Initiation of insulin pump therapy in patients with type 1 diabetes

Dr Pang Shir Wey Gloria
Specialist in Paediatric Endocrinology
Department of Paediatrics and Adolescent Medicine
JHKCH

Introduction to hybrid closed loop therapy



What is an insulin pump?

An insulin pump is a medical device used for the administration of insulin in the treatment of diabetes mellitus, also known as continuous subcutaneous insulin therapy

What is hybrid closed loop system?

If you have type 1 diabetes, you already use a treatment loop – you measure your blood glucose levels, work out how much insulin you need, then take a dose of insulin. For this, you need a blood glucose meter, your brain, and an insulin pen.

If you're using a hybrid closed loop system, you use a CGM instead of a blood glucose meter, an insulin pump instead of a pen, and an algorithm instead of your brain.

A century of diabetes technology



Insulin discovered: Frederick Banting, Charles Best, 1921

1920

First commercial insulin: Iletin, Eli Lilly & Co, 1923





First self-monitoring device: Ames reflectance meter

1960



Backpack insulin and glucagon intravenous pump



First subcutaneous insulin pump: the Auto Syringe (D. Kamen)

Intravenous closed-loop glucose control (Biostator): Albisser *et al.* [12]; Pfeiffer *et al.* [13]; Mirouze, Selam *et al.* [14].

First use of subcutaneous insulin pump, Tamborlane *et al.* 1978 [18]; Pickup *et al.* 1979 [17].

The Minimal Model of Glucose Kinetics, Bergman & Cobelli, 1979 [44].

1980



Subcutaneous Continuous Glucose Monitoring introduced: the Minimed CGMS, 1999

- Blood glucose meters and insulin pumps become smaller, better, and more automated;
- Mathematical models of diabetes become larger. More precise, and more complex.



2000



In silico model of the human metabolism accepted by FDA as a substitute to animal trials: Kovatchev, Cobelli, Dalla Man, Breton 2008 [40].



DiAs: First wearable closed-loop system: Keith-Hynes *et al.* 2012 [65].



Medtronic 670G – first commercial hybrid closed-loop: automated basal rate and manually administered boluses, 2017.

Pivotal trial of Tandem Control IQ using Dexcom G6 sensor and the DiAs algorithm to automate basal rate *and* correction boluses *without sensor fingerstick calibration*, 2018–2019.



2020

The first closed loop pump

In the early 1960s, Dr. Arnold Kadish developed a closed-loop device for blood glucose control using a double-lumen autoanalyzer to measure blood glucose linked to an intravenous insulin infusion pump

Although it worked, the prototype was considered so bulky, worn as a backpack, and complicated, that it was never commercialized



.Diabetes therapy 2020 May 14;11(6):1251–1269. **Evolution of Insulin Delivery Devices: From Syringes, Pens, and Pumps to DIY Artificial Pancreas**

The first commercial closed loop pump

Biostator Glucose Controller in 1976

60 kg bedside device

Used for post- surgery cases in Type 1 diabetes patients and diabetic ketoacidosis

Closed loop artificial pancreas system which delivers insulin or dextrose intravenously and requires a small amount of venous blood which continuously flows through the machine to analyze blood glucose concentrations



•. A H Clemens, P H Chang, R W Myers 1977:Suppl 7:23-33. **The development of Biostator, a Glucose Controlled Insulin Infusion System (GCIIS)**

Programmable implantable Medications systems

MiniMed Implantable Pump or MIP
(derived from PIMS)

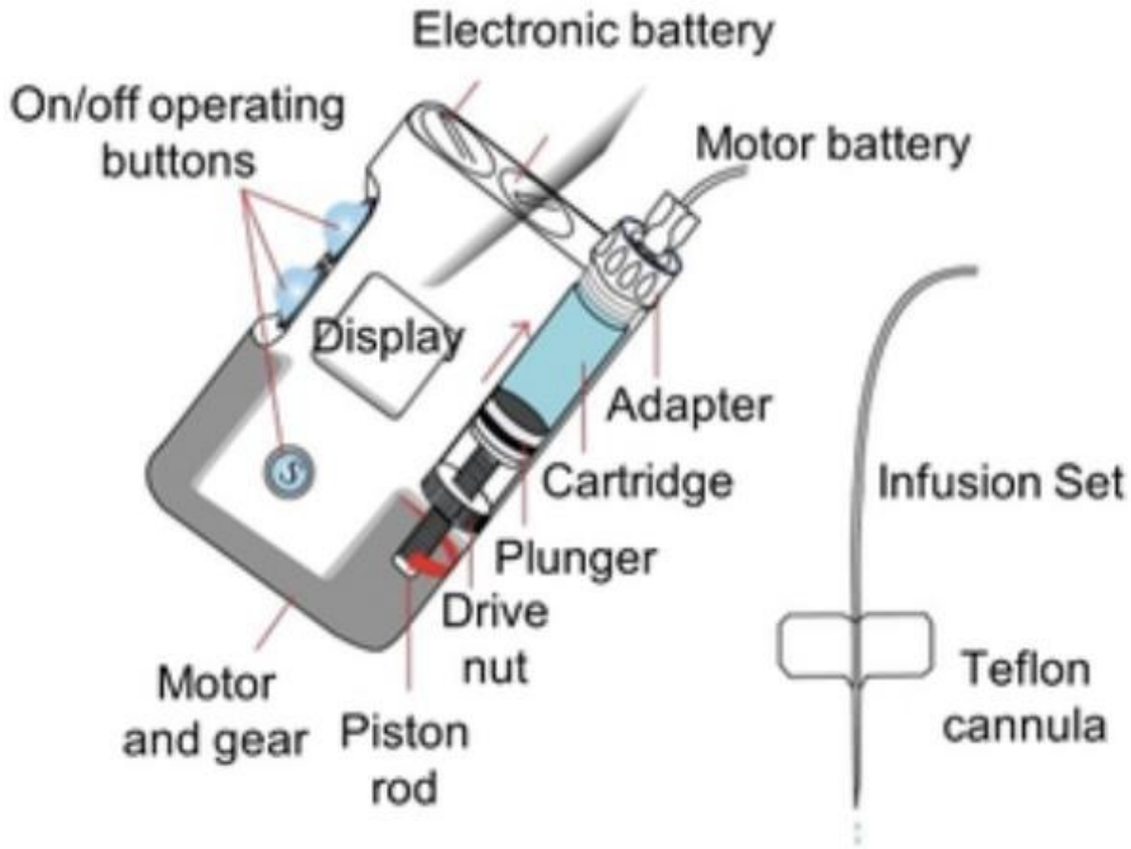
The implantable insulin pump is surgically implanted under the skin and a catheter from the pump extends into the peritoneal cavity



Mohammad Towhidul Islam Rimon, Md Wasif Hasan, Mohammad Fuad Hassan, Sevki Cesmeci
Pharmaceutics. 2024 Advancements in Insulin Pumps: A Comprehensive Exploration of Insulin **Pump** Systems, Technologies, and Futu
Directions

(a)

Traditional insulin pump



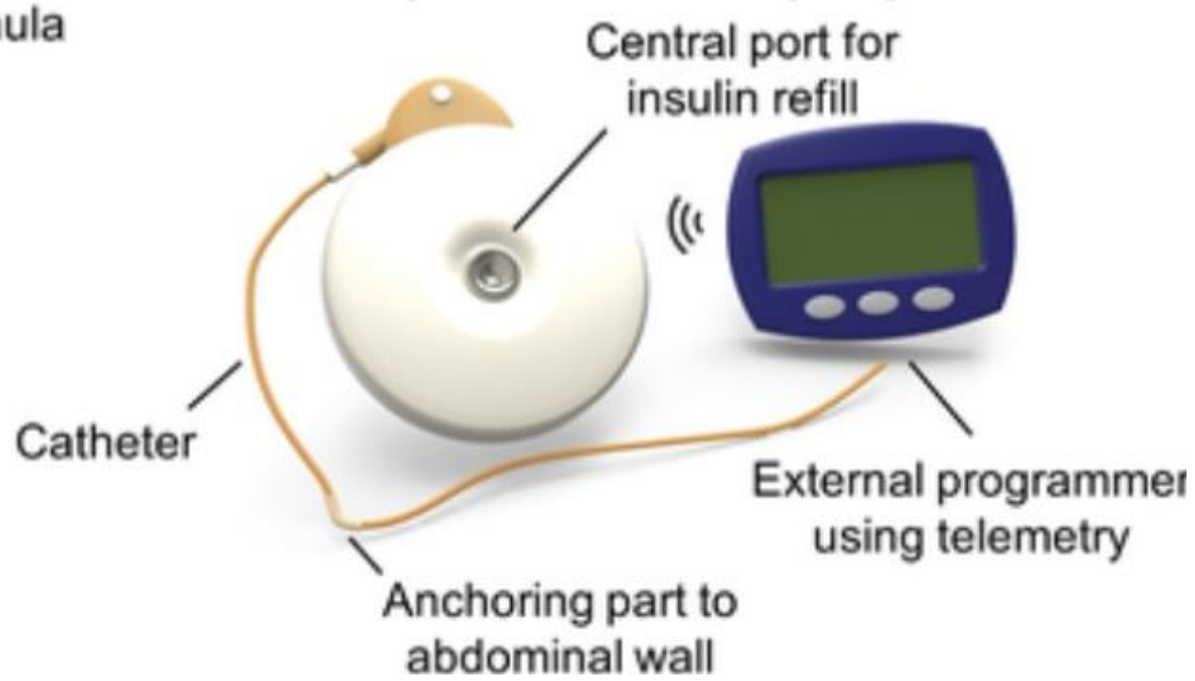
(b)

Insulin patch pump

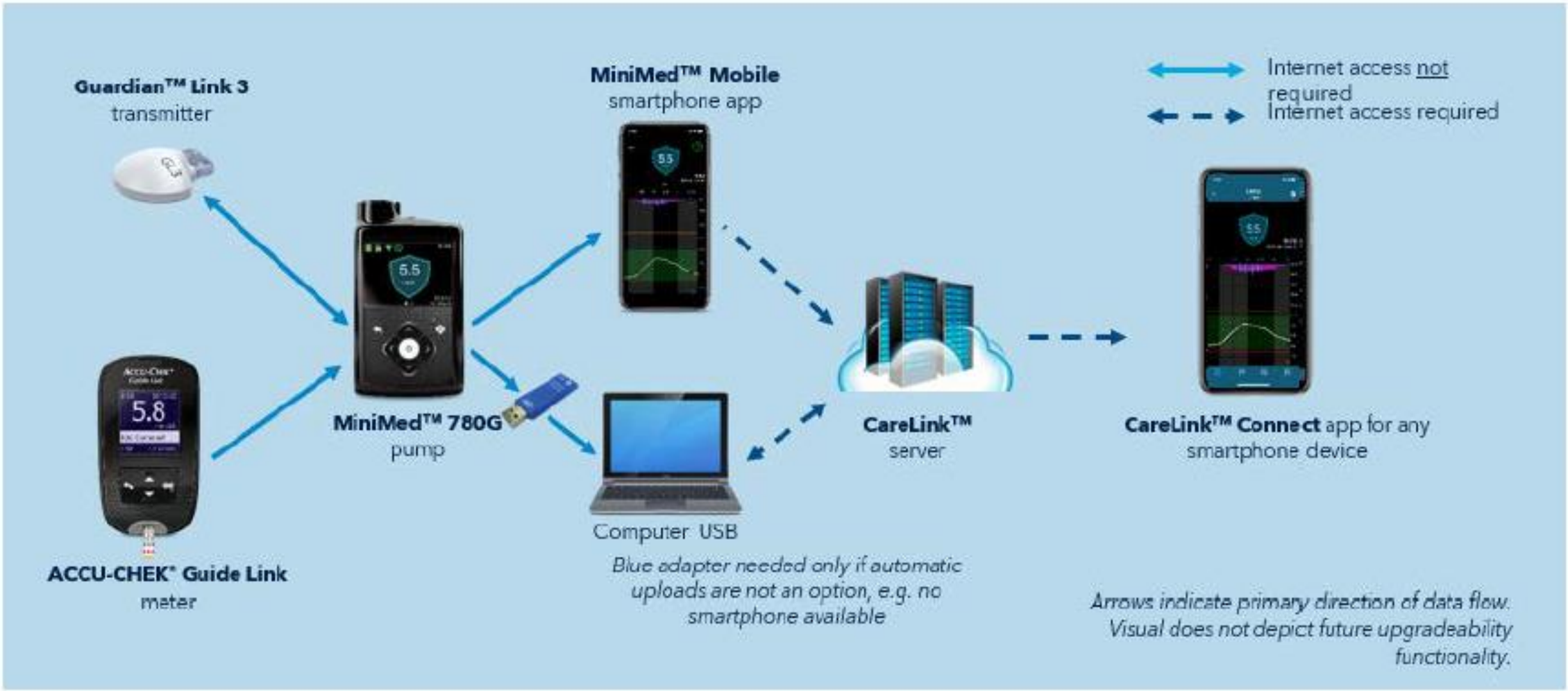


(c)

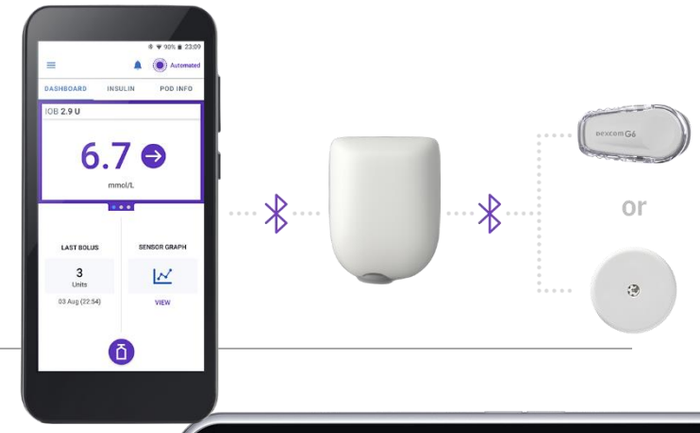
Implantable insulin pump



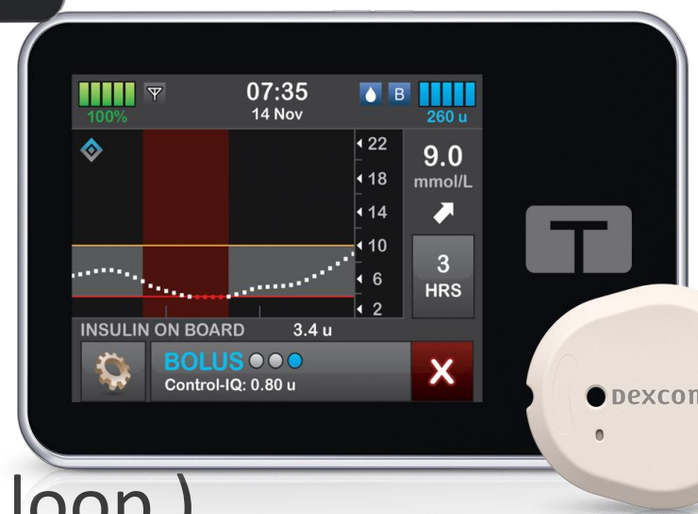
Automated pumps with closed loop







Automated pumps with closed loop)



Medtronic 780G **(** with Smartguard closed loop)

Insulet Omnipod 5 **(** with SmartAdjust closed loop**)**

Ypso pump (with APS closed loop)

Tandem t:slim X2 (with Control –IQ closed loop)

Tidepool Loop app with integrates with other insulin pumps and CGMS



	MiniMED 780G	TANDEM Tslim	OMNIPOD 5	Ypso Pump
Approved for	7-80 y (HCL for >7 y)	Min basal rate 0.1U/hr (Control IQ for > 6yo)	>2 yo	Automode for > 1yo
Hybrid closed loop	Smartguard	Control IQ	SmartAdjust	CamAPS
Weight	95.7g	112g	Pod 26g	83g
CGM connection	MiniMed Guardian 3, 4	Dexcom G6,7	Dexcom G6, 7, Libre 2	Dexcom G6
Waterproof	3.6 m for 24 hours	1 m for 30 minutes	7.6 m for 1 hour	1 m for 60 minutes
Set target	5.5/6.1/6.7mmol/L	6.3mmol/L	customizable 6.1- 8.3mmol/L	5.8mmol/L <customizable, 4.4-11.0mmol/L>
Suspends insulin	yes	yes	yes	Yes
Auto corrections	Yes, every 5 minutes	60% of programmed rate to 6.1mmol/L target	yes, microbolus of up to 400% of the patient's adaptive basal rate, every 5 minutes	auto-calculating basal rates and correction factors and delivers as an extended bolus every 8-12 minutes
Special features	Meal recognition technology: helps to correct in the event of a forgotten bolus or if carbs were miscalculated.	Hybrid closed-loop system that automatically adjusts the basal rate and can give automated correction boluses (every hour). Exercise and sleep modes	No tubing Activity feature for higher glucose target and reduced basal	Touchscreen Pump information can be viewed on a mobile device with an app through Bluetooth-enabled data sharing.

ADVANCEMENT IN MINIMED PUMP

	670G	780G
Autobasal target	6.7mmol/L	5.5mmol/L, 6.1mmol/L, 6.7mmol/L
Correction bolus target	8.3mmol/L	6.7mmol/L
Meal corrections	BG required	SG suffices in Smartguard, BG required in manual mode
Autocorrection boluses	No autocorrection boluses	Autocorrection boluses available with SG
Safe basal	Exits after 90min of safe basal	Baseline insulin delivery replaces safe basal action required banner and time to exit information Exits after 4 hours if “action required” not taken
Exits	“Alarms” can cause Auto Mode exits	Alarms do not cause SmartGuard™ exits;
Max delivery time out	Maximum delivery timeout occurs after 90 minutes of Safe basal	expanded to 7 hours
Minimum delivery time out	Minimum delivery timeout after 2.5 hours of Safe basal	expanded to 3-6 hours
Suspend on low and suspend before low	Must be turned back on after Auto mode exit	Automatically turn on when SmartGuard™ feature exits if either feature was on manual mode
Fixed high alert	Auto Mode only	Prolonged SG >13.9 mmol/L over 3 hours, both Manual and SmartGuard™ modes
Fixed low alert	2.8 mmol/L	3.0 mmol/L

Key features of 780G

New meal detection technology that auto adjusts basal and bolus insulin every 5 minutes as needed, making 12 autocorrections per hour

Safe meal bolus reduces bolus if hypoglycaemia is predicted

Glucose target set as low as 5.5mmol/L

Low glucose suspend kicks in even during manual mode

Guardian sensor 4 requires no fingerpricks while using Smartguard in automode

Patient selection

Specifications and contraindications for Medtronic pump

The MiniMed 780G system is indicated and approved for patients with Type 1 diabetes above 7 years of age

The SmartGuard™ feature cannot be used for people who require <8 units or >250 units of total daily insulin dose per day

The system has not been studied in pregnant women, persons with Type 2 diabetes, or in person using other antihyperglycemic therapies that do not include insulin.

Use of clinical judgment is always recommended in cases where patients cannot read instructions on the pump screen, refuse to routinely check glucose, or are unwilling to announce meals before eating.

Pump initiation

Manual Mode

Every patient starts in Manual Mode (with or without CGMS) which operates similar to traditional pump technology in that:

- Basal insulin delivers evenly over each hour using prescribed rates the patient has programmed into the pump
- All boluses are initiated by the patient
- Food boluses use the grams the patient enters and the programmed ICR

Correction boluses are based on the patient's glucose readings, ISF, BG target range and AIT



Initial settings for MDI users

Basal:

Reduce total daily dose (TDD) by 15-25%

Basal insulin dose: reduced TDD x 0.5

If half the dose is >0.4units/kg, use weight dose

- BW In kg x 0.3 for adults
- BW in kg x 0.2 for children
- BW in kg x 0.4 for adolescents

Basal insulin /24 = hourly basal rate

1 or 2 basal rates (night time-day time)

Bolus:

ICR 450/ TDD

ISF 100/ TDD

BG target: 5.5-6.7mmol/L

AIT: 2 hours

Initial CGMS and Smartguard settings from MDI and Pump users

CGMS:

Suspend before low: ON

Low limit threshold: 3.9mmol/L

Alert before Low: OFF

Alert on low: ON by default

Alert on High: OFF

MINIMED™ 780G SYSTEM

Advanced Hybrid Closed Loop Therapy

QUICK REFERENCE GUIDE

Medtronic

Next Generation SmartGuard™ Feature = Auto Basal + Auto Correction

Customizable Auto Basal Targets: 5.5 mmol/L default | 6.1 mmol/L | 6.7 mmol/L
Customizable Bolus Settings: Insulin Carb Ratio (ICR) | Active Insulin Time (AIT) | Auto Corrections - ON or OFF

GETTING STARTED

INITIAL SETTINGS FOR MDI USERS

BASAL:
Reduce Total Daily Dose (TDD) by 15–25%
Basal Insulin Dose: Reduced TDD × 0.5
(If half the dose is > 0.4 units per kg, use weight dose below*)
Basal insulin /24 = hourly basal rate
1 or 2 basal rates (night time–day time)

BOLUS:

ICR:	450/TDD
Sensitivity factor:	100/TDD
Blood glucose target:	5.5-6.7 mmol/L
AIT:	2-3 hours

INITIAL SETTINGS FOR PUMP USERS

BASAL:
Use current pump settings

BOLUS:

ICR:	450/TDD
Sensitivity factor:	100/TDD
Blood glucose target:	5.5-6.7 mmol/L
AIT:	2–3 hours

INITIAL CGM AND SMARTGUARD™ SETTINGS FOR MDI AND PUMP USERS

CGM:

Suspend before low:	ON
Low limit:	3.8 mmol/L
Alert before low:	OFF
Alert on low:	ON by default
Alert on high:	OFF

SmartGuard™ Feature:

Auto basal target:	5.5 mmol/L
Auto corrections:	ON

FOLLOW UP

Data Analysis	Time in Range	A1C	Time below 3.9 mmol/L	Time below 3.0 mmol/L	SmartGuard™ Use	Sensor Use
Goals	> 70%	< 7.0% Adults (< 53 mmol/mol) < 7.5% Peds (< 58 mmol/mol)	< 4%	< 1%	≥ 85%	≥ 85%

If goals are met, no changes required. If goals are not met, adjust settings.

Time ABOVE Range is HIGH	Use Meal Bolus Wizard report to evaluate: ■ **Pre-prandial glucose:** if rise occurs, counsel patient on bolusing earlier before meal ■ **Post-prandial glucose:** if glucose is rising more than 3.3 mmol/L, ICR most commonly needs to be adjusted to provide a larger meal dose (i.e. ICR change from 10 to 8)
Time BELOW Range is HIGH	Use Meal Bolus Wizard report to assess: ■ Timing of bolus ■ Overestimating of carbs (avg carbs/meal are listed) ■ Smaller meal bolus may be needed (i.e. ICR change from 8 to 10) ■ If persistent **lows** occur with a bolus: consider higher Auto basal target ■ If persistent **lows** occur after **auto** correction boluses: use longer AIT (i.e. 2.0 to 2.5 hours) ■ If low during sleep, evaluate if smaller meal/snack bolus is needed prior to bed
If Sensor Use is < 80%	■ Educate on sensor use and care ■ Explore reasons for underuse

* Weight doses: weight in kg x 0.3 for adults, x 0.2 for peds, x 0.4 for adolescence | MDI = Multiple Daily Injections | CGM = Continuous Glucose Monitoring

MINIMED™ 780G SYSTEM

Advanced Hybrid Closed Loop Therapy

QUICK REFERENCE GUIDE

Medtronic

BEST PRACTICES

Keep interventions at a minimum. After updating a setting, allow the system time to adapt

Carb entry + Auto correction boluses ON + lowest Auto basal target + lowest AIT = Achieving diabetes goals

Optimize ICR and AIT

If high Auto correction % (>30%):
- Evaluate if boluses are omitted
- Evaluate meal bolus report to assess bolus timing and ICR adequacy
  - If post-prandial elevated, consider intensifying carb ratio (more insulin) or refine carb counting if not consistent

CLINICAL TIPS

Encourage carb counting and pre-meal bolusing

Start new sensor during a fasting period or wait 2–3 hours after bolusing

Caution using multiple correction doses in manual mode

Majority of patients will run a bit above the target glucose setting

Keep manual mode basal rates up to date

Depending on CGM slope and past insulin delivery, a food bolus may be reduced to help mitigate low SG

Sync to CareLink™ feature allows automatic uploads, giving HCPs up-to-date access to data

IMPORTANT SAFETY INFORMATION — MINIMED™ 780G SYSTEM

The MiniMed™ 770G system is intended for continuous delivery of basal insulin (at user selectable rates) and administration of insulin boluses (in user selectable amounts) for the management of type 1 diabetes mellitus in personstwo years of age and older requiring insulin as well as for the continuous monitoring and trending of glucose levels in the fluid under the skin. The MiniMed™ 770G system includes SmartGuard™ technology, which can be programmed to automatically adjust delivery of basal insulin based on continuous glucose monitoring (CGM) sensor glucose values and can suspend delivery of insulin when the SG value falls below or is predicted to fall below predefined threshold values.

The Medtronic MiniMed™ 770G system consists of the following devices: MiniMed™ 770G insulin pump, the Guardian Link (3) transmitter, the Guardian Sensor (3), one-press serter, and the Accu-Chek Guide Link blood glucose meter. The system requires a prescription.

The Guardian Sensor (3) has not been evaluated and is not intended to be used directly for making therapy adjustments, but rather to provide an indication of when a fingerstick may be required. All therapy adjustments should be based on measurements obtained using a blood glucose meter and not on values provided by the Guardian Sensor (3).

WARNING: Tibique reprimique deterruisset at mei, ea vel alucius temporibus voluptatibus. Indoctum petentium reformidans ut quo. Mazim repudiandae ut pro. Quo ei nominavi molestiae, in sed doctus ancillae antiopam, ea latine tincidunt vim. Mazim repudiandae ut pro. Quo ei nominavi molestiae, in sed doctus ancillae antiopam, ea latine tincidunt vim.

WARNING: Tibique reprimique deterruisset at mei, ea vel albucius temporibus voluptatibus. Indoctum petentium reformidans ut quo. Mazim repudiandae ut pro. Quo ei in sed doctus ancillae antiopam, ea latine tincidunt vim.

Guardian™ Sensor (3)
The Guardian™ Sensor (3) is intended for use with the MiniMed™ 770G system to continuously monitor glucose levels in persons with diabetes. The sensor is intended for single use and requires a prescription. The Guardian™ Sensor (3) is indicated for 7 days of continuous use. The Guardian™ Sensor (3) has been studied and is approved for use in the following sensor insertion sites by persons of the following ages:

APPROVED AGE	SENSOR INSERTION SITE
2–13	Abdomen and Buttocks
14 and above	Abdomen and Arm

Guardian™ Link (3) Transmitter
The Guardian™ Link 3 transmitter is intended for use with MiniMed™ 770G system. The transmitter powers the glucose sensor, collects and calculates sensor data, and sends data via Bluetooth wireless technology to the pump. The transmitter is intended for single-patient multi-use.

Accu-Chek Guide Link Meter
The Accu-Chek Guide Link Blood Glucose Monitoring System is comprised of the Accu-Chek Guide Link meter and the Accu-Chek Guide test strips. The Accu-Chek Guide Link Blood Glucose Monitoring System is intended to quantitatively measure glucose in fresh capillary whole blood from the fingertip, palm, and upper arm as an aid in monitoring the effectiveness of glucose control. The Accu-Chek Guide Link Blood Glucose Monitoring System is intended for in vitro diagnostic single-patient use by people with diabetes The Accu-Chek Guide Link Blood Glucose Monitoring System is intended to be used by a single person and should not be shared. This system is not for use in diagnosing or screening for diabetes mellitus and not for neonatal use. Alternative site testing should be done only during steaty-state times (when glucose is not changing rapidly). The Accu-Chek Guide control solutions are for use with the Accu- Chek Guide Link Blood Glucose Monitoring System to check that the meters and test strips are working together properly and that the test is performing correctly. The Accu-Chek Guide Link Blood Glucose Monitoring System is intended to be used to wirelessly transmit glucose values to a compatible MiniMed pump with Bluetooth wireless technology through the use of Bluetooth low energy communication.

950M22178-011 30MAR2020 © 2020 Medtronic. All rights reserved. Medtronic, Medtronic logo and Further, Together are trademarks of Medtronic. All other brands are trademarks of a Medtronic company.

Manual Mode setting: Let’s go!

11 year old boy

Body weight 35kg

HbA1c 6.1%

Currently regime:

Novorapid 6 units pre breakfast

Novorapid 8 units pre lunch

Novorapid 6 units pre dinner

Tresiba 12 units pre breakfast

CHO intake (g) : 50/10/60/0/60/10

Setting up SmartGuard

The SmartGuard feature requires a 48-hour warm-up period before activation. This warm-up period begins at midnight after the pump starts delivering insulin and it does not require sensor use. During the warm-up period, the pump collects and processes data for use by the SmartGuard feature.

Setting up SmartGuard

To prepare the pump for the SmartGuard feature:

1. Cancel any active Temp Basal rates
2. Confirm that insulin delivery is not suspended
3. Set the carb ratio
4. Review the high and low limit settings
5. High and low limit settings apply when in Manual mode and when using the SmartGuard feature

SMARTGUARD

AUTOBASAL

AUTOCORRECTION



SmartGuard features

Regulates basal insulin in response to real-time sensor glucose values.

Designed to maximize Time in Range of 3.9–10 mmol/L

Goal: to spend 85% (or more) of time in the SmartGuard feature to achieve Time in Range goals

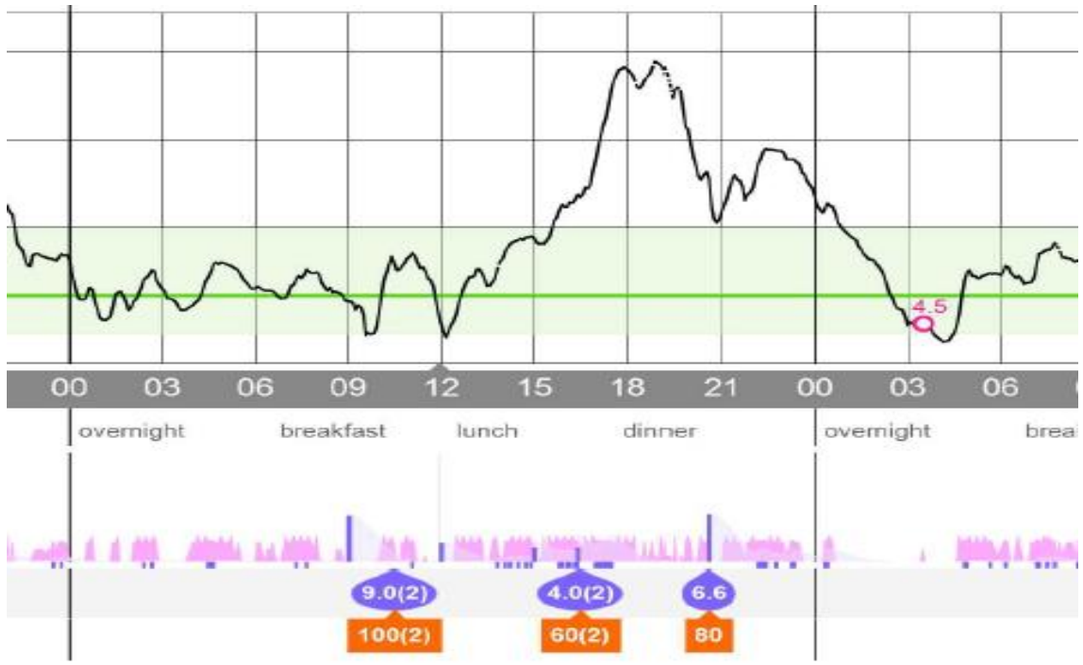
Uses the programmed insulin carb ratio (ICR) & active insulin time (AIT)

Autobasal→ How is 5 min autobasal determined

1. Current SG
2. PID algorithm:
   - Proportional: how far SG is away from set target
   - Integral: how long SG has been away from target
   - Derivative: How rapidly SG has been changing
3. Insulin on board
4. Automode max delivery

Automode max delivery is recalculated every 24 hours using fasting values and median total daily dose.

AUTOBASAL ADJUSTMENT



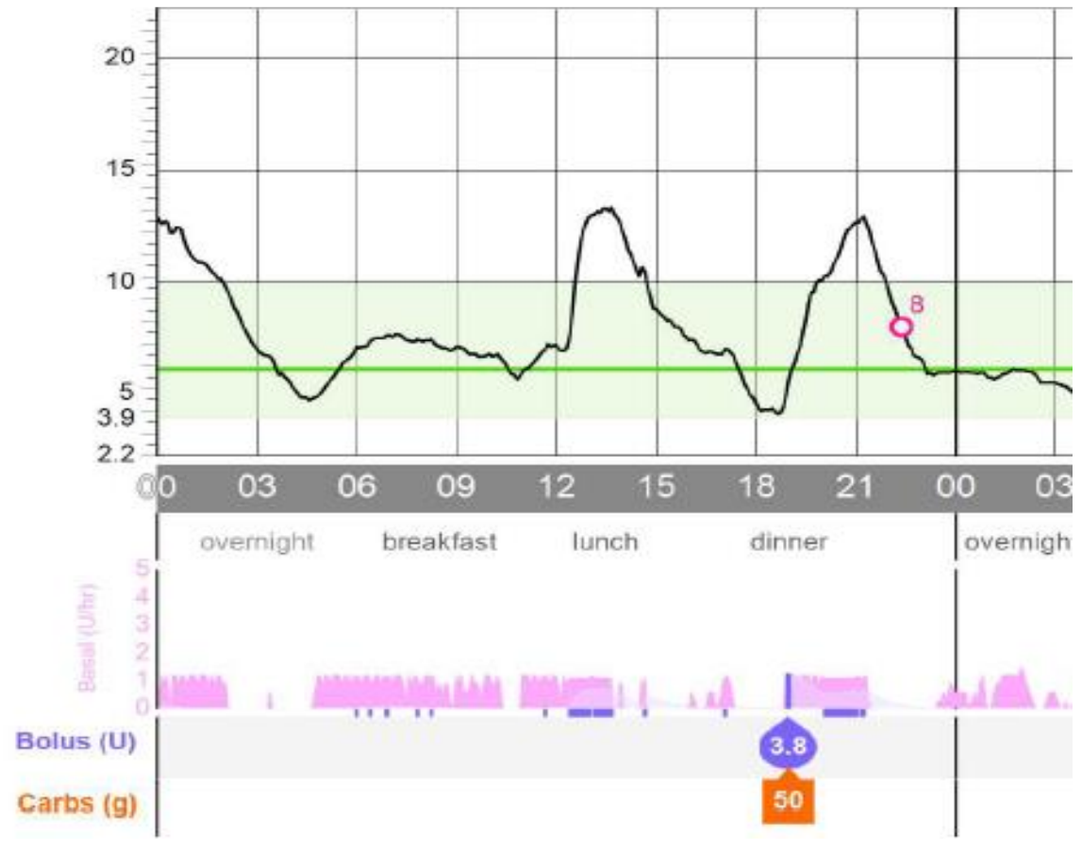
DROPPING GLUCOSE LEVEL

AUTOBASAL SUSPENDED

Autocorrection:

- Auto correction bolus occurs when:
  - Maximum auto basal delivery is reached
  - SG is above set target of 6.7mmol/L
- Can be delivered every 5 minutes
- Active insulin impacts auto corrections

AUTOCORRECTION ADJUSTMENT



Glucose peak then comes down

MISSED BOLUS→ AUTOCORRECTION

Who controls what?

Setting	Doctor/Patient	Automode
Glucose target	✅	
Basal rate		✅
Insulin carb ratio	✅	
Active insulin time	✅	
Insulin sensitivity factor		✅
Autocorrections		✅

Insulin sensitivity factor and Dual wave/ Split boluses ARE NOT AVAILABLE IN SMARTGUARD

TIPS FOR Automode settings

Only 2 settings are set at Manual mode impact insulin delivery at Automode

1. Insulin carbohydrate ratio→ MOST COMMONLY NEED TO BE ADJUSTED
2. Active insulin time→ Impacts correction dose amounts only if there is active insulin from previous food or correction bolus

Basal rate, insulin sensitivity factor etc are calculated by the algorithm.

Patient’s note

Understand that the pump is not fully automatic

1. Enter carbs and boluses before eating, 10-15minutes before meal
2. Enter BG for calibrations
3. Give correction boluses if recommended
4. Follow SMARTGUARD INSTRUCTIONS to keep in automode

Try to work with the pump; not over (entering fake carbs), not under (not adjusting ICR)

When the pump requires an action to stay in Smartguard feature, it delivers insulin at a fixed basal rate for maximum of four hours

Condition	Action
Smartguard has reached time limit for minimum delivery, which is 3-6 hours depending on the reason	Enter a BG
Smartguard delivering insulin at maximum limit for 7 hours	Enter a BG and follow required steps
No SG data available for more than 5 min	Enter BG and fix sensor alert

Don’t forget to check manual mode settings against the automode during consultation!!!

Exercise

Start Temp Target 1-2 hours before the exercise starts

Start exercise in target range

If low before / during exercise, consider taking supplemental carbs - but do not enter and bolus for supplemental carbs through the SmartGuard™ Bolus Feature*

If disconnecting the pump for exercise (e.g. contact sport), manually suspend insulin delivery to ensure correct tracking of insulin delivery - but keep manual suspension of the pump to a minimum

Turn off Temp Target 0-15 minutes after exercise

Post-exercise meal: usual bolus or slight reduction

NOTE: AUTOCORRECTION TURNS OFF AT EXERCISE MODE!!

Multidisciplinary care

DM nurse education at HKCH

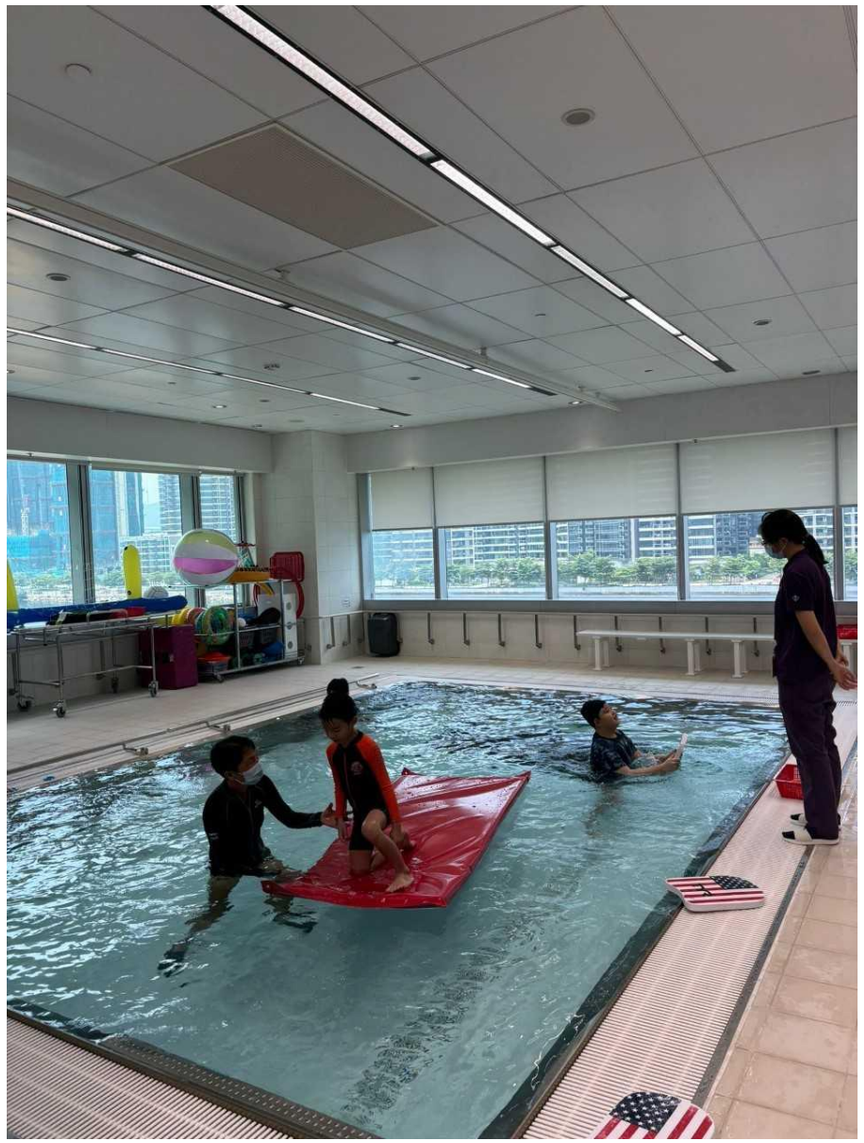




School visit for pump education by DM nurse



Physiotherapy at IRC hydrotherapy pool



Dietician education and cooking class



Clinical Psychologist support



Conclusion

1. Insulin pumps have been evolving and are becoming more automated, though input from doctors and patients is still exceedlingly important for success control of diabetes
2. When using automode→ allow time for changes and remember that the pump is learning to do its job
3. At clinic visits, check the settings at manual mode to match that of automode

THANK YOU!

