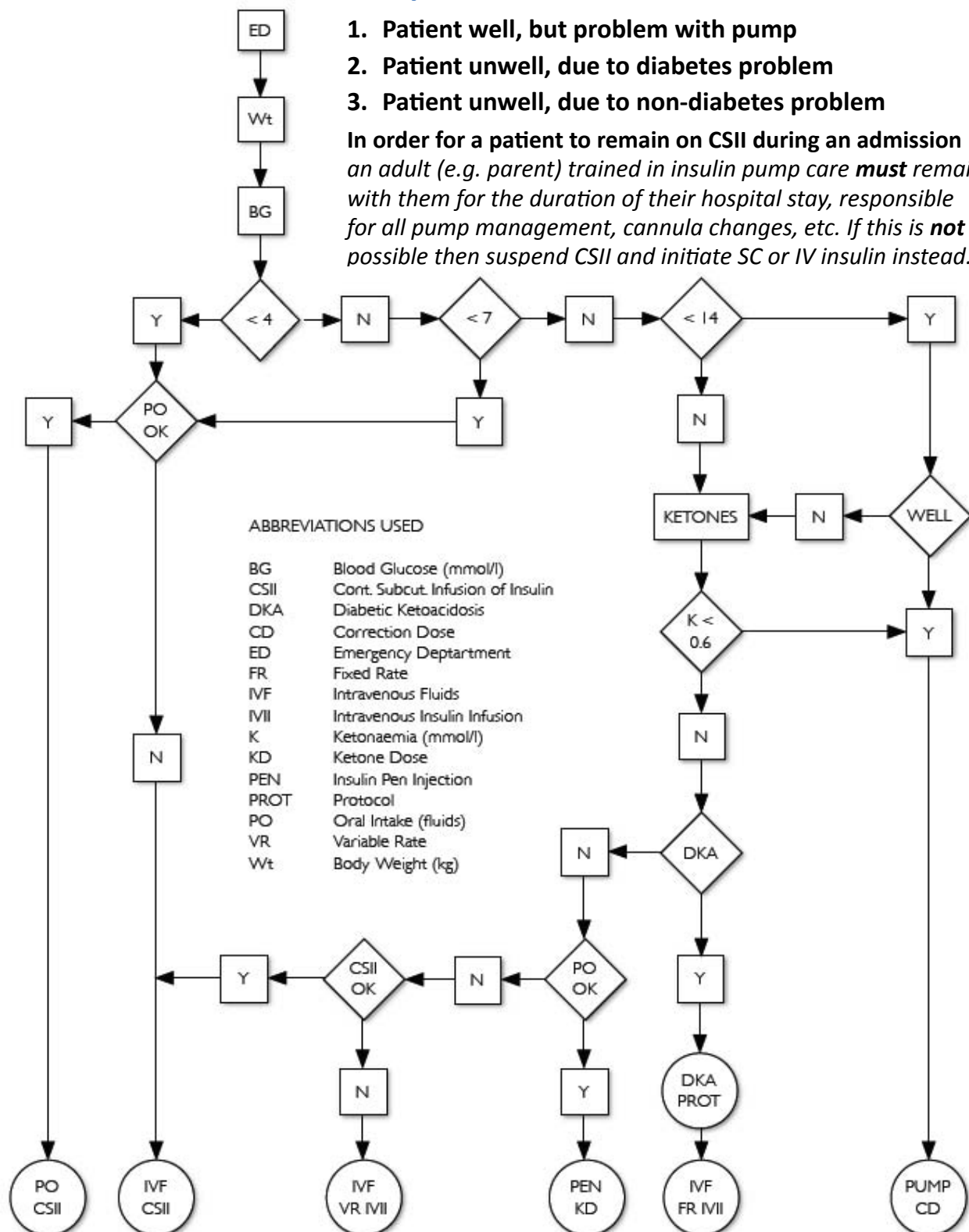


Insulin Pump Management According to Blood Glucose & Ketonaemia

Pump Patient Presentations (See p 12-14)

1. Patient well, but problem with pump
2. Patient unwell, due to diabetes problem
3. Patient unwell, due to non-diabetes problem

In order for a patient to remain on CSII during an admission an adult (e.g. parent) trained in insulin pump care **must** remain with them for the duration of their hospital stay, responsible for all pump management, cannula changes, etc. If this is **not** possible then suspend CSII and initiate SC or IV insulin instead.



The above flow chart is a guide to clinical management in most situations, but should be used in conjunction with the information from Pages 13-16 of the Guideline. Other factors such as knowledge of the patient's medical condition, management considerations (e.g. admission requirements, need to remain nil by mouth, etc.), and the proper functioning of the pump itself must all be taken into account when planning appropriate clinical care.

Insulin Pump Calculation Sheet

Helpline Numbers: Medtronic 01923 205 167
 Animas 0800 055 6606
 Roche/Accu-Chek 0800 731 2291

Calculating "Off Pump" Regular Insulin Doses

Check if U100 or Diluted Insulin Used!

U10 Insulin Divide calculated U100 dose by 10
U20 Insulin Divide calculated U100 dose by 5
U50 Insulin Divide calculated U100 dose by 2
U100 Insulin No adjustment required

- **Avg Total Daily Dose (ATDD)** Units (see Appendix)
- **Basal Insulin Dose** $ATDD \div 4$ Units Levemir, Lantus 12 hourly
- **Carbs Insulin Dose** $ATDD \div 6$ Units Novorapid at Main meals

Calculating Correction Dose of Novorapid using Insulin Sensitivity

- **Insulin Sensitivity** $100 \div ATDD$ mmol/l BG fall per Unit Novorapid
- **Correction Dose** $BG\ Fall \div IS$ Units Novorapid 3 - 4 hourly

Calculating Ketone Dose of Novorapid

- **Ketone Dose** $ATDD \div 6$ Units Novorapid 3 - 4 hourly

↑
Give alone or add to any Regular Novorapid Dose at meal times
 ↓

Round **DOWN** all SC Insulin doses to nearest 0.5 Units (if using 0.5 unit increment pen device)

Initial Variable Rate IV Infusion of ACTRAPID Insulin

NB: Do NOT Use Novorapid IV

BLOOD GLUCOSE RANGE (mmol/l)	ACTRAPID INFUSION RATE (ml/hr of 1 U/ml solution)	EQUIVALENT TO INSULIN/kg (Units/kg/hr)
> 22	$ATDD^* \times 0.1$	0.1
14 - 22	$ATDD^* \times 0.07$	0.07
8 - 13.9	$ATDD^* \times 0.04$	0.04
4 - 7.9	$ATDD^* \times 0.02$	0.02
< 4	$ATDD^* \times 0.01$ (& Increase [Dextrose])	0.01 (& Increase [Dextrose])

* Use Patient Body Weight (in kg) in place of ATDD if latter not available (e.g. pump failure) (See Pages 12-17 for more details on how to use and adjust the above VRI prescription).

Please let us know if you have any comments about how this document might be improved, or if you find any errors in or omissions from the text. Thank you.