

Continuous Glucose Monitoring System: Practice Guide for Diabetes Nurse

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Preface

One important goal in management of diabetes mellitus (DM) is prevention of development of chronic diabetic complications, which arise as a result of poor glycemic control. Availability of continuous glucose monitoring (CGM), first introduced in 1999, is transforming the way diabetes is managed, especially in patients with type 1 DM.

CGM technology allows for continuous recording of glucose readings and acquisition of daily profile without the discomfort associated with frequent finger pricking, the continual data thus generated can help patients and health care professionals to make informed and timely treatment decisions. CGM has been shown to lower A1C, reduce glucose excursion, and minimize hypoglycemic frequencies, and is particularly useful in management of insulin-treated patients especially those on complex treatment regimen and/or with hypoglycemia unawareness. With advancement of CGM technology, CGM derived metrics such as time in range and coefficient of variation have also found application as valid parameters for every day DM management, with potential relevance in clinical research and incorporation into the standards of clinical practice guidelines.

When applied appropriately, modern diabetes technology like CGM can improve the lives and health of people with diabetes. On the other hand, the complexity and rapidly changing technology landscape can be a deterrent to patient and provider implementation. Appropriate educational and technical support for both people with diabetes and health care providers are thus needed to solidify the emerging status of continuous glucose data as a standard of care for daily DM management quality.

As CGM systems become more affordable and accessible to patients with diabetes, it is timely for our AHKDN educators to appraise the literature and draw up this guidebook to disseminate the knowledge and techniques of this novel monitoring modality. Their tremendous efforts in extensively reviewing the literature and elegantly writing up this guidebook to promote the best evidence-based practice are commendable. Given continuous advancement in the field, we could envisage future update of this guidebook for application of the innovations to advance diabetes management and benefitting the ever increasing population of people with diabetes in Hong Kong.

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Practice Guide for Diabetes Nurse

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Chapter 1: Background

The cornerstone of diabetes management is to prevent diabetes complications by achieving optimal glycemic control with minimal hypoglycemic events. Continuous glucose monitoring (CGM) has been rapidly developed and used with increasing popularity in recent years. Application of this valuable tool can facilitate people with diabetes and health care professionals to reach this desirable goal. Furthermore, individuals with diabetes will not have to perform blood glucose testing with blood glucose analyzers too frequently. CGM data thus provide actionable information for better self-diabetes management with much reduced discomfort associated with frequent finger pricking .

Given the new technology and different models of CGM, diabetes nurses have an urge to acquire the modern knowledge and skills to keep abreast with the rapid advancement and growing popularity of this innovative technology for diabetes monitoring. A workgroup under AHKDN was therefore set up to study the issue. After detailed discussion, a consensus was made to review the effectiveness of CGM in the management of diabetes through literature search, spanning the period from 2008 to 2018 with Google Scholar, PubMed, and UpToDate.

By using the PICO method, an Evidence Based Practice (EBP) statement was set :
The aim of the review was to assess the effects of the training and practice guide on continuous glucose monitoring (CGM) for DM nurse to enhance patient's glycemic control and behaviour of diabetes self-management in daily care.

Participants

Diabetes nurses who provide care and education to diabetic patients on CGM

Intervention:

Training strategies defined as providing the practical guide on CGM and conducting the workshop on CGM

Outcome:

Enhancement of patient outcomes in terms of stable glycemic control with less hypoglycaemia and hyperglycemia, also improving the health behaviour of diabetes self-management on diet control, exercise and medication compliance.

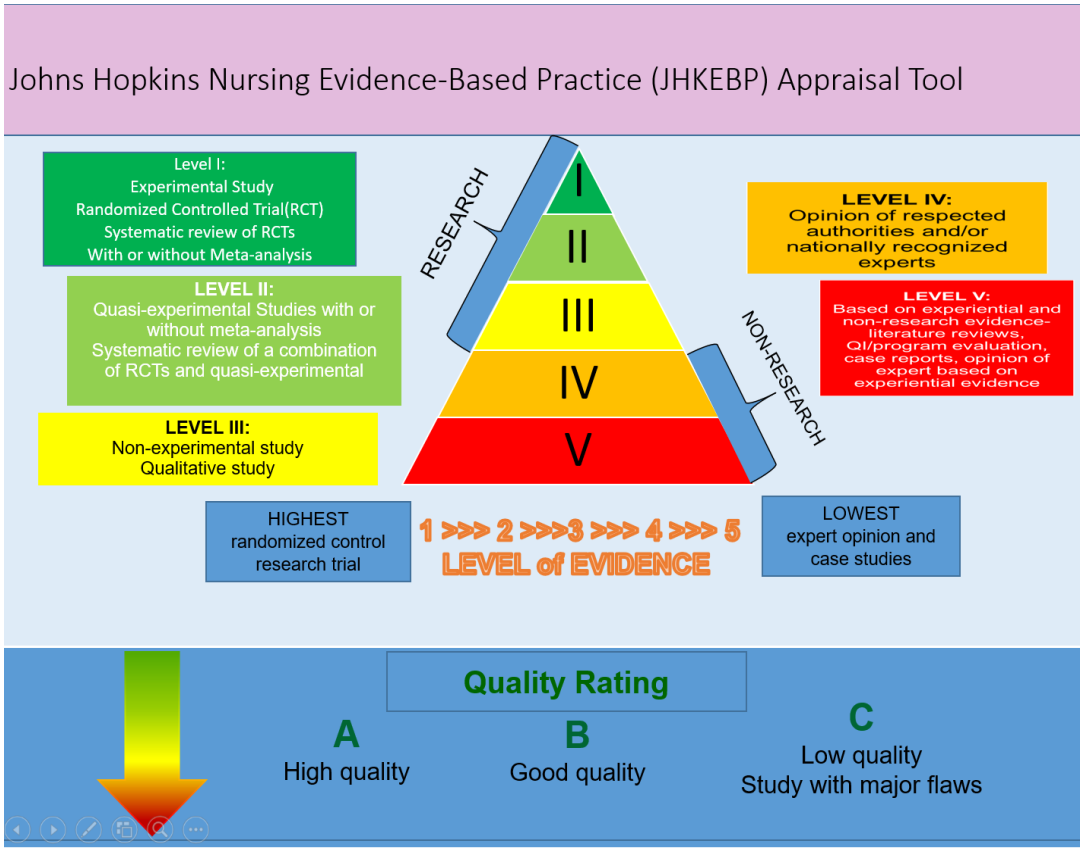
The EBP statement was:
"To enhance patient outcomes through training and practical guide on continuous glucose monitoring (CGM) for diabetes nurses."

We used the Johns Hopkins Nursing Evidence-Based Practice (JHKEBP) Appraisal Tool [1](see

Appendix 1) to evaluate the evidence and state the evidence level in the findings.
The tool is to appraise research at 5 levels as follows:
Level I: Randomized Control Trial (RCT)
Level II: Quasi-Experimental
Level III: Non-Experimental or Qualitative
Non-research: Level IV: Clinical Practice Guidelines / Consensus or Position statement
Level V: Literature review / Expert Opinion and others

The quality of research is based on quality rating as
A: High quality **B:** Good quality **C:** Low quality or major flaws

Appendix 1



The project aimed to guide diabetes nurses:
1.1 to recognize different brands and features of CGMS
1.2 to provide quality care management to individual patients on CGM

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1. Dang,D. & Dearholt, S. (2017). Johns Hopkins Nursing Evidence-based Practice: model and guidelines. 3rd ed. Indianapolis, IN: Sigma Theta Tau International.

Chapter 2: Indication **Evidence Level**

There are two types of CGM available in the market - Retrospective Continuous Glucose Monitoring (rCGM) and Real-time Continuous Glucose Monitoring (rtCGM).

Retrospective CGM (rCGM) Level IVA

Retrospective CGM (also known as 'masked' or professional CGM) for patients with Type 2 Diabetes Mellitus (T2DM) provides actionable information derived from the rCGM report to healthcare professionals (HCP) and patients. rCGM used in Diabetes Clinics and eventually in Primary Care, is a tool to review glucose patterns and share decision-making with the patient at a clinic visit or remotely[1, 3, 5, 6].
The retrospective CGM serves the purpose as a diagnostic tool to assess the short-term glycemic patterns and understand how they are influenced by diet, glucose-lowering medications, and physical activity, without the patient's behavior influenced by the feedback of glucose results. It also acts as a therapeutic tool by allowing the HCP to make appropriate therapeutic treatment recommendations.

Target groups and Indications:

1 Patients with:

1.1 Hyperglycemia [4,5,6]: Level IIIA

- 1.1.1 unknown hyperglycemia
- 1.1.2 night-time/early-morning (on awakening) hyperglycaemia
- 1.1.3 postprandial hyperglycaemia (discordance between carbohydrate intake and rapid-acting insulin dose)
- 1.1.4 late-afternoon hyperglycaemia (under-titration or insufficient duration of basal insulin)

1.2 Hypoglycemia [2,4,5,6] Level IIIA

- 1.2.1 HbA1c above target with suspected hypoglycemia (silent and symptomatic)
- 1.2.2 Analysis of hypoglycaemia, pattern, causes; detection of hypoglycaemia unawareness

1.3 Brittle diabetes: variability analysis, assessment of potential causes Level IIIA

2	Measure glycemic control directly rather than through the surrogate metric of hemoglobin A1C permitting the observation of a wide variety of metrics that includes[6]: 2.1 glycemic variability 2.2 the percent of time within, below and above target glucose levels 2.3 the severity of hypo- and hyperglycemia throughout the day and night.	Level IIIA
3	Manage diabetic patients better in specific/difficult clinical situations associated with unstable glucose patterns[,2,3,4,5] 3.1 hemodialysis /chronic dialysis: discrepancy between HbA1c and self-monitored blood glucose (underestimation of HbA1c in dialysis patients, low/high hemoglobin) 3.2 pregnancy: optimization of glycaemic control[5] 3.3 cystic fibrosis 3.4 bariatric surgery: excessive glycemic excursions after surgery 3.5 insulinoma: evaluation of hypoglycemia 3.6 Hirata's disease: anti-insulin autoantibodies to the insulin receptor 3.7 shift-work schedules 3.8 defective compliance	Level IVA
4	Analyze glycemic effects of new interventions to facilitate decision making effectively and efficiently[1,2,4,5] 4.1 pharmaceuticals (duration of action, pharmacodynamics, safety, and efficacy) 4.2 make more informed clinical decisions about treatment changes and dose titrations 4.3 psycho-educational for behavior modification 4.4 flexible insulin therapy (FIT): assessment of FIT algorithms 4.5 Physical activity (glycaemic effect of activity, validation of therapeutic actions to prevent hypoglycaemia during physical activity)	Level IVA

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2. Currie CJ, Poole CD & Papo NL (2009). An overview and commentary on retrospective, continuous glucose monitoring for the optimization of care for people with diabetes. Current Medical Research and Opinion, 25(10), 2389-400.
3. Rodbard D (2017). Continuous Glucose Monitoring: A Review of Recent Studies Demonstrating Improved Glycemic Outcomes. Diabetes Technology & Therapeutics,19,S3.
4. Tcheugui JBE (2017). Expert Critique on Use of CGM in Type 2 Diabetes a Subject of Debate – Cost, patient selection at issue. https://www.medpagetoday.com/reading-room/endocrine-society/diabetes/62728
5. Joubert M & et al (2015). Indication, organization, practical implementation and interpretation guidelines for retrospective CGM recordings: A French position statement. Diabetes & Metabolism, 41(6) 498-508.
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Real-time Continuous Glucose Monitoring (rtCGM)	Evidence
rtCGM supplements the missing information from HbA1c and self-blood glucose monitoring. It shows the glucose concentration in the body's interstitial fluid in near real time and provides glucose trend in previous few hours, and rate of change (trend) arrow of glucose and glucose direction. Some devices with programmable alerts/alarms to provide the additional safety advantage. Moreover, rtCGM facilitate monitoring of time in range and the intra and inter-day glycemic excursions.[1] There are different levels of evidence to show the effectiveness and efficiency of rtCGM in diabetes management among different groups of subjects.	Level IVA
1. **Type 1 DM in adults who apply rtCGM on nearly daily basis**	
1.1 Facilitate the achievement of HbA1c level to target[1-10]	Level IA
1.2 Expedite the improvement of HbA1c level up to 12 months[2,4,8,11]	Level IA
1.3 Reduce hypoglycemia exposure[3,12-15]	Level IB
2. **T1DM in children and adolescents**	
2.1 Facilitate the achievement of HbA1c level to target [1-5,8,16,17]	Level IA
2.2 Reduce hypoglycemia exposure[4,14]	Level IC
2.3 Detect abnormal patterns of glycemia[2]	Level IIA
2.4 Benefits to those subjects with or without any comorbidities who have undertaken high levels of physical activity or treatments that can make blood glucose control difficult[8,18]	Level VA
2.5 Detect any symptomatic or asymptomatic hypoglycemia by the rtCGM with alarm function for those subjects with history of frequent severe hypoglycemia[8,18], impaired awareness of hypoglycemia associated with adverse consequences (e.g. seizures or anxiety) [8,18] and inability to recognize or communicate about symptoms of hypoglycemia (e.g. cognitive or neurological disabilities)[8,18]	Level VA
2.6 Caution: There is no conclusion yet for or against the use of rtCGM in children with T1DM who are under 8 years old[5]	Level IA
3. **T1DM in neonates, infants, and pre-school children**	
3.1 Caution: Use of CGM in neonates appears safe, feasible and has been associated with better glycemic status, but there is no conclusive evidence yet of improved clinical outcomes[19]	Level VA

4. **T1DM in adult using CSII and requiring frequent self-adjustment of insulin dose**

   4.1 Decrease HbA1c levels and time spent in hypoglycemia[2,20,21] — Level IA

5. **T2DM in adult on MDI or CSII**

   5.1 Improve HbA1c levels when applied on nearly daily basis [14,22] — Level IA

   5.2 Reduce the time spent in hypoglycemia[14] — Level IB

6. **Pregnant women on insulin therapy**

   6.1 Benefit those who develop severe hypoglycemia[23] (with or without impaired awareness of hypoglycemia) and / or have unstable blood glucose levels[23]. — Level VA

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Chapter 3

Information of CGM

The following table summarizes the features and specificity of CGMS based on the user manuals and websites of different CGMS manufacturers.

Name	**Abbott-** **Freestyle Libre** [#1]	**Celki** **Dexcom 4**[#2]	**Celki** **Dexcom 5**[#3]	**Medtronic** **i-pro 2**[#4]	**Medtronic** **Guardian Connect**[#5]
Sensor duration	14 days p10	7 days p15	7 days p31	Up to 144 hours (6 days) p4	7 full days p33
Transmitter	No	Yes p15	Yes p6	Yes p10	Yes p2
Receiver / Recorder	No p8 (Use Reader Device)	Yes p15	the app or receiver, p52	No	No – mobile device
Sensor Insertion Site	Arm p18 2.5cm (1 inch) away from injection site p18	Adult- Abdomen Paedi- Abdomen & upper buttock (2-17) p8 Insulin injection should be at least 7.62 cm (3 inches) away from sensor site p9	Adult- Abdomen Paedi- Abdomen - upper buttock (2-17) p21 Insulin injection should be at least 7.5 cm (3 inches) away from sensor site p24	Not specified in the user manual. Abdomen insert site (adequate SC Fat) in clinical study p53-61 Never insert sensor within 5cm (2 inches) from a pump infusion set or within 3 inches (7.5 cm) from a manual injection site) p19	Avoid the 2 inches (5.0 cm) area around the navel p9 An insertion site that has an adequate amount of subcutaneous fat – abdomen and back of upper arm p9

Startup time (Initiation with finger prick glucose)	1 hour (1 hour after insertion) p22	2 hours (2 hours after installation 2 finger sticks) p49	2 hours (2 hours after installation 2 finger sticks) p73	1 hour (1st and 3rd hour (back up) after installation) p15	2 hours (2 hours after installation 2 finger sticks) p29
Calibration	No (Need to scan the sensor at least once every 8 hours) p76	Yes, BG test x 2 for 1st calibration then every12 hrs (2 times per day 12 hours apart) p49 Do not use alternative blood glucose site testing (blood from your palm or forearm, etc.) for calibration. p50	Yes, BG test x 2 for 1st calibration > every12 hrs (2 times per day 12 hours apart) p23, 73 Do not use alternative blood glucose site testing (blood from your palm or forearm, etc.) for calibration. P26	Yes, 4 times per day p15	Yes, BG for 1st calibration within 2 hours, 2nd calibration within 6 hours, and subsequently every 12 hours p29
Real-time display - sensor glucose, graphic and trend	Yes, 2.2 – 27.8 mmol/L p75, but graph displays glucose readings up to 21 mmol/L (glucose values over 21 mmol/L displayed at 21 mmol/L) p25	Yes, 2.2 – 22.2 mmol/L p59	Yes, 2.2 – 22.2 mmol/L p171	Not available	Yes, 2.2 – 22.2 mmol/L p69

Data capture (Glucose reading update)	Every 1 minute, record at every 15 minutes[2]	Every 5 minutes p6	Every 5 minutes p31	Every 5 minutes p8	Every 5 minutes p46
Accuracy	During times of rapidly changing glucose (more than 0.1 mmol/L per minute), sensor glucose may not be accurate and require blood glucose test p4	less accuracy if less than 12 hours calibration p8, entering BG value within 5 minutes p9	less accuracy if less than 12 hours calibration p17, entering BG value within 5 minutes p24	Calibrate three or more times in a calendar day to improve accuracy p60	Calibrate three to four times at regular intervals throughout the day to improve accuracy. entering BG value immediately after BG test p30
Software/ Download Capability	Freestyle Libre Desktop software/ LibreView Web-based[2]	Dexcom Studio software	Dexcom G5 Mobile app p49 / Dexcom CLARITY® on phone/ web-based program p368	Carelink Pro Software p6	Guardian Connect app p2
DM population	4 years old and older (4-17 supervised by adult) p3	Age 2 and older p7	over 2 years old p21	No specific age but clinical study 18-75 years old p44	Age 14-75 years old p1

Approved for insulin adjustment without finger prick	Not mention	No p7	Yes p31	Not available	No p5
Confirmation with finger prick blood glucose if hypoglycemia	Yes p4 or appear in the screen	Yes p7	No, but need to cross check if any discrepancy from symptoms p31	Not available	Yes p30
Removed before MRI/CT/ Diathermy, other devices to generate strong magnetic fields or ionizing radiation	• Yes and also under X-ray machine p7 • Not mention diathermy	Yes p26	Yes p19	Yes also under X-ray machine p5,19	Yes also under X-ray machine p7

Alert system	Not available	Yes, Do not expect alerts until after the 2-hour startup p43	Yes, Do not expect alerts until after the 2-hour startup p21	Not available	Yes, alert on or before high (5.6 – 22 mmol/L) or low (3.3-5 mmol/L) up to 60 min p32,36,37 Raise alert: One arrow signals a 1 mg/dL (0.06 mmol/L) rise; two arrows signal a 2 mg/d (0.11 mmol/L) rise; and three arrows signal a 3 mg/dL (0.17 mmol/L) rise Fall alert: One arrow signals a 1 mg/dL (0.06 mmol/L)fall; two arrows signal a 2 mg/dL (0.11 mmol/L) fall; and three arrows signal a 3 mg/dl (0.17 mmol/L), fall p32,38
Sensor storage	4°C to 25°C p6 Relative humidity 10 -90% p76	2° C -25ºC 0-95% relative humidity p114	2° C-25° C p22 15%-85% relative humidity p282	2°C to 30°C p7	2 °C to 27 °C p22

Waterproof/ Water resistant	Do not immerse sensor deeper than 1 metre (3 feet) or longer than 30 minutes in water (1 meter 30 min) p60	Transmitter p114 and Sensor p45 are water resistant	Sensor with attached transmitter is water resistant p8 for up to 8 feet deep for 24 hour p334	Do not immerse sensor deeper than 2.4 meter or longer than 30mins in water No limit for swimming on surface of water / showering p18	After the transmitter and sensor are connected, they form a waterproof seal to a depth of 8 feet (2.4 meters) for up to 30 minutes p53
Receiver distance	To scan the sensor, the reader is held 1cm to 4 cm above the sensor p23	The transmission range from the transmitter to receiver is up to 6 meters without obstruction, but much less distance if the transmitter is in water p9	Avoid separating the transmitter and receiver by more than 20 feet. Range is less in or under water p25	Wireless device/mobile phone interference: keep mobile phone > 12 inches (30 cm) from CGM system device p6	Keep the distance between the transmitter and the compatible mobile device to <20 feet (6.1 meters) p10
Additional feature	Built-in meter for blood glucose and blood ketone test p8, blood glucose range 1.1 - 27.8 mmol/L p45, also insulin calculator for rapid acting insulin	Not available	Mobile communication through blue-tooth and Apps for 5 smart devices / HCP / Relatives p387	Not available	Mobile communication through blue-tooth and Apps for 5 smart devices / HCP / Relatives p20

	Reader can store approximately 90 days of glucose reading and notes p9 Mobile apps can replace reader and share 20 smart devices/HPC/Relatives[12]				
Interference substances	ascorbic acid (vitamin C) – falsely high; salicylic acid – slightly low[1] p6	Taking medications with paracetamol / acetaminophen – falsely high p7	Taking medications with paracetamol / acetaminophen – falsely high p19	Taking medications with paracetamol / acetaminophen – falsely high p13	Taking medications with paracetamol / acetaminophen – falsely high p6
Warning	Not evaluated for use in • Pregnant women • Persons on dialysis • with other implanted medical device p5	Not approved for use in • Children or adolescents • Pregnant women • Persons on dialysis p23	Not approved for use in • Pregnant women • Persons on dialysis • Not for critically Ill patients p21,38	No specific information for special population Must return the iPro 2 to clinic within 10 days of the end of the study, all data could be lost due to low/no battery p55	Continuous glucose monitoring is not recommended for people who are unwilling or unable to perform a minimum of two meter blood glucose tests per day or for people who are unable or unwilling to

	• Patients with hypoglycemic unawareness p2 • Severe dehydration may cause inaccurate results p6				maintain contact with their healthcare professionals p3
Cross checking Glucose	• Rapidly changing glucose level, interstitial glucose not accurately reflecting blood glucose[7] • Need finger stick glucose to confirm hypo/ hyperglycaemia and insulin dose adjustment (except Dexcom G5)[6p47,2p7] • Use the same glucometer[2p105]				
Skin reaction	Possible risks: skin allergy, bleeding, swelling, irritation and or infection[6p25,4p12,2p35,]				
Travelling	Notify security personnel to perform a visual inspection instead of through the x-ray[6p68, 3p25] Freestyle Libre - Not to scan or turn on reader on flight and check finger prick glucose/ketone[6p68]				
* Insertion site: Avoid areas with scars, moles, stretch marks, or lumps. Select an area of skin that generally stays flat during normal daily activities (no bending or folding)[5p9]. Dexcom 4[2] - The transmitter battery will last at least 6 months. Once you see the transmitter low battery screen, replace the transmitter as soon as possible. Your transmitter battery may drain as quickly as one week after this alert appears. Low transmitter icon will be displayed on receiver.[P18] Fully charging an empty receiver battery takes about 3 hours with the wall charger and about 5 hours with a computer and will last about 3 days with normal use[p39].					

Dexcom 5[3] – transmitter battery lasts approximately 3 months [p135] and a message is displayed on the receiver or smart phone if the transmitter battery is to expire in 3 weeks [p137]. The low battery icon is displayed at the right upper corner of the receiver screen [p138]. The receiver is rechargeable and it takes about 3 hours for full charge, and the rechargeable battery will last about 2 days [p336,352]. A different low battery icon is displayed at the left upper corner of the receiver screen as well.

Guardian Connect[5] – Use life: transmitter can be cleaned up to 122 times or one year. If you continue to use the transmitter beyond 122 times or one year, the cleaning process may damage the device[p50]. The transmitter contains a non-replaceable, rechargeable battery that you can recharge as needed with the charger. The charger needs one AAA alkaline battery. The transmitter will need to be charged before you use it[p12]. A fully charged transmitter works at least seven days without recharging. If the transmitter is left on the charger for more than 60 days, the battery will be permanently damaged[p13].

#All the page numbers refer to those in the respective product manual.

References: (information of CGM)

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5. Guardian Connect system user guide©2018 Medtronic MiniMed, Inc.
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Chapter 4:
Nursing Practice Guide for Continuous Glucose Monitoring (CGM)

There has been rapid advancement of CGM technology in recent years including accuracy, simple procedures of sensor insertion, diminished frequency of sensor calibration, and reducing cost of CGM. Two types of CGM are available in Hong Kong, retrospective CGM (rCGM) in T2DM provides actionable information for healthcare professionals and patients to review glucose patterns and share decision-making with patients in clinic visits[1,2]. Real time CGM (rtCGM) provides instant glucose reading, glucose trend of previous few hours and rate of change (trend) arrow to facilitate daily management decision-making by the patient and retrospectively, the ambulatory glucose profile (AGP) data report in clinic visit as well.

Level VA

Randomized control trials (RCTs)[3-12] have demonstrated the effectiveness of rtCGM on improving HbA1c, reducing hypoglycaemia exposure and prevention of hypoglycemia in Type 1 and Type 2 diabetes undergoing intensive therapy and using it on nearly daily basis.

Level IA

Some case studies demonstrated the benefit of rCGM to improve HbA1c, engage patient in lifestyle modification and reduce the glucose fluctuation through the informing discussion with patients and coaching from health care professionals in type 2 diabetes.[13]

Level VA

However, there were some barriers to using rtCGM from user's perspective in an observational study which might explain the reason for the large drop-out rate in some studies[14]. When we look into the inclusion and exclusion criteria of patient recruitment, the patients were required to have self-monitoring blood glucose (SMBG) regularly such as 2 times a day or 75% usage of rtCGM before randomization. Some studies necessitated patient assessment for the willingness and ability of using rtCGM or knowledge on diabetes management. Therefore, the following considerations should be made when diabetes nurses assess patient's readiness of using rtCGM:
i) Knowledge of diabetes management
ii) Financial Status
iii) Adherence of self-monitoring blood glucose (SMBG)

Level IIIA

Practical Checklist[15-16]

Level VB

1. Before introducing CGM (rCGM / rtCGM), we need to assess the following items:

1.1 Medical history and treatment
1.2 Pattern of using CGM – regular or intermittent
1.3 Readiness of using CGM for reviewing the glucose excursions and adherence of self-monitoring blood glucose
1.4 Ability of handling the CGM technology
1.5 Knowledge of diabetes management

1.6 Type of CGMS
1.7 rCGM is a “blind” monitoring approach and will not induce the stress of glucose fluctuation to patient, also reflect the glucose trends in usually lifestyle style.
1.8 rtCGM is to show the glucose concentration in interstitial fluid and glucose trend in near real time, it facilitates the treatment decision making of diabetes management to prevent hypoglycaemia and hyperglycaemia.

Education on Retrospective CGM (rCGM)[14] Level VB

1. Before rCGM installation

1.1 The difference between interstitial fluid and capillary blood glucose
1.2 Setting up the goal of using rCGM
1.3 The importance of keeping record on medications, diet, exercise and hypoglycemia .
1.4 The relationship of rCGM accuracy with the proper technique, frequency and timing of SMBG tests for calibration (SMBG for calibration should be avoided at times of rapid glucose change)
1.5 Reviewing the technique of self-monitoring of blood glucose (SMBG) and equipment conditions to ensure high quality data
1.6 CGM sensor placement according to manufacturer’s instruction

2. After completion of rCGM

2.1 Reviewing the quality of rCGM data and identifying important information including glucose pattern, hypoglycemia during day and night time (aware and unaware), glucose variability and stability.
2.2 Discussing the report with patient’s daily record to find out any modifiable behavior with reference to and evaluation of the existing treatment
2.3 Recording the findings in patient’s medical record

Education on Real time CGM (rtCGM)[14-15] Level VB

1. Before rtCGM installation

1.1 The difference between interstitial fluid glucose and capillary blood glucose
1.2 Setting up the goal of using rtCGM
1.3 The importance of keeping record on medications, diet, exercise and hypoglycemia .
1.4 The relationship of rtCGM accuracy with the proper technique, frequency and timing of SMBG tests for calibration (SMBG for calibration should be avoided at times of rapid

glucose change)

1.5 Reviewing the technique of self-monitoring of blood glucose (SMBG) and equipment conditions to ensure high quality data

1.6 The reason for using capillary blood glucose to confirm hypoglycemia

1.7 The reason for lower interstitial fluid glucose than capillary blood glucose in the initial few hours

1.8 The display information including glucose reading, glucose trend of previous few hours and arrow trends (rate of change (ROC) according to the manufacturer's information)

1.9 Reviewing or intensifying education on Insulin to carbohydrate ratio (ICR), insulin sensitivity factor (ISF), insulin dose adjustment principles and safety using the ROC to optimize glycemic control for diabetes patients on intensive treatment (CSII or MDI)

1.10 Providing insight into the effects of medications and lifestyle choices

1.11 Teaching the meaning of ROC to predict and prevent hypoglycemia through appropriate action in type 2 DM subjects on basal insulin and OADs

1.12 CGM sensor placement according to manufacturer's instruction

2. After completion of rtCGM

2.1 Reviewing the quality of rtCGM data and identifying the important information including glucose pattern, hypoglycemia during day and night time (awareness and unawareness), glucose variability and stability

2.2 Discussing the report with patient's daily record to find out any modifiable behavior from the patient and evaluating the immediate management or treatment decision in daily life

2.3 Evaluating the appropriateness of ICR and ISF for fine adjustment

2.4 Picking up some special events such as intensive and long duration exercise, and sick days for education

2.5 Installing the software to download the personal continuous glucose profile report and providing education for self-evaluation and lifestyle modification

2.6 Recording the findings in medical record

Key points for patient preparation and education Level VB

1. **Pre-CGM Initiation**
   - 1.1 The difference between interstitial fluid and capillary glucose, and how this explains for the lag time
   - 1.2 The limitation in rtCGM data accuracy within the first 24 hours of insertion
   - 1.3 Realistic goal of using CGM
   - 1.4 Managing emotions around glycemic excursions
   - 1.5 Insulin action time and expected post-meal patterns if applicable
2. **Calibration**
   - 2.1 The importance of handwashing prior to fingerstick monitoring
   - 2.2 Calibration intervals and proper technique to ensure the accuracy
3. **Sensor insertion procedure and placement**
   - 3.1 According to the CGM user manual
4. **rtCGM display information[17]**
   - 4.1 The significance of alarm/alerts, glucose trend data and trend arrows in making treatment decision
   - 4.2 How to use the trend arrows in individual treatment decision
5. **Cross Checking Glucose**
   - 5.1 At times of rapidly changing glucose levels when interstitial glucose does not accurately reflect blood glucose. Testing of blood glucose with the blood glucose analyser to confirm hypoglycemia/hyperglycemia, especially when there is symptom discrepancy
6. **Log Sheet Entries**
   - 6.1 Recording SMBG readings, food intake, physical activity and duration, medications and dosage, and other events (such as hypoglycemic symptoms, stress, or illness)

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Chapter 5: Patient Education Materials

We incorporate expert recommendation and information from CGMS manuals and websites of different manufacturers to prepare the following patient education materials.

General Patient Information Sheet for continuous glucose monitoring (CGM)

1 What is CGM?

The sensor contains a wire with a supply of glucose oxidase at the tip which is inserted in subcutaneous tissue. Glucose oxidase catalyses a biochemical reaction in the presence of glucose and oxygen that transfers electrons to a receiving molecule and creates an electronic current, whose magnitude can be measured and converted into a glucose concentration. The device calculates and stores glucose readings every five minutes and shows the glucose graphic by 288 readings in 24 hours.

2 Pre-CGM Initiation

2.1 **Education and training are required for patients to benefit from CGM**

2.2 The goal of using CGM:

To understand the relationship between medications, diet and exercise for the individual with the glucose graphic, health care professional would recommend the following individually according to the patient's conditions:

2.2.1 Type of continuous glucose monitoring system:

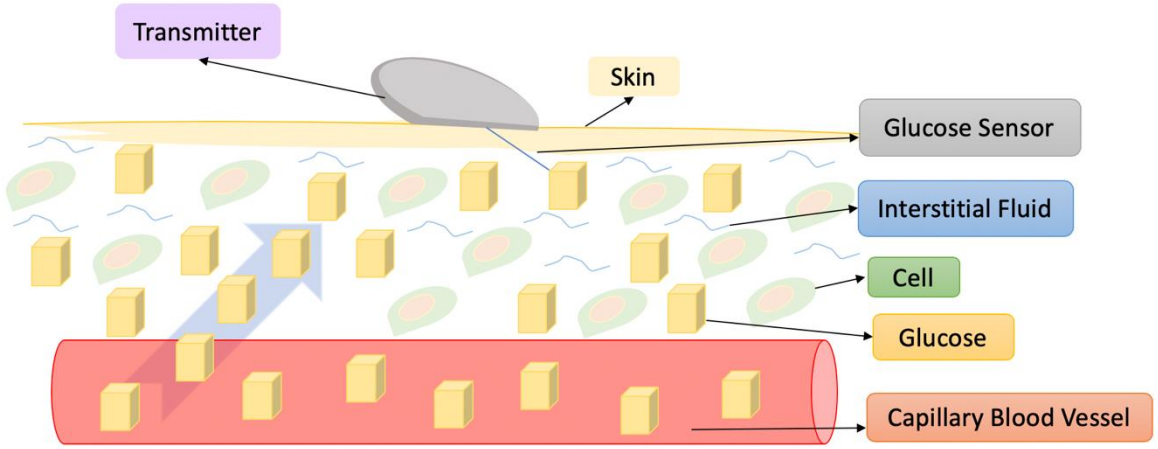
- ☐ Real-time CGMS
- ☐ Retrospective CGMS

2.2.2 Using pattern

- ☐ Intermittent use for adjusting the treatment plan for diabetes
- ☐ Long term use for monitoring glucose level, detecting hypoglycemia, diet modification and learning bolus insulin adjustment

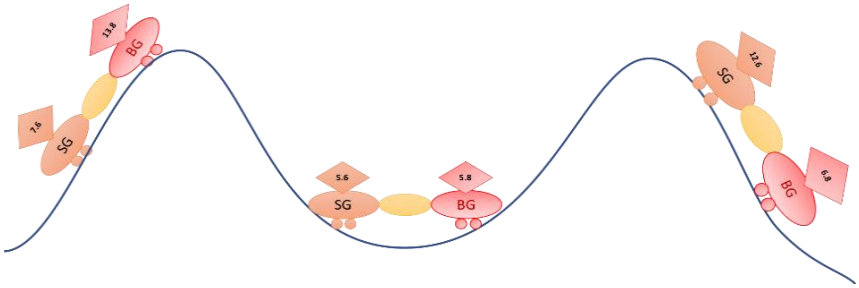
2.3 Special precaution

2.3.1 The difference between interstitial fluid and capillary blood glucose and physiological lag time



Physiological lag time between SG and BG~5-10 minutes

2.3.2 Great difference between blood glucose and senor glucose value while rapid changes



SG = sensor glucose
BG = blood glucose

3 Installation of CGMS

3.1 Calibration

3.1.1 A CGM device should be calibrated according to the manufacturer's instructions

3.1.2 The calibration should be done at times of stable glucose levels, e.g fasting or pre-meals, and according to the recommended interval to ensure the accuracy of CGM

3.1.3 CGM accuracy depends on the quality of blood glucose test data

3.1.4 Patients should ensure the normal function of blood glucose meter, proper storage of test strips and use before the expiry date.

3.1.5 Patients must ensure their hands are clean and dry (no lotion or cream on the skin) and the blood sample is sufficient for a test (some glucose meters will return a falsely low value when not enough blood is applied)

3.1.6 Patients should enter the blood glucose test result for calibration as soon as possible

3.2 Patients should perform the blood glucose tests for treatment decision and insulin dose adjustment in the event of:

3.2.1 Symptoms and signs of hypoglycemia or hyperglycemia

3.2.2 Unmatched symptoms and signs with sensor glucose value
3.2.3 Rapid changes of sensor glucose

3.2.4 Sensor glucose below 4 mmol/L

4 After Installation of CGMS

4.1 Log Sheet Entries

4.1.1 Recording the BG meter readings, food items and amount, number of carbohydrates, physical activity and duration, medications and dosage, and other events (such as symptoms of hypoglycemia and management, stress, or illness).

4.1.2 Advising the patient to keep the log sheet at all times so he/she can write down the information immediately after each event. Record the time and date within 5 minutes of each BG meter reading.

4.2 Skin Reaction

4.2.1 Possible risks: skin allergy, bleeding, swelling, itchy, blister and or infection
4.2.2 Causes for skin irritation: sensor probe, sensor tape, additional tape, adhesive aid
4.2.3 Removing the sensor and notifying the doctor or diabetes nurse

4.3 Travelling

4.3.1 Medical certificate for use of CGMS

4.3.2 Notify security personnel and contact aviation authority

4.4 CT Scan/MRI/Diathermy/other devices which generate strong magnetic fields or ionizing radiation

4.4.1 Remove before the captioned examination and procedure

4.5 Sensor Life

4.5.1 Recommendation of sensor duration according to respective user guides.

4.5.2 Sensor decay >20% variation from SMBG, poor signal transmission and also association with skin infection/irritation if prolonged use

病人使用連續性葡萄糖監察系統須知

1 何為連續性葡萄糖監察系統？

是應用電化學反應，將葡萄糖感應器的幼軟管植入皮下組織，通過感應器上的糖氧化酶每 5 秒鐘測量皮下組織液內氧的消耗或氫氧離子產生的電流訊號，透過葡萄糖接收器，將電流訊號轉換成葡萄糖數值。每五分鐘記錄一次平均葡萄糖值，在 24 小時獲得 288 個於組織液的葡萄糖值並連成曲線呈現葡萄糖趨勢圖。

2 安裝連續性葡萄糖監察系統前

使用前需要接受教育及訓練，充分發揮此系統的優點：

2.1 使用此系統的目的

透過趨勢圖明白藥物、食物及運動對個別糖尿病人的影響，醫護人員亦會因應不同的情況作出下列建議：

2.1.2 連續性葡萄糖監察系統

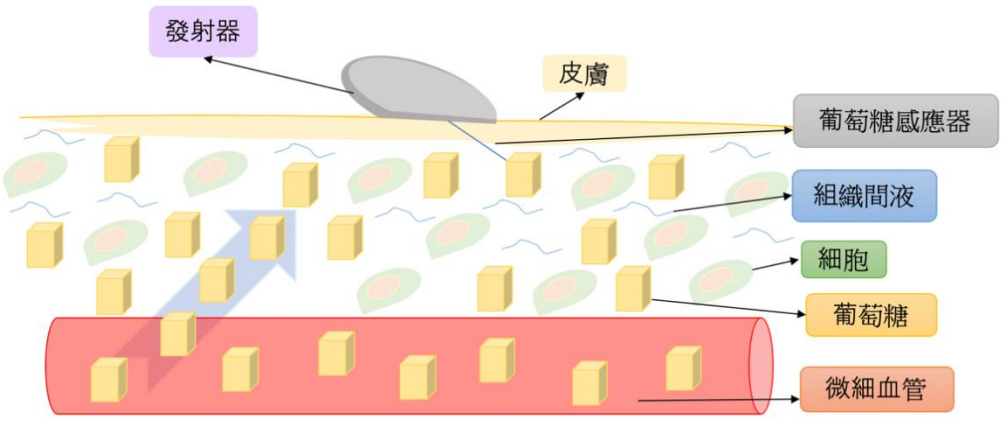
- ☐ 實時連續性葡萄糖監察系統
- ☐ 回顧性連續性葡萄糖監察系統

2.1.2 使用時間性

- ☐ 間斷性地評估血糖趨勢以調整糖尿病的治療方案
- ☐ 長期性地跟進血糖趨勢以監察低血糖反應，自行在飲食及餐前胰島素進行調節

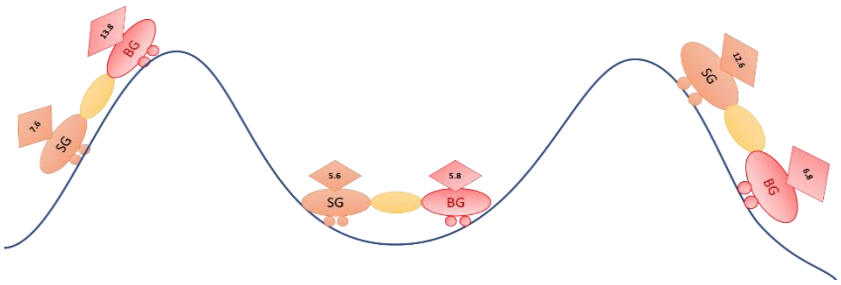
2.2 特別注意事項

2.2.1 微血管葡萄糖與組織液葡萄糖的分別及生理性的時間差距



在生理上，感應器葡萄糖值反應會延遲微血管葡萄糖值5 – 10 分鐘

2.2.2 微血管葡萄糖值及感應器葡萄糖值在血糖快速轉變時差距擴大



SG = 感應器葡萄糖值
BG= 微血管葡萄糖值

3 安裝連續性葡萄糖監察系統

3.1 系統較正

3.1.1 跟從所使用系統的要求，定時進行血糖測試作較對
3.1.2 進行較對必須在血糖較穩定如空腹或餐前時，並要跟從個別系統的要求較對次數以確保連續性葡萄糖監察準確
3.1.3 連續性葡萄糖監察系統的準確性有賴準確血糖測試結果
3.1.4 確保血糖機操作正常、血糖測試紙儲存在正確及在有效期內
3.1.5 測試血糖前必須洗手及抹乾，測試程序必須正確
3.1.6 血糖測試結果要盡快輸入接收器作較正

3.2 在下列情況需要進行血糖測試以決定治療行動及調整餐前胰島素劑量

3.2.1 出現有血糖過高或過低的徵狀
3.2.2 出現的徵狀與顯示的感應器葡萄糖值不吻合
3.2.3 當感應器葡萄糖值有快速的改變時
3.2.4 感應器葡萄糖值低於 4 mmol/L

4 安裝連續性葡萄糖監察系統後

4.1 填寫記錄表

4.1.1 記錄藥物劑量、食物種類和份量、運動時間和強度、低血糖徵狀和處理方法以及患病和壓力事情等作為分析葡萄糖趨勢變化的原因
4.1.2 隨身攜帶記錄簿盡快填寫所有資料或利用手機應用程式作完整記錄

4.2 皮膚反應

4.2.1 留意皮膚可能出現的問題：皮膚過敏、出血、腫脹、痕癢、水泡或發炎
4.2.2 出現皮膚刺激反應的原因：感應器軟管、感應器膠布、另加膠布或輔助黏貼用品
4.2.3 要移除感應器並通知醫護人員

4.3 外遊

4.3.1 攜帶需要使用連續性葡萄糖監察系統醫療證明文件

4.3.2 主動通知安檢人員及航空公司

4.4 電腦斷層掃描/磁力共振/透熱療法/其他高磁場或離子放射線程序

4.4.1 進行以上檢驗或程序前必須先行移除感應器

4.5 感應器時限

4.4.1 跟從個別系統的使用指引不能超越安裝感應器時限

4.4.2 超越安裝感應器時限會使接收器電流訊號減弱或皮膚出現刺激反應／發炎

Reference

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General Patient Information Sheet for intermittently scanned continuous glucose monitoring (isCGM)

1. What is isCGM?

The sensor contains a wire with a supply of glucose oxidase enzyme at the tip which is inserted into subcutaneous tissue. However, the system utilizes the Wired Enzyme technology by which the enzyme is cross-linked with mediator molecules (an osmium complex) into a polymer matrix. Glucose which diffuses from the interstitial tissue through the outer membrane into the enzyme matrix is oxidized by glucose oxidase, the resulting electrons are then retrieved by the osmium mediator to provide direct signalling to the sensor electrode and generate a glucose value. Also this system is factory-calibrated during the manufacturing process and does not require blood glucose testing for calibration. The device measures glucose levels every minute and records every 15 minutes, user must scan the sensor with a reader to get the current glucose value. Glucose data of the most recent 8 hours are stored in the sensor and provide the glucose trend in the reader/mobile app.

2. Pre-isCGM Initiation

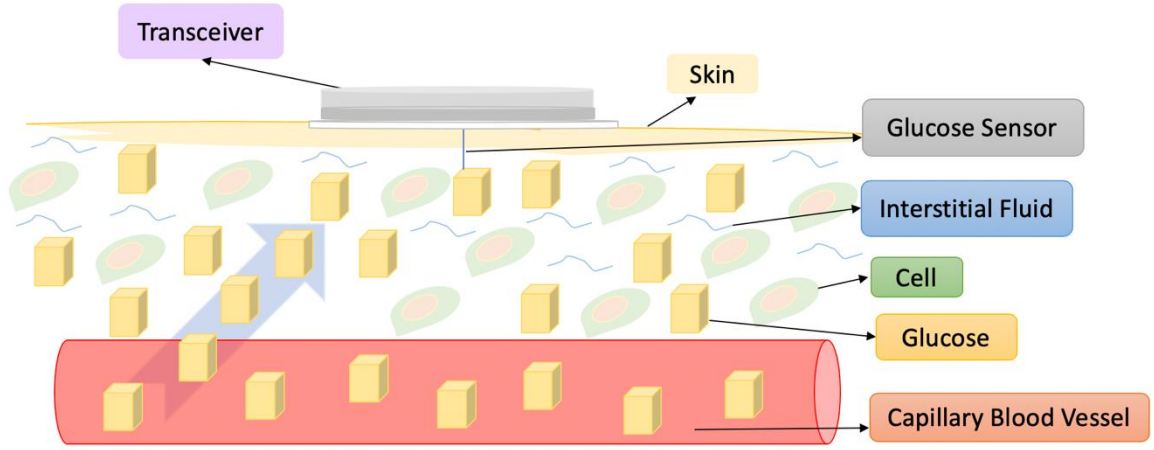
2.1 Education and training are required for patients to benefit from CGM.

2.2 The goal of using isCGM:
Understanding the relationship between medications, diet and exercise for the individual with the glucose graphic, health care professional would recommend the following option according to the patient's condition:

2.2.1 Type of continuous glucose monitoring system:
☐ Real-time isCGM

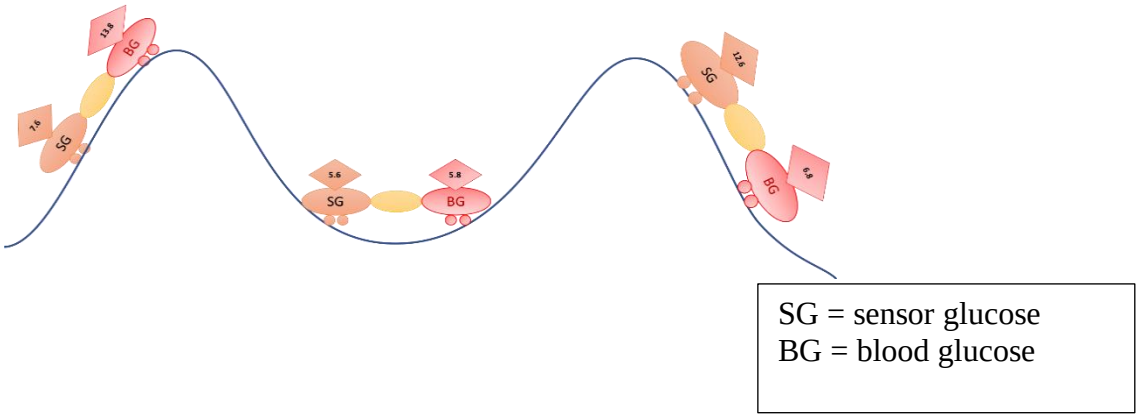
2.2.2 Using pattern
☐ Intermittent use for adjusting the treatment plan for diabetes
☐ Long term use for monitoring glucose trend, detecting hypoglycemia, diet modification and learning bolus insulin adjustment

2.3 Special precaution
2.3.1 The difference between interstitial fluid and capillary blood glucose and physiological lag time



Physiological lag time between SG and BG~5-10 minutes

2.3.2 Great difference between blood glucose and sensor glucose value while rapid changes



SG = sensor glucose
BG = blood glucose

3. Installation of isCGM

3.1 Scanning the glucose reading

3.1.1 Sensor can save glucose data for 8 hours

3.1.2 Patients should scan the sensor with the reader for glucose level at least once every 8 hours

3.1.3 The reader / mobile app shows the current glucose reading and the glucose graphic trend in past 8 hours

3.1.4 Glucose data prior to the previous 8 hours will be lost if the sensor is not scanned for more than 8 hours

3.1.5 The reader can save glucose data history for 90 days

3.1.6 Patients should ensure the normal function of blood glucose meter, proper storage of test strips and use before the expiry date

3.1.7 Patients must ensure their hands are clean and dry, and also perform the blood glucose tests properly

3.2 Patients should perform the blood glucose tests for treatment decision and insulin dose adjustment in the event of:

3.2.1 Symptoms and signs of hypoglycemia or hyperglycemia

3.2.2 Unmatched symptoms and signs with sensor glucose value

3.2.3 Rapid changes of sensor glucose

3.2.4 Sensor glucose below 4 mmol/L

4 After Installation of CGMS

4.1 Log Sheet Entries

4.1.1 Recording the BG meter readings, food items and amount, number of carbohydrates, physical activity and duration, medications and dosage, and other events (such as symptoms of hypoglycemia and management, stress, or illness)

4.1.2 Advising the patient to keep the log sheet at all times so he/she can write down the information immediately after each event. Record the time and date within 5 minutes of each BG meter reading

4.2 Skin Reaction

4.2.1 Possible risks: skin allergy, bleeding, swelling, itchy, blister and or infection

4.2.2 Causes for skin irritation: sensor probe, sensor tape, additional tape, adhesive aid

4.2.3 Removing the sensor and notifying the doctor or diabetes nurse

4.3 Travelling

4.3.1 Medical certificate for use of CGMS
4.3.2 Notify security personnel and contact aviation authority

4.3.3 Performing blood glucose monitoring instead of scanning the sensor while on plane

4.4 X-Ray/CT Scan/MRI/other devices which generate strong magnetic fields or ionizing radiation

4.4.1 Remove before the captioned examination and procedure

4.5 Sensor Life

4.5.1 Recommendation of sensor duration according to respective user guides

4.5.2 Sensor decay >20% variation from SMBG, poor signal transmission and also association with skin infection/irritation if prolonged use

病人使用間歇掃描式葡萄糖監察系統須知

1. **何為間歇掃描式葡萄糖監察系統？**

是應用電化學反應，將葡萄糖感應器的幼軟管植入皮下組織，利用聯網酵素技術(wired enzyme technology) ，軟管上的糖氧化酶只會結合葡萄糖，並將電子信號直接輸送到感應器的電極，轉化成葡萄糖數值。每分鐘測量皮下組織液葡萄糖數值，每十五分鐘記錄一次平均葡萄值，感應器能存儲 8 小時的葡萄糖值數據，所以每 8 小時必須掃描感應器一次，將數據傳送到閱讀器可儲存 90 日。儲存的葡萄糖值會連成曲線呈現葡萄糖趨勢圖。此外，這系統在生產過程已進行葡萄糖值較正，不需每天進得血糖測試作系統較正。

2. **安裝間歇掃描式葡萄糖監察系統前**

使用前需要接受教育及訓練，明白使用此系統的優點，包括：

2.1 使用此系統的目的

透過趨勢圖明白藥物、食物及運動對個別糖尿病人的影響，醫護人員亦會因應不同的情況作出下列建議：

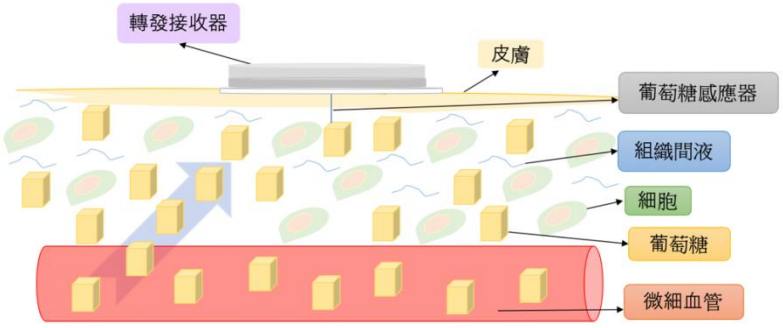
2.1.1 實時間歇掃描式葡萄糖監察系統

2.1.2 使用時間性

- □ 間斷性地評估血糖趨勢以調整糖尿病的治療方案
- □ 長期性地跟進血糖趨勢以監察低血糖反應，自行在飲食及餐前胰島素進行調節

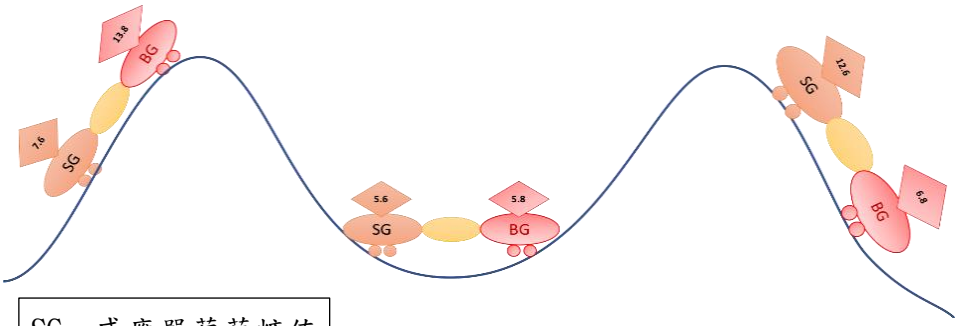
2.2 特別注意事項

2.2.1 微血管葡萄糖與組織液葡萄糖的分別及生理性的時間差距



在生理上，感應器葡萄糖值反應會延遲微血管葡萄糖值5 – 10 分鐘

2.2.2 微血管葡萄糖值及感應器葡萄糖值在血糖快速轉變時差距擴大



SG =感應器葡萄糖值
BG= 微血管葡萄糖值

3. 安裝間歇掃描式葡萄糖監察系統

3.1 葡萄糖值儲存系統

3.1.1 感應器可以儲存 8 小時的葡萄糖值資料
3.1.2 跟從所使用系統的要求，最少每 8 小時自行掃描感應器一次
3.1.3 每次掃描會顯示即時葡萄糖值及過去 8 小時的葡萄糖趨勢曲線圖
3.1.4 若超過 8 小時進行掃描感應器，會失去 8 小時以前的葡萄糖值資料
3.1.5 將葡萄糖值儲存在閱讀器內可保存 90 日
3.1.6 確保血糖機操作正常、血糖測試紙儲存在正確及在有效期內
3.1.7 測試血糖前必須洗手及抹乾，測試程序必須正確

3.2 在下列情況需要進行血糖測試以決定治療行動及調整餐前胰島素劑量

3.2.1 出現有血糖過高或過低的徵狀
3.2.2 出現的徵狀與顯示的感應器葡萄糖值不吻合
3.2.3 當感應器葡萄糖值有快速的改變時
3.2.4 感應器葡萄糖值低於 4mmol/L

4. 安裝間歇掃描式葡萄糖監察系統後

4.1 填寫記錄表

4.1.1 記錄藥物劑量、食物種類和份量、運動時間和強度、低血糖徵狀和處理方法以及患病和壓力事情等作為分析葡萄糖趨勢變化的原因
4.1.2 隨身攜帶記錄簿盡快填寫所有資料或利用手機應用程式作完整記錄

4.2 皮膚反應

4.2.1 留意皮膚可能出現的問題：皮膚過敏、出血、腫脹、痕癢、水泡或發炎
4.2.2 出現皮膚刺激反應的原因：感應器軟管、感應器膠布、另加膠布或輔助黏貼用品
4.2.3 要移除感應器並通知醫護人員

4.3 外遊

4.3.1 攜帶需要使用間歇掃描式葡萄糖監察系統醫療證明文件

4.3.2 主動通知安檢人員及航空公司

4.3.3 在機上要進行血糖測試代替掃描葡萄糖值

4.4 X 光/電腦斷層掃描/磁力共振/其他高磁場或離子放射線程序

4.4.1 進行以上檢驗或程序前必須先行移除感應器

4.5 感應器時限

4.4.1 跟從個別系統的使用指引不能超越安裝感應器時限

4.4.2 超越安裝感應器時限會使接收器電流訊號減弱或皮膚出現刺激反應／發炎

Reference

1. AADE (2015). AADE Continuous Glucose Monitoring Summit White Paper.
2. E Cengiz & WV. Tamborlane. (2009) A Tale of Two Compartments: Interstitial Versus Blood Glucose Monitoring. Diabetes Technology & Therapeutics, 11(S1), S11-16.
3. FreeStyle Libre System IN-SERVICE GUIDE ©2017 Abbott. ADC-05821 v2.0 10/17
4. User manual of Freestyle Libre Flash blood glucose monitoring system ©2017 Abbott.

Patient Information on Using FreeStyle Libre Flash Glucose Monitoring System



Sensor Duration	14 days
Sensor Insertion Site	1) Apply sensors only on the back of upper arm. Avoid areas with scars, moles, stretch marks or lumps. 2) Select an area of skin that generally stays flat during normal daily activities (no bending or folding). Choose a site that is at least 2.5 cm (1 inch) away from an insulin injection site. To prevent discomfort or skin irritation, you should select a different site other than the one most recently used. 
Calibration	No calibration is necessary Finger prick blood glucose testing would still be needed: 1) During times of rapidly changing glucose levels (as indicated by up or down arrows) when interstitial fluid glucose levels may not accurately reflect blood glucose levels 2) If FreeStyle Libre shows hypoglycaemia or impending hypoglycaemia 3) When symptoms do not match the system readings For a full 24 hours of data, users must scan the sensor at least once every 8 hours
Sensor Storage	4°C to 30°C, relative humidity 10-90%
Waterproof/ Water Resistant	The sensor is waterproof in up to 1 meter of water for 30 minutes and can be worn during all daily activities including bathing and showering.
Receiver Distance	To scan the sensor, the reader is held 1 to 4cm above the sensor for 1 second
Additional Feature	1) Built-in meter for blood glucose and blood ketone test, also insulin calculator for rapid acting insulin. 2) The reader is reusable and has rechargeable battery that must be charged every 7 days. 3) Do not scan the sensor or power on the reader using the Home Button while flying, if restricted by flight regulations. Insert a strip to perform a blood glucose or ketone test.

	4) The reader is for use by a single person. It must not be used on more than one person including other family members due to risk of spreading infection.
Precaution	1) Taking ascorbic acid (vitamin C) - readings falsely high / salicylic acid - slightly low 2) Libre senor must be removed prior to X-ray, CT scan or MRI examination
Accuracy	falsely low estimation in 1st 24 hours
Approved for insulin adjustment without finger prick	No

Reference: FreeStyle Libre User Manual ©2017 Abbott

Arrow Trends
Abbott Libre
↑ rising quickly > 0.1 mmol/L per minute (more than 1.5 mmol/L in 15 minutes)
↖ rising 0.06 - 0.1 mmol/L per minute (between 0.9 - 1.5 mmol/L in 15 minutes)
→ changing slowly < 0.06 mmol/L per minute (less than 0.9 mmol/L in 15 minutes)
↘ falling 0.06 - 0.1 mmol/L per minute (between 0.9 - 1.5 mmol/L in 15 minutes)
↓ falling quickly > 0.1 mmol/L per minute (more than 1.5 mmol/L in 15 minutes)



有關 FreeStyle Libre 使用者信息

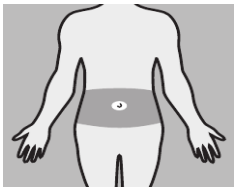
感應器佩戴時間	14 天
感應器植入部位	1) 僅在上臂背面植入感應器。避免有疤痕、痣、妊娠紋或腫塊的區域 2）選擇在日常活動中通常保持平坦，無彎曲或折疊的皮膚區域。選擇距離胰島素注射部位至少 2.5 厘米（1 英寸）的部位。為防止不適或皮膚刺激，應轉換植入位置，避免經常重複同一區域 
校對	無需校對 在以下情況，仍然需要進行血糖測試： 1）當血糖水平快速變化（如↑或↓箭頭所示），感應器葡萄糖值可能無法準確反映血糖值時 2）如果 FreeStyle Libre 顯示低血糖或即將發生低血糖 3）徵狀與系統讀數不符時 必須至少每 8 小時掃描一次感應器，以確保獲得完整的 24 小時數據
感應器存儲溫度	4°C 至 30°C，相對濕度 10-90%
防水性	感應器防水可達 1 米水深，持續 30 分鐘，可在日常活動中佩戴，包括沐浴和淋浴
接收信號距離	當掃描感應器時，將閱讀器保持在感應器上方 1 至 4 厘米處，持續 1 秒鐘
附加功能 / 特性	1）閱讀器內置血糖和血酮測試的儀表，以及用於速效胰島素的胰島素計算器 2）閱讀器可重複使用，並且具有可充電電池，必須每 7 天充電一次 3）如果受到航空管制，請勿在飛行時掃描感應器或打開閱讀器電源，需插入試紙進行血糖或酮測試 4）閱讀器只供個人使用。基於傳播感染的風險，不得多人使用包括其他家庭成員在內
注意事項	1) 必須在 X 射線/電腦斷層掃描/磁力共振/其他高磁場或離子放射線程序之前移除感應器 2) 服用抗壞血酸（維生素 C）- 葡萄糖讀數錯誤高 /水楊酸 - 葡萄糖讀數略低
準確性	首 24 小時感應器葡萄糖讀數有偏低情況
可根據感應器葡萄糖值作出治療決定（胰島素劑量調整）	否

葡萄糖走勢箭頭
Abbott Libre
↑葡萄糖急促上升每分鐘超過 0.1 mmol/L (或 15 分鐘內超過 1.5 mmol/L)
↖葡萄糖上升每分鐘 0.06 - 0.1 mmol/L (或 15 分鐘內上升 0.9 - 1.5 mmol/L)
→葡萄糖慢慢轉變每分鐘少於 0.06 mmol/L (或 15 分鐘內少於 0.9 mmol/L)
↘葡萄糖下降每分鐘 0.06 - 0.1 mmol/L (或 15 分鐘內下降 0.9 - 1.5 mmol/L)
↓葡萄糖急促下降每分鐘超過 0.1 mmol/L (或 15 分鐘內超過 1.5 mmol/L)

Reference: FreeStyle Libre User Manual ©2017 Abbott



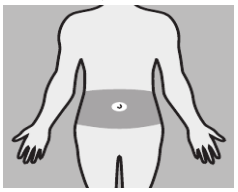
Patient Information on Using Medtronic iPro 2

Sensor duration	6 days
Sensor Insertion Site	1) Avoid the 5 cm (2 inches) area around the navel to help ensure a comfortable insertion site and to help with sensor adhesion 2) Avoid areas where clothing might cause irritation (for example beltline) 3) Never insert sensor within 5 cm (2 inches) from a pump infusion set or within 7.5 cm (3 inches) from a manual injection site 4) Choose an insertion site that has an adequate amount of subcutaneous fat  Shown here are the best body areas (shaded) for sensor insertion
Calibration	1) On the first day: ・Take first BG meter reading at least 1 hour after insertion ・Take a second BG meter readings at least 3 hours after insertion ・Collect at least one more meter reading before going to bed 2) Collect at least 4 BG meter readings each day, such as before breakfast, lunch, dinner and bedtime
Sensor Storage	2°C to 30°C
Waterproof/ Water Resistant	The iPro 2 and sensor are watertight at a depth of up to 2.4 meters (8 feet) for 30 minutes. There is no time limit if swimming on the surface of a pool or showering.
Precaution	1) Cellular phone interference: keep 30 cm (12 inches) from CGM system device 2) The iPro2 must be removed (but the sensor can be left in) prior to an X-ray, CT scan, MRI, diathermy devices. Simply reconnect the iPro2 afterward. 3) Taking medications with paracetamol/acetaminophen while wearing the sensor may falsely raise sensor glucose readings
Confirmation with finger prick blood glucose if hypoglycemia	Yes, need fingerstick glucose when necessary to confirm hypo/hyperglycaemia

Reference: iPro 2 User Guide ©2016 Medtronic MiniMed, Inc.



有關 Medtronic iPro 2 的使用者信息

感應器佩戴時間	6 天
感應器植入部位	1）避免肚臍周圍 5 厘米（2 英寸)的區域，以確保插入部位舒適並幫助感應器粘附。 2）避免衣服可能引起刺激的區域（例如腰帶）。 3）切勿將感應器插入距離胰島素泵輸注管路 5 厘米（2 英寸）或胰島素注射部位 7.5 厘米（3 英寸）的範圍內。 4）選擇具有足夠皮下脂肪量的植入部位。  這裡顯示感應器植入的最佳身體區域（陰影部份）。
校對	進行血糖測試並輸入讀數作校對 1）第一天： ・植入後至少 1 小時進行 ・植入後至少 3 小時進行 ・睡前 2）其後，每天至少 4 次進行校對，例如在早餐，午餐，晚餐和就寢時間之前
感應器存儲溫度	2˚C 至 30˚C
防水性	iPro 2 和感應器連接後防水深度達 2.4 米（8 英尺），持續 30 分鐘。如果游泳或淋浴，沒有時間限制。
注意事項	1）手機干擾：距離 CGM 系統設備 30 厘米(12 英寸) 2）必須在 X 射線/電腦斷層掃描/磁力共振/透熱療法之前移除 iPro2（但可以留下感應器）之後只需重新連接 iPro2 即可 3）佩戴感應器時服用含撲熱息痛/乙酰氨基酚的藥物可能會錯誤地提高感應器葡萄糖讀數
如低血糖，需用血糖機確認	是

Reference: iPro 2 User Guide ©2016 Medtronic MiniMed, Inc.

Patient Information on Using Dexcom G4 / G5



Sensor Duration	7 days
Sensor Insertion Site	Adult - abdomen (ensure adequate amount of subcutaneous fat, should be either above or below belt line, flat and free from rubbing) Age between 2 and 17 - abdomen / upper buttocks Insulin injection should be at least 7.5 cm (3 inches) away from sensor site
Calibration	Calibrate 2 hours after insertion. First calibration requires 2 finger sticks done consecutively. Calibration required every 12 hours at any rate of change.
Confirmation with finger prick blood glucose if hypoglycemia	Dexcom G4: Yes Dexcom G5: No, but need to cross check if any discrepancy from symptoms
Sensor storage	2° C -25° C
Waterproof/ Water Resistant	Dexcom G4: Transmitter is not waterproof; sensor is water resistant in shower, bathing or swimming if the transmitter is fully snapped in; receiver cannot get wet Dexcom G5: Sensor with attached transmitter is water resistant for up to 8 feet deep for 24 hours, so you can wear it while bathing and swimming
Receiver Distance	The transmission range from the transmitter to the receiver is up to 20 feet without obstruction. Wireless communication does not work well through water so the range is much less if in a pool, bathtub, or on a water bed
Additional Feature	1) The receiver has internal rechargeable battery. Each charge last for about 3 days 2) Dexcom G5: Mobile communication through blue-tooth and Apps for 5 compatible smart devices
Precaution	1) Do not bring the Dexcom sensor, transmitter and receiver with Share, iPhone, or iPod touch into a room containing medical equipment such as MRI, CT, or diathermy. Exposure to these types of equipment could heat and damage the devices so that they are unable to send or receive glucose information. 2) Taking medications with paracetamol/acetaminophen while wearing the sensor may falsely raise sensor glucose readings
Approved for insulin adjustment without finger prick	Dexcom G4: No Dexcom G5: Yes

Arrows Trends
Dexcom
↑↑Rapidly rising more than 0.16 mmol/L each minute (or more than 2.5 mmol/L in 15 minutes)
↑ Rising 0.11-0.16 mmol/L each minute (or up to 2.5 mmol/L in 15 minutes)
↖ Slowly rising 0.06-0.11 mmol/L each minute (or up to 1.67 mmol/L in 15 mintues)
→ Constant; not increasing/decreasing more than 0.06 mmol/L each minute (or by up to 0.83 mmol/L in 15 minutes)
↘ Slowly falling 0.06-0.11 mmol/L each minute (or up to 1.67 mmol/L in 15 mintues)
↓ falling 0.11-0.16 mmol/L each minute (or up to 2.5 mmol/L in 15 minutes)
↓↓Rapidly falling more than 0.16 mmol/L each minute (or more than 2.5 mmol/L in 15 minutes)

Reference: 1. User ‘s Guide Dexcom G4® Platinum (Pediatric) Continuous Glucose Monitoring System Receiver with *Share*TM© 2015 Dexcom, Inc.
2. User Guide for Dexcom G5 ®Mobile Continuous Glucose Monitoring (CGM) system © 2017 Dexcom, Inc.

有關 Dexcom G4 / G5 的使用者信息



感應器佩戴時間	7 天
感應器植入部位	成人 – 腹部（確保足夠皮下脂肪量，應在皮帶線上方或下方，平坦且無摩擦的部位植入） 年齡在 2 到 17 歲之間 – 腹部/臀部上部 胰島素注射應距離感應器部位至少 7.5 厘米（3 英寸）。
校對	進行血糖測試並輸入讀數作校對 1）首次於植入感應器後 2 小時。首次校準需要連續完成 2 次血糖測試讀數 2）其後每 12 小時必須校對一次
如低血糖，需用血糖機確認	Dexcom G4: 是 Dexcom G5: 否，但症狀和感應器顯示的葡萄糖值有任何差異，必需要檢查血糖
感應器存儲溫度	2° C -25° C
防水性	Dexcom G4： 發射器不防水 ； 感應器在淋浴，沐浴或游泳時具有防水功能 ；接收器不能弄濕 Dexcom G5： 帶有發射器的感應器防水深達 8 英尺，持續 24 小時，因此可以在沐浴和游泳時佩戴它
接收信號距離	從發射器到接收器的傳輸範圍在沒有障礙物下高達 20 英尺。無線通信在水中不能良好運作，因此在泳池，浴缸或水床上，則範圍要小得多
附加功能 / 特性	1）接收器內置可充電電池，每次充電持續約 3 天。 2) Dexcom G5： 通過藍芽和 Apps 進行通信，兼容最多 5 個照顧者共享 24 小時實時數據
注意事項	1）請勿將 Dexcom 感應器，發射器及接收器帶和有分享功能的 iPhone 或 iPod touch 帶入具磁力共振，電腦掃描或透熱療法等醫療設備的房間。暴露於這些類型的設備可能會加熱和損壞儀器，使它們無法發送或接收葡萄糖值信息 2）佩戴感應器時服用含撲熱息痛/乙酰氨基酚的藥物可能會錯誤地提高感應器葡萄糖讀數
可根據感應器葡萄糖值作出治療決定（胰島素劑量調整）	Dexcom G4: 否 Dexcom G5: 是

葡萄糖走勢箭頭
Dexcom
↑↑每分鐘快速上升超過 0.16 mmol/L (或 15 分鐘內超過 2.5 mmol/L)
↑每分鐘上升 0.11-0.16 mmol/L (或 15 分鐘內上升至 2.5 mmol/L)
↖每分鐘緩慢上升 0.06-0.11 mmol/L (或 15 分鐘內上升至 1.67 mmol/L)
→不變;每分鐘不增加/減少超過 0.06 mmol/L (或 15 分鐘內最高可達 0.83 mmol/L)
↘每分鐘緩慢下降 0.06-0.11 mmol/L (或 15 分鐘內最高可達 1.67 mmol/L)
↓每分鐘下降 0.11-0.16 mmol/L (或 15 分鐘內下降至 2.5 mmol/L)
↓↓每分鐘快速下降超過 0.16 mmol/L (或 15 分鐘內超過 2.5 mmol/L)

Reference: 1. User ‘s Guide Dexcom G4® Platinum (Pediatric) Continuous Glucose Monitoring System Receiver with *Share*TM© 2015 Dexcom, Inc.
2. User Guide for Dexcom G5 ®Mobile Continuous Glucose Monitoring (CGM) system © 2017 Dexcom, Inc.



Patient Information on Using Guardian Connect

Sensor Duration	7 days
Sensor Insertion Site	Adult – abdomen or upper arm (ensure adequate amount of subcutaneous fat) Age between 14 and 75 Insulin injection should be at least 7.5 cm (3 inches) away from sensor site.
Calibration	Calibrate within 2 hours after insertion, then calibrate within 6 hours after first calibration. Subsequent Calibration required every 12 hours at any rate of change.
Confirmation with finger prick blood glucose if hypoglycemia	Yes
Sensor storage	2 °C -27 °C
Waterproof/ Water Resistant	After the transmitter and sensor are connected, they form a waterproof seal to a depth of 2.4 meters (8 feet) for up to 30 minutes.
Receiver Distance	Decrease the distance between the transmitter and the compatible mobile device to 6.1 meters (20 feet) or less
Additional Feature	1. Mobile communication through blue-tooth and Apps 2. Predicted high and low alert within 10-60 minutes 3. Share 24-hour real time data with maximum 5 care partners 4. Receive SMS alert
Precaution	1) Do not bring the sensor and transmitter into a room containing medical equipment such as X-Ray, MRI, CT, or diathermy. Exposure to these types of equipment could heat and damage sensor and transmitter, so that they are unable to send or receive glucose information. 2) Taking medications with paracetamol/acetaminophen while wearing the sensor may falsely raise sensor glucose readings.
Approved for insulin adjustment without finger prick	No

Arrows Trends
Guardian Connect
↑↑↑ Rapidly rising more than 0.17 mmol/L each minute (or more than 2.5 mmol/L in 15 minutes)
↑↑ Rising 0.11-0.16 mmol/L each minute (or up to 2.5 mmol/L in 15 minutes)
↑ Slowly rising 0.06-0.11 mmol/L each minute (or up to 1.67 mmol/L in 15 mintues)
↓ Slowly falling 0.06-0.11 mmol/L each minute (or up to 1.67 mmol/L in 15 mintues)
↓↓ falling 0.11-0.16 mmol/L each minute (or up to 2.5 mmol/L in 15 minutes)
↓↓↓ Rapidly falling more than 0.17 mmol/L each minute (or more than 2.5 mmol/L in 15 minutes)

Reference: Guardian Connect CGM System User Guide @ Medtronic



有關 Guardian Connect 的使用者信息

感應器佩戴時間	7 天
感應器植入部位	成人 – 腹部或上臂（確保足夠皮下脂肪量） 14 到 75 歲之間 胰島素注射應距感應器部位至少 7.5 厘米（3 英寸）。
校對	進行血糖測試並輸入讀數作校對 1）第一天： ・植入後至少 2 小時進行 ・植入後至少 6 小時進行 2）其後每 12 小時必須校對一次
如低血糖，需用血糖機確認	是
感應器存儲溫度	2°C -27°C
防水性	連接發射器和感應器後，它們將形成防水密封，防水深度達 2.4 米（8 英尺），持續 30 分鐘
接收信號距離	發射器和兼容流動設備之間的距離為 6.1 米 (20 英尺)或更短
附加功能 / 特性	1）通過藍牙和 Apps 進行通信 2）在 10-60 分鐘內發出預測高低警報 3）與最多 5 個照顧者共享 24 小時實時數據 4） 接收短信提醒
注意事項	1）請勿將感應器和發射器帶入具有X光，磁力共振，電腦掃描或透熱療法等醫療設備的房間。 暴露於這類型設備會加熱和損壞感應器和發射器，令他們無法發送或接收葡萄糖值信息 2）佩戴感應器時服用含乙酰氨基酚或撲熱息痛的藥物可能會錯誤地提高感應器葡萄糖讀數
可根據傳感器葡萄糖值作出治療決定(胰島素劑量調整)	否

葡萄糖走勢箭頭
Guardian Connect
↑ ↑ ↑每分鐘快速上升超過 0.17 mmol/L （或 15 分鐘內超過 2.5 mmol/L）
↑ ↑每分鐘上升 0.11-0.16 mmol/L （或 15 分鐘內上升至 2.5 mmol/L）
↑每分鐘緩慢上升 0.06-0.11 mmol/L （或 15 分鐘內上升至 1.67 mmol/L）
↓每分鐘緩慢下降 0.06-0.11 mmol/L （或 15 分鐘內最高可達 1.67 mmol/L）
↓ ↓每分鐘下降 0.11-0.16 mmol/L （或 15 分鐘內下降至 2.5 mmol/L）
↓ ↓ ↓每分鐘快速下降超過 0.17 mmol/L （或 15 分鐘內超過 2.5 mmol/L）

Reference: Guardian Connect CGM System User Guide @ Medtronic

Chapter 6: Special consideration before interpretation Evidence

Continuous glucose monitoring (CGM) has increased in popularity as a daily management tool for people with diabetes and as a diagnostic and research instrument for healthcare providers. Achieving better clinical outcomes absolutely hinges on appropriate analysis and interpretation of data collected by CGM systems[1,2,3]. Level VB

Before evaluating a set of CGM data, it is vital to qualify the information. It means verifying that the data are reliable and representative of the user's true patterns[3]. Level VB

<u>Qualification of the CGM data</u>

Level VB

1. Make sure the clock and time are set correctly on the receiver
2. Verify that sufficient calibrations were performed if required
3. Ask about the conditions under which the data were collected. Were there special circumstances such as stress, travel, unusual physical activity, illness, or use of steroid medications
4. Ensure that the data are reasonably accurate
   - 4.1 In Medtronic's CareLink Personal, take a look at the mean absolute difference percentage (MAD%) for each full week on the Sensor Daily Overlay report. The MAD is the average difference between sensor and meter readings expressed as a percentage. If the MAD% is more than 18%, the data may not be worth reviewing[1]
   - 4.2 On the Dexcom Daily Trend reports, observe the discrepancy between the calibration values (denoted as red diamonds) and the simultaneous sensor values (the blue dots). If there are many large discrepancies, consider passing up on the data analysis
   - 4.3 In the Ambulatory Glucose Profile, the data sufficiency requires minimum 2 weeks of monitoring and at least 70% of CGM data over a 2-week period[2]

5. Instruct the CGM device users to keep written or computerized logs of factors that influence their glucose levels, such as
   5.1 Timing and content of meals
   5.2 Duration and nature of exercise
   5.3 Dosage of insulin and other diabetes medications
   5.4 Noteworthy events (restaurant meals, illnesses, unusual stress, pump infusion setting changes, menses, etc)

CGM devices generate glucose values around-the-clock, the data are not skewed by more frequent monitoring during periods of high or low glucose or by checking only before meals. The statistics generated by CGM devices are thus more valid than those garnered from blood glucose analyzers[3]. Level VB

References:

1. Blevins, T.C. (2010). Professional Continuous Glucose Monitoring in Clinical Practice. Journal of Diabetes Science and Technology, 4: 440-456.
2. Danne, T, Nimri, E, Battelino, T, Bergenstal, R.M., & et al. (2017) International Consensus on Use of Continuous Glucose Monitoring. Diabetes Care, 40: 1631-1640.
3. Scheiner, G. (2016). CGM Retrospective Data Analysis. Diabetes Technology & Therapeutics, 18, Suppl 2-14-22.

Chapter 7 Interpretation of results

Evidence

CGM provides a lot of useful glucose data to help with diabetes management. There are however several brand-specific software programs and reports from different CGM manufactures. In December 2017, a consensus statement for standardized CMG reporting format was published aligning the definition of core CGM metrics, priorities for routine display and use of AGP modal day visualization[1]. One-page AGP summary is available on Libreview, Dexcom Clarity and Medtronic Carelink in some western countries[2]. However, it is only available for Dexcom G5, and a partial AGP report for Libreview in Hong Kong. Dexcom G4 and Medtronic Carelink provide specific software programs and reports by their own company.

Level IVA

Level VA

Given the increased complexity for acquiring and interpreting CGM data in Hong Kong, we recommend the steps of data interpretation based on principles of the consensus statement.

Understanding of CGM metrics

1. Data sufficiency
    - 1.1 14 days of CGM data correlate well with 3 months of CGM data in type 1 diabetes study, particularly for mean glucose, time in range and hyperglycemia measures[3] — Level IIIB
    - 1.2 At least 70% data or ~10days of CGM wear is required to provide a reliable indicator of usual patterns[4] — Level VA
2. Glucose exposure
    - 2.1 Sensor glucose average provides an estimation of the Glucose Management Indicator (GMI, the proposed term to replace eHbA1c) which is derived from CGM-driven mean glucose in 10-14 days by a standard formula[5,6] — Level VA
    - 2.2 It should be more correlated to laboratory HbA1c if there is no special event or change of anti-diabetic medications[5,6]
    - 2.3 Average glucose and GMI may be higher than laboratory HbA1c during a short

period of acute hyperglycemia[5,6]

2.4 Average glucose and GMI may be lower than laboratory HbA1c after starting new carbohydrate-reduced diet, an intensive exercise or during the first few weeks after starting a new effective anti-diabetic medication[5,6]

3. Time in Range (TIR)

3.1 Higher percentage of time in range to indicate better HbA1c[8] Level VA

3.2 The common default range is 3.9-10 mmol/L[8] Level VA

3.3 Correlation of CGM-derived TIR data and laboratory HbA1c with type 1 diabetic subjects who have a mean laboratory HbA1c of 6.9%[7,8] Level IIIB

3.3.1 Time in Range (TIR) (3.9-10 mmol/L) ~ 72% or 17.3 hours/day

3.3.2 Time in Hypoglycemia (TIHypo) (<3.9 mmol/L) ~ 3% or 43 min/day (<1% or ~ 14 min/day of this <3.0 mmol/L)

3.3.3 Time in Hyperglycemia (TIHyper) (> 10 mmol/L) ~ 25% or 6 hours/day (<6% or ~86min/day of this >13.9 mmol/L)

3.4 Correction of CGM-derived TIR data and laboratory HbA1c obtained from an analysis of a series of clinical trials on type 1 and type 2 diabetes[6,8] Level IIIB

Measured TIR (3.9-10mmol/L)	Laboratory HbA1c	95% CI
40%	8.1%	7.1 - 9.1%
50%	7.7%	6.7 - 8.7%
60%	7.3%	6.3 - 8.3%
70%	6.9%	5.9 - 7.9%
80%	6.5%	5.5 - 7.5%

3.5 Action of hypoglycemia[2] Level VA

3.5.1 <3.9-3 mmol/L : alert and monitor

3.5.2 < 3 mmol/L : clinically significant, immediate action required

3.6 Action of hyperglycemia[2] Level VA

3.6.1 >10-13.9 mmol/L : alert and monitor

3.6.2 > 13.9 mmol/L : clinically significant, immediate action required

3.7 Type 1 Diabetes: for age < 25 years old, if the HbA1c goal is 7.5%, then set TIR target approximately 60%[9] Level IVA

3.8 Older/High-Risk Type 1 and Type 2 Diabetes[9] Level IVA

3.8.1 Time in Range (TIR) (3.9-10 mmol/L) >50% or 12 hours/day

3.8.2 Time in Hypo (TIHypo) (<3.9 mmol/L) <1% or 15 min/day

3.8.3 Time in Hyper (TIHyper) (> 13.9 mmol/L) <10% or <2 hours 24 minutes

3.9 During Pregnancy (Type 1 Diabetes)[9] Level IVA

** Percentage of time in range is based on limited evidence

3.9.1 Time in Range (TIR) (3.5-7.8 mmol/L) >70% or > 16 hours 48 minutes

3.9.2 Time in Hypo (TIHypo) (<3.5 mmol/L) <4% or 1 hour and (< 3.0 mmol/L) <1% or 15 minutes

3.9.3 Time in Hyper (TIHyper) (> 7.8 mmol/L) <25% or <6 hours

3.10 During Pregnancy (Gestational & Type 2 Diabetes)[9] Level IVA

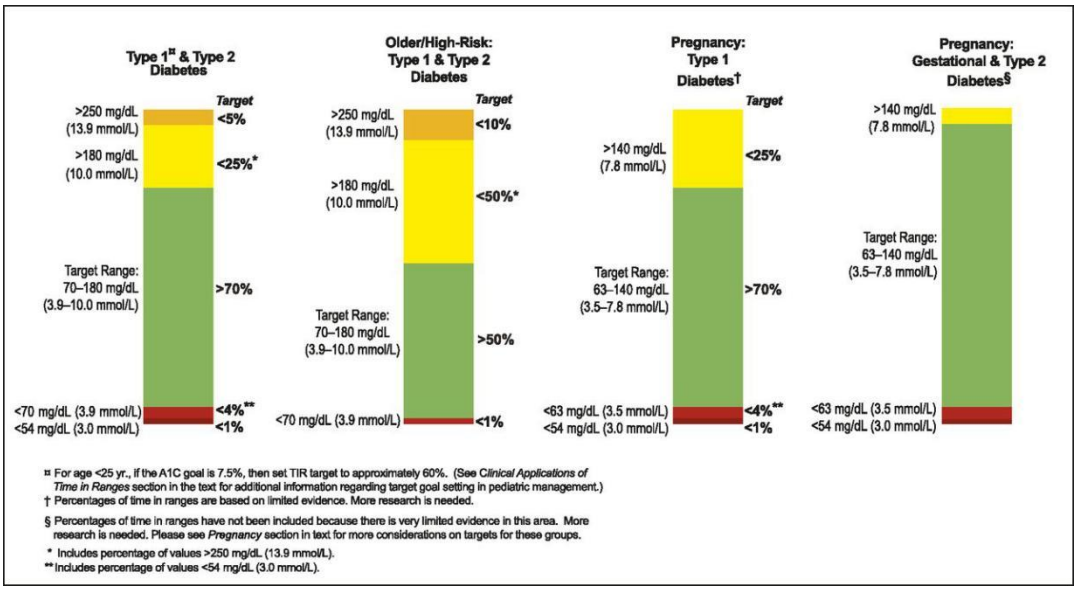
** Percentage of time in range has not been established because of very limited evidence

3.10.1 Time in Range (TIR) (3.5-7.8 mmol/L)

3.10.2 Time in Hypo (TIHypo) (<3.5 mmol/L)

3.10.3 Time in Hyper (TIHyper) (> 7.8 mmol/L)

CGM-based targets for different diabetes populations



Tadej Battelino et al. Dia Care 2019;42:1593-1603

4 Glycemic Variability (GV)

4.1 Coefficient of variation (CV) : < 36% means stable glucose profile[10] Level IIIB

4.2 Standard deviation (SD) : <33% of mean sensor glucose value means stable glucose profile[11] Level VA

4.3 Inter-quartile Range (IQR) : using in AGP – visualize the pattern, the wider cloud between 25th-75th percentile means great CV vs ribbon shape between 25th-75th percentile meaning less CV[2] Level VA

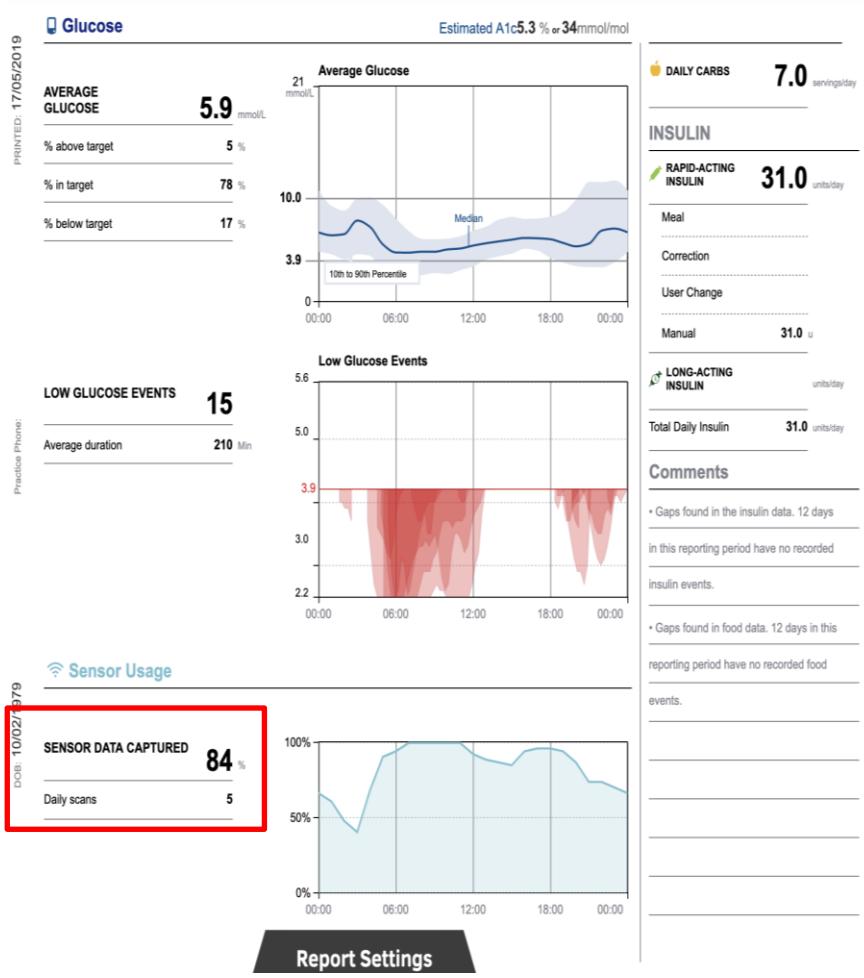
Steps of CGM data interpretation

1. Review the data sufficiency and accuracy

1.1 Libre[3,4]

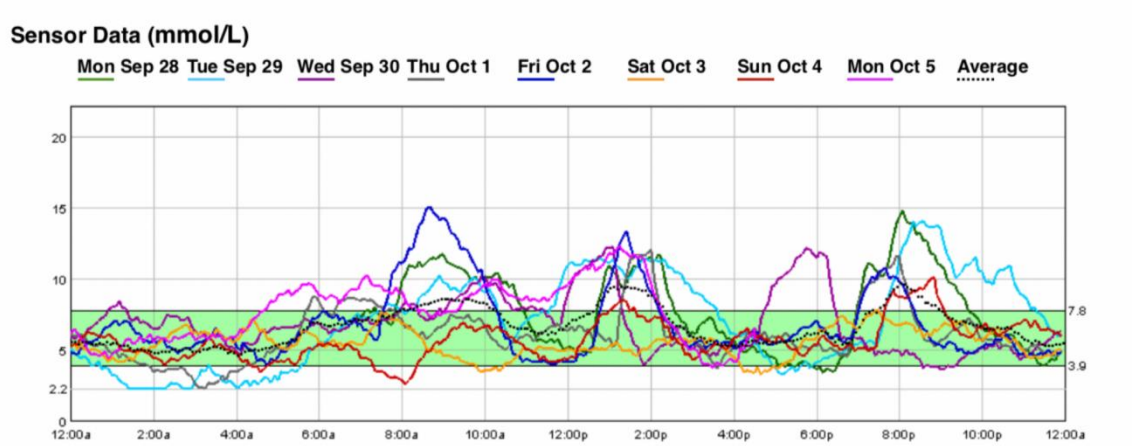
1.3.1 Duration 14 days Level IIIB

1.3.2 Data capture > 70% Level VA



1.2 Medtronic

1.2.1 The mean absolute difference percentage (MAD%) is the average difference between sensor and meter readings expressed as a percentage. If the MAD% is more than 18%, the data may not be worth reviewing[12]. Level VB



	Mon Sep 28	Tue Sep 29	Wed Sep 30	Thu Oct 1	Fri Oct 2	Sat Oct 3	Sun Oct 4	Mon Oct 5	Average / Total
# Sensor Values	205	288	288	288	288	288	288	199	2,132
Highest	14.9	14.1	12.3	12.1	15.1	7.9	10.1	12.4	15.1
Lowest	3.3	2.2	3.7	2.3	3.9	3.3	2.6	3.7	2.2
Average	7.9	7.1	6.9	6.1	6.9	5.5	5.7	7.7	6.6
Standard Dev.	2.9	3.2	2.0	1.9	2.6	1.0	1.4	2.1	2.4
MAD %	6.0	13.7	16.3	9.1	7.3	11.3	24.2	15.0	13.1
Correlation	0.99	0.84	N/A	N/A	N/A	N/A	0.94	0.93	0.91
# Valid Calibrations	4	4	5	3	4	5	4	5	34
Designation									

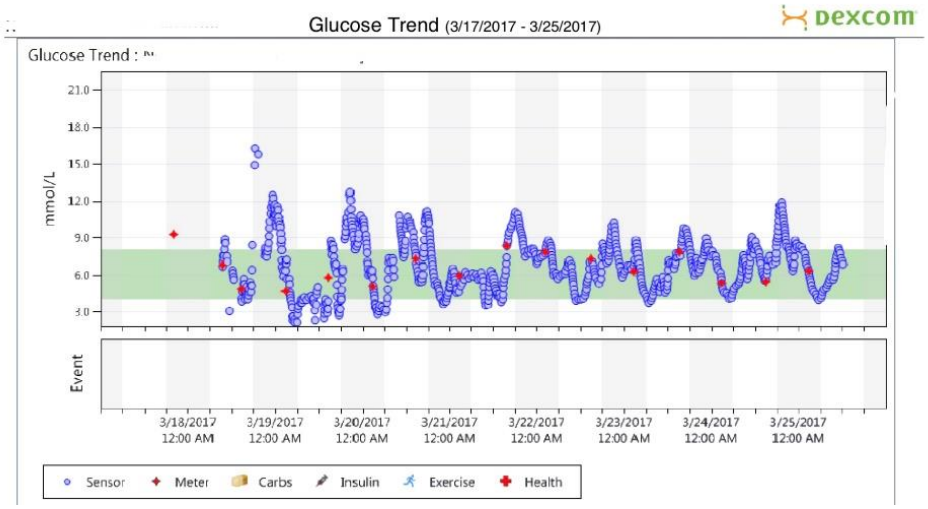
X: Use Clinical Judgment S: No Sensor Data C: No Calibration BG's

1.3 Dexcom

1.3.1 Full capture readings are 288/ day, so adequacy of readings captured should be observed Level VB

Target Chart	Date	% in Target	% in Low	% in High	# of Readings	Min	Mean	Max	Std. Dev.	2
87 12	Sat, 3/25/2017	87 %	1 %	12 %	147	3.88	6.03	8.55	1.40	
72 27	Fri, 3/24/2017	72 %	1 %	27 %	288	3.94	7.02	11.93	1.74	
80 16	Thu, 3/23/2017	80 %	4 %	16 %	288	3.66	6.64	9.93	1.53	
78 17	Wed, 3/22/2017	78 %	4 %	17 %	288	3.88	6.62	10.27	1.53	
71 23	Tue, 3/21/2017	71 %	6 %	23 %	286	3.39	6.66	11.15	1.99	
19 30 51	Mon, 3/20/2017	51 %	19 %	30 %	273	2.72	6.59	11.32	2.48	
30 33 37	Sun, 3/19/2017	37 %	30 %	33 %	251	Low	6.15	12.76	2.96	

1.3.2 On the daily trend report, observe the discrepancy between the calibration values (red diamonds) and the sensor values (blue dots) If there are too many discrepancies, (consider passing up the data analysis[13]).



Level VB

2 Mark the factors that may affect the management plan in the daily profile sheet[2,4] Level VA

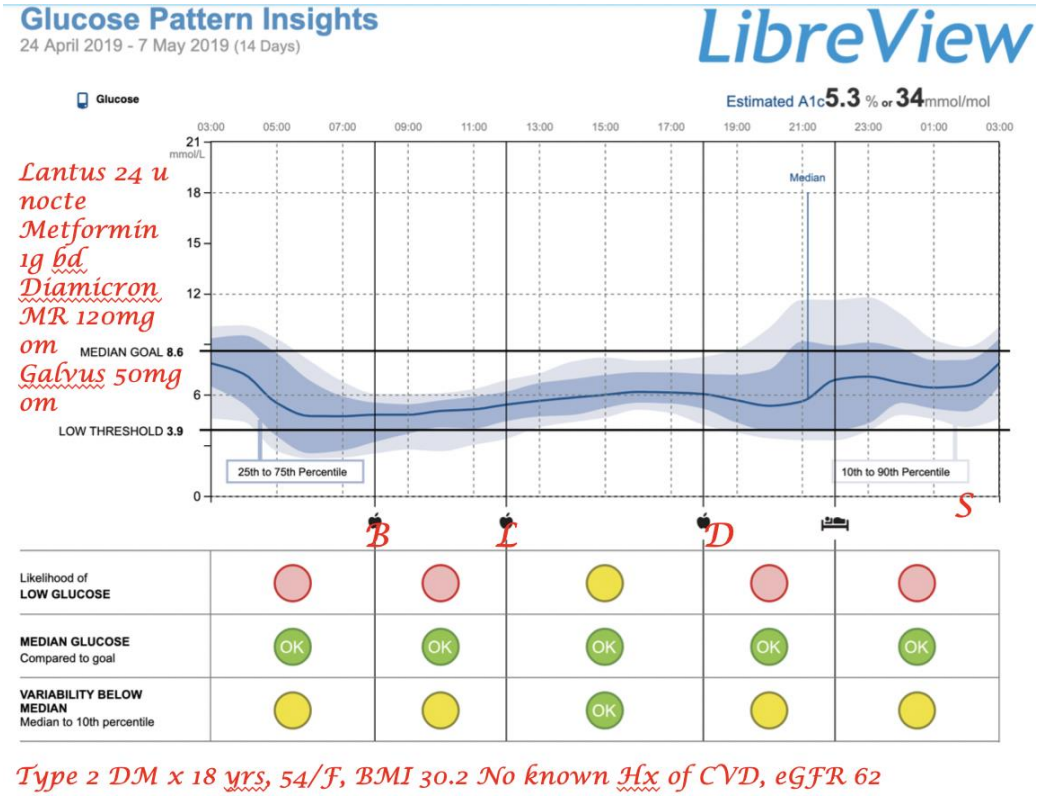
2.1 Age, Type of DM, DM duration, Hx of known CVD, eGFR, weight

2.2 Current medications (if on insulin, daily dose - units/kg)

2.3 Daily routine including meal-time, snacking, exercise and medications or injection time

3 Ask the patient to express their thought on their own profiles and let patients provide honest, helpful insights to explain the glucose pattern[4] Level VA

3.1 Show the marked-up (daily routine and medications) glucose profile pattern such as ambulatory glucose profile (AGP profile)

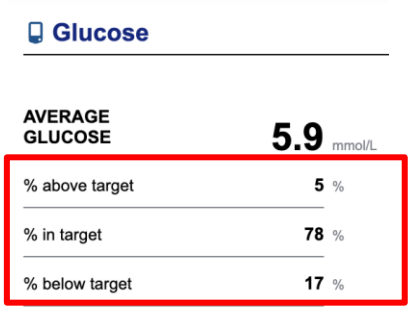


Type 2 DM x 18 yrs, 54/F, BMI 30.2 No known Hx of CVD, eGFR 62

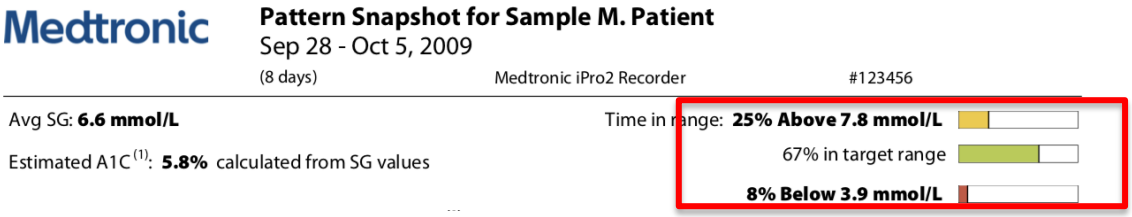
3.2 Compare TIR bar chart with reference range with their own TIR Level IVA

Very high	<5%
High	<25%
Target	>70%
Low	<4%
Very Low	<1%

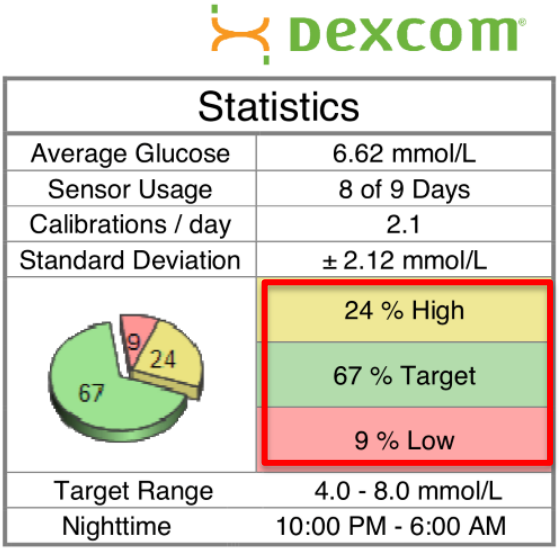
3.2.1 Libre sample



3.2.2 Medtronic Sample



3.2.3 Dexcom Sample



4 Looking for patterns of low glucose level[2] Level VA

- 4.1 Identify midnight hypoglycemia and assess the recurrent episodes or isolated episode
- 4.2 Identify daytime pre and post meals hypoglycemia
- 4.3 Consider 3 – 4 hours after meal as post meal glucose profile
- 4.4 Monitor for weekdays vs weekends hypoglycemia
- 4.5 Obtain patient's information to assess contributors of hypoglycemia
- 4.6 Determine if hypoglycemia is caused by basal insulin dose

5 Looking for pattern of high glucose level[2]

5.1 Identify daytime pre and post meal and midnight hyperglycemia

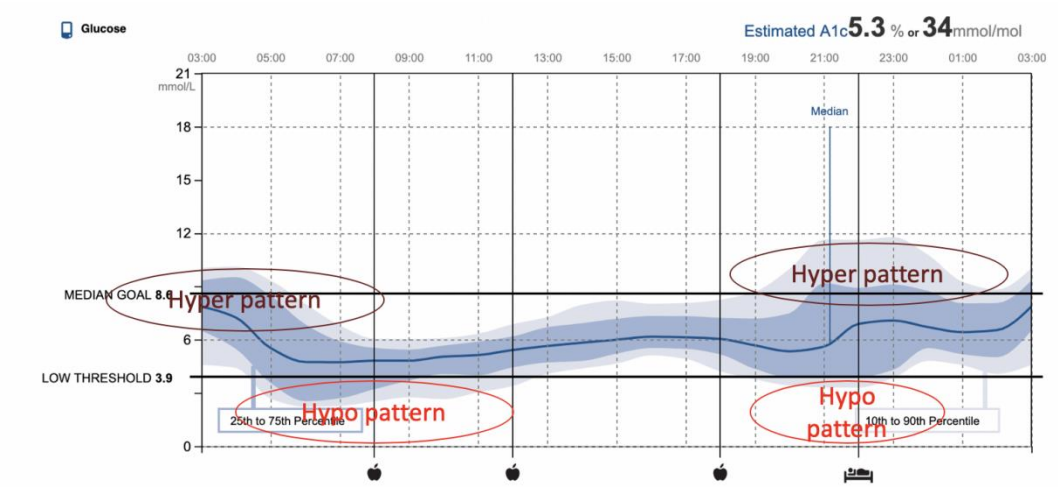
5.2 Consider 3 – 4 hours after meal as post meal glucose profile

5.3 Monitor for weekdays vs weekend hyperglycemia

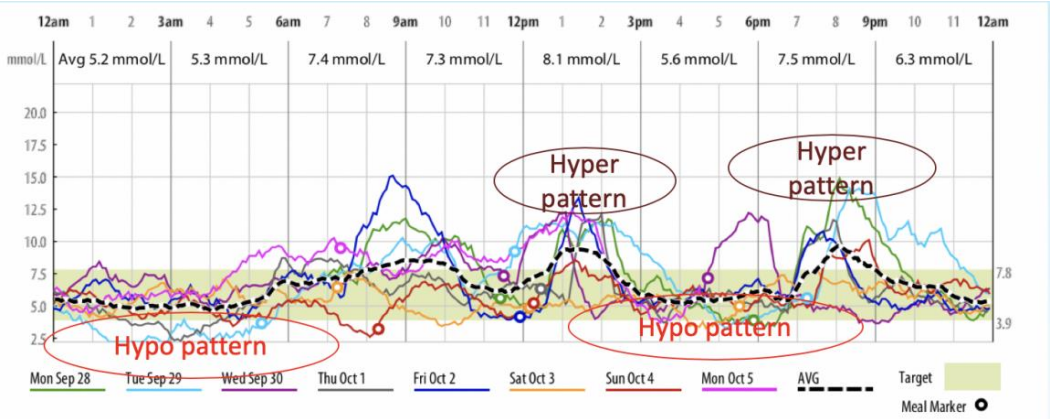
5.4 Obtain patient's information to assess contributors of hyperglycemia

5.5 Determine if hyperglycemia is caused by basal insulin dose

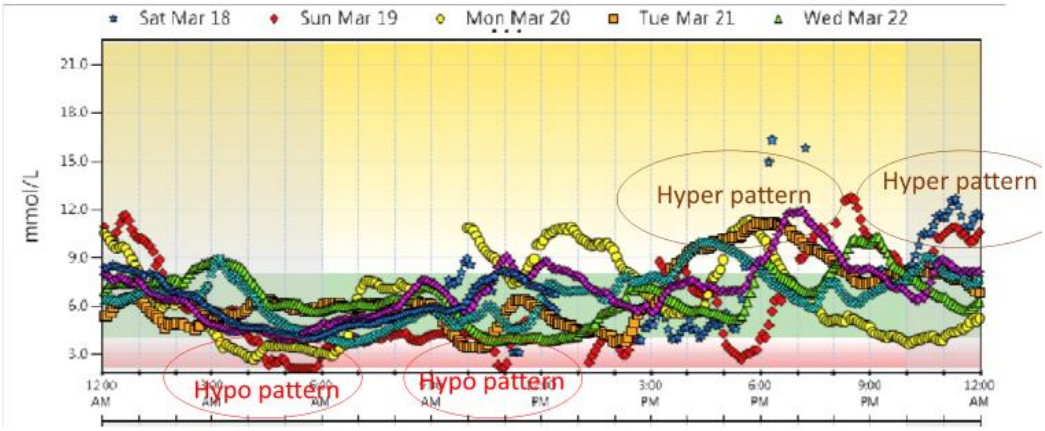
5.5.1 Libre sample



5.5.2 Medtronic Sample



5.5.3 Dexcom Sample



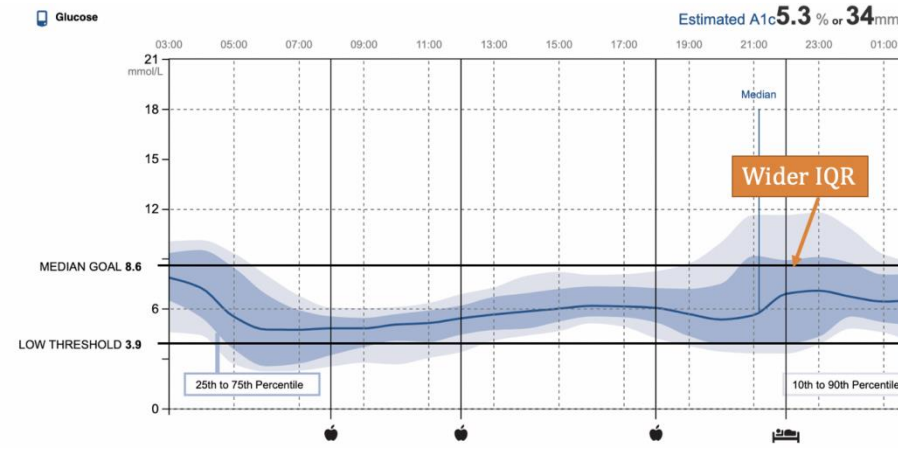
6 Look for areas of wide glucose variability[2] (high GV) Level VA

6.1 Aim to minimize the high GV by adjusting the timing or amount

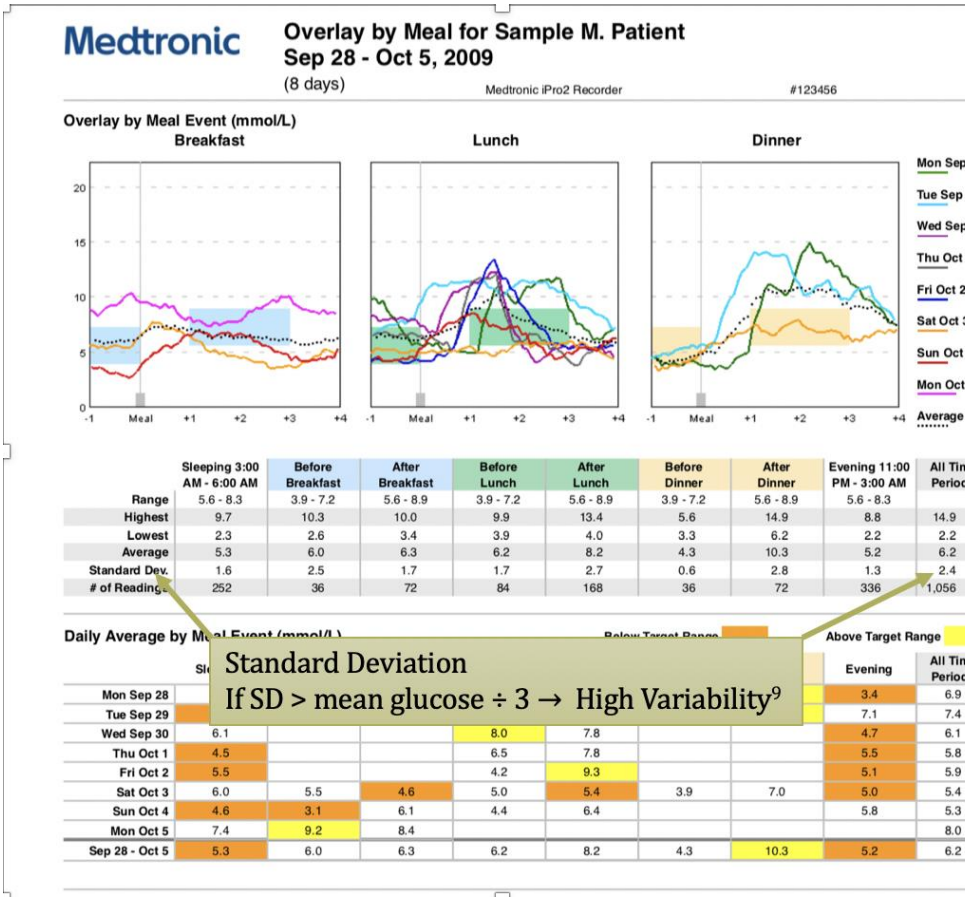
6.1.1 Timing: insulin and meals, weekday and weekend, snacks, exercise, stress

6.1.2 Amount: insulin (daily dose or carb counting), insulin:carb ratio, exercise intensity.

6.1.2.1 Libre sample



6.1.2.2 Medtronic sample



Medtronic

Overlay by Meal for Sample M. Patient
Sep 28 - Oct 5, 2009
(8 days)

Medtronic iPro2 Recorder #123456

Overlay by Meal Event (mmol/L)

Breakfast | Lunch | Dinner

Mon Sep
Tue Sep
Wed Sep
Thu Oct
Fri Oct 2
Sat Oct
Sun Oct
Mon Oct
Average

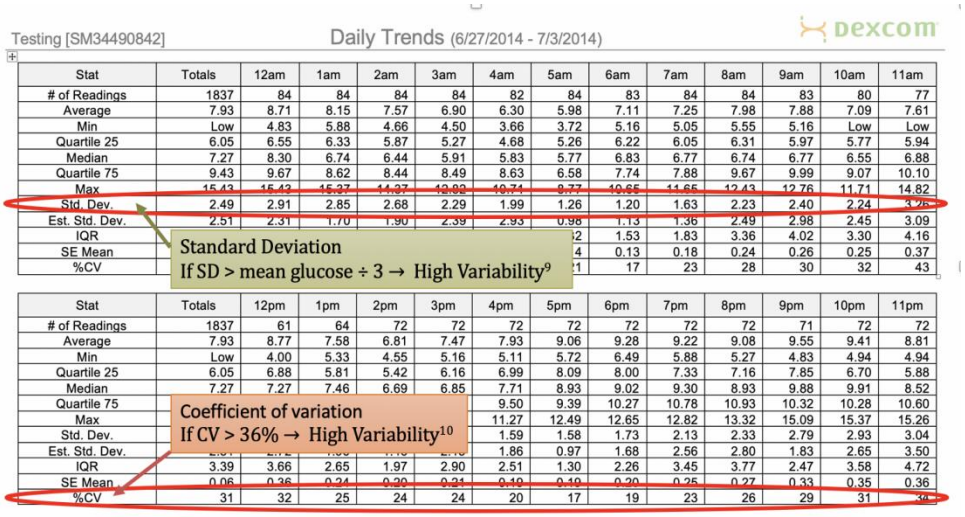
	Sleeping 3:00 AM - 6:00 AM	Before Breakfast	After Breakfast	Before Lunch	After Lunch	Before Dinner	After Dinner	Evening 11:00 PM - 3:00 AM	All Tin Period
Range	5.6 - 8.3	3.9 - 7.2	5.6 - 8.9	3.9 - 7.2	5.6 - 8.9	3.9 - 7.2	5.6 - 8.9	5.6 - 8.3	
Highest	9.7	10.3	10.0	9.9	13.4	5.6	14.9	8.8	14.9
Lowest	2.3	2.6	3.4	3.9	4.0	3.3	6.2	2.2	2.2
Average	5.3	6.0	6.3	6.2	8.2	4.3	10.3	5.2	6.2
Standard Dev.	1.6	2.5	1.7	1.7	2.7	0.6	2.8	1.3	2.4
# of Reading	252	36	72	84	168	36	72	336	1,056

Daily Average by Meal Event (mmol/L) — Above Target Range

	Sl							Evening	All Tin Period
Mon Sep 28								3.4	6.9
Tue Sep 29								7.1	7.4
Wed Sep 30	6.1			8.0	7.8			4.7	6.1
Thu Oct 1	4.5			6.5	7.8			5.5	5.8
Fri Oct 2	5.5			4.2	9.3			5.1	5.9
Sat Oct 3	6.0	5.5	4.6	5.0	5.4	3.9	7.0	5.0	5.4
Sun Oct 4	4.6	3.1	6.1	4.4	6.4			5.8	5.3
Mon Oct 5	7.4	9.2	8.4						8.0
Sep 28 - Oct 5	5.3	6.0	6.3	6.2	8.2	4.3	10.3	5.2	6.2

Standard Deviation
If SD > mean glucose ÷ 3 → High Variability[9]

6.1.2.3 Dexcom Sample



Testing [SM34490842]

Daily Trends (6/27/2014 - 7/3/2014)

dexcom

Stat	Totals	12am	1am	2am	3am	4am	5am	6am	7am	8am	9am	10am	11am
# of Readings	1837	84	84	84	84	82	84	83	84	84	83	80	77
Average	7.93	8.71	8.15	7.57	6.90	6.30	5.98	7.11	7.25	7.98	7.88	7.09	7.61
Min	Low	4.83	5.88	4.66	4.50	3.66	3.72	5.16	5.05	5.55	5.16	Low	Low
Quartile 25	6.05	6.55	6.33	5.87	5.27	4.68	5.26	6.22	6.05	6.31	5.97	5.77	5.94
Median	7.27	8.30	6.74	6.44	5.91	5.83	5.77	6.83	6.77	6.74	6.77	6.55	6.88
Quartile 75	9.43	9.67	8.62	8.44	8.49	8.63	6.58	7.74	7.88	9.67	9.99	9.07	10.10
Max	15.43	15.43	15.37	14.37	12.93	10.71	8.77	10.65	11.65	12.43	12.76	11.71	14.82
Std. Dev.	2.49	2.91	2.85	2.68	2.29	1.99	1.26	1.20	1.63	2.23	2.40	2.24	3.26
Est. Std. Dev.	2.51	2.31	1.70	1.90	2.39	2.93	0.98	1.13	1.36	2.49	2.98	2.45	3.09
IQR							2	1.53	1.83	3.36	4.02	3.30	4.16
SE Mean							4	0.13	0.18	0.24	0.26	0.25	0.37
%CV							1	17	23	28	30	32	43

Standard Deviation
If SD > mean glucose ÷ 3 → High Variability[9]

Stat	Totals	12pm	1pm	2pm	3pm	4pm	5pm	6pm	7pm	8pm	9pm	10pm	11pm
# of Readings	1837	61	64	72	72	72	72	72	72	72	71	72	72
Average	7.93	8.77	7.58	6.81	7.47	7.93	9.06	9.28	9.22	9.08	9.55	9.41	8.81
Min	Low	4.00	5.33	4.55	5.16	5.11	5.72	6.49	5.88	5.27	4.83	4.94	4.94
Quartile 25	6.05	6.88	5.81	5.42	6.16	6.99	8.09	8.00	7.33	7.16	7.85	6.70	5.88
Median	7.27	7.27	7.46	6.69	6.85	7.71	8.93	9.02	9.30	8.93	9.88	9.91	8.52
Quartile 75						9.50	9.39	10.27	10.78	10.93	10.32	10.28	10.60
Max						11.27	12.49	12.65	12.82	13.32	15.09	15.37	15.26
Std. Dev.						1.59	1.58	1.73	2.13	2.33	2.79	2.93	3.04
Est. Std. Dev.						1.86	0.97	1.68	2.56	2.80	1.83	2.65	3.50
IQR	3.39	3.66	2.65	1.97	2.90	2.51	1.30	2.26	3.45	3.77	2.47	3.58	4.72
SE Mean	0.06	0.36	0.24	0.20	0.21	0.19	0.10	0.20	0.25	0.27	0.33	0.35	0.36
%CV	31	32	25	24	24	20	17	19	23	26	29	31	3

Coefficient of variation
If CV > 36% → High Variability[10]

7 Identify the possible contributors of midnight hypoglycemia/hyperglycemia[2] Level VA

7.1 Basal rates or long acting insulin dose

7.2 Physical activity including type, duration and time of day

7.3 Alcohol intake

7.4 Other evening activities

8 Identify the possible contributors of daytime hypoglycemia/hyperglycemia[2]

8.1 Physical activity including type, duration and time of day

8.2 Meal/insulin dosing times

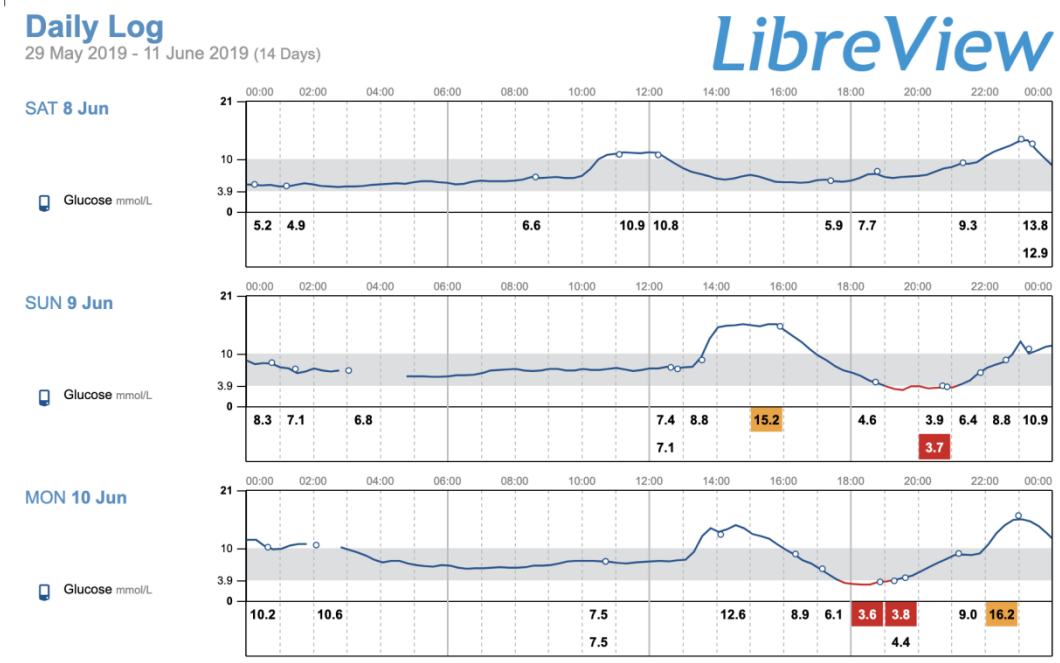
8.3 Missing meal after insulin dosing or missed mealtime insulin dose

8.4 Meal quality (high or low glycemic index)

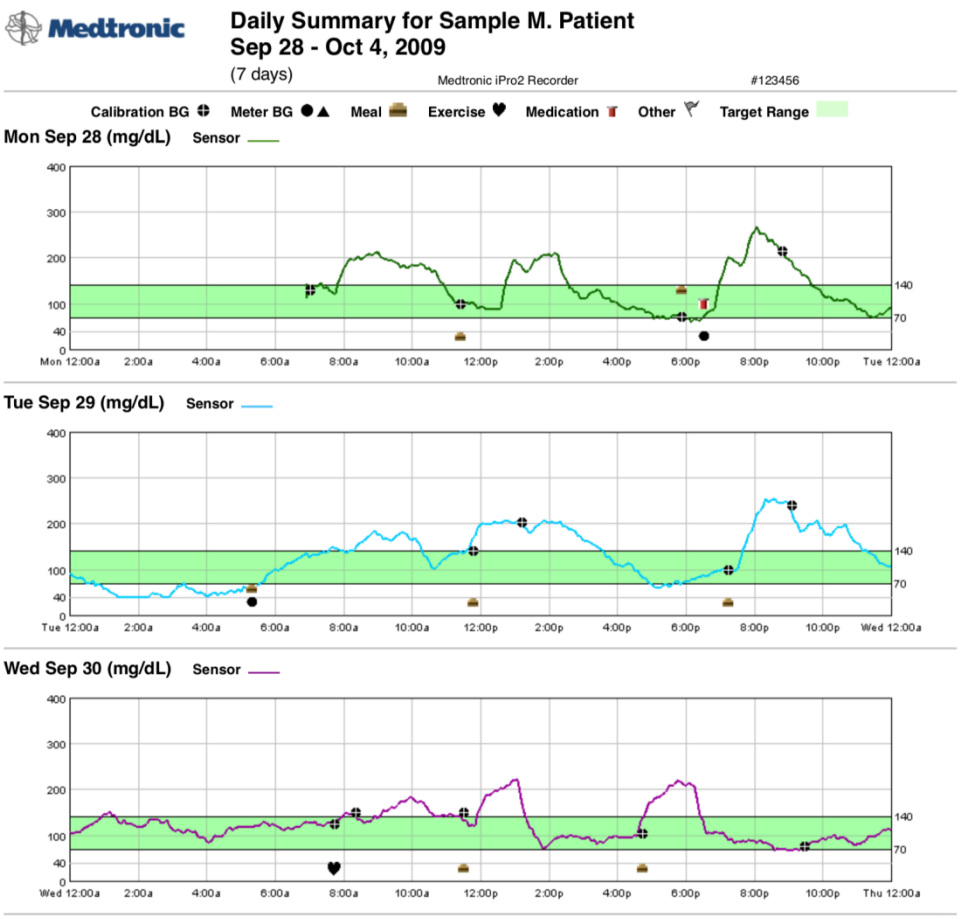
8.5 Insulin stacking from aggressive use of correction dose

8.6 Inappropriate insulin carbohydrate ratio or insulin sensitivity factor

8.6.1 Libre Sample



8.6.2 Medtronic Sample



8.6.3 Dexcom Sample



9 Agree on an action plan with the patient[2,4] Level VA

9.1 Get rid of lows overnight: reduce insulin and modify the behavior factors

9.2 Reduce variability: insulin timing and amount of food, consider carb counting

9.3 Look at least 12-18 hours past the time of hyperglycemia for secondary effects on glucose (hypoglycemia) when treating a pattern of hyperglycemia, address the hypoglycemia.

9.4 Repeat 2-week profile if not achieve in TIR

9.5 Teach how to use trend arrows

Rate of change trend Arrows in CGM systems in Hong Kong Market

	Medtronic – Guardian Connect	Dexcom – G4 & G5	Abbott – Freestyle Libre
↑ ↑ ↑	Glucose rising at rate ≥ 0.17mmol/L per minute	N/A	N/A
↑ ↑	Glucose rising at rate ≥ 0.11mmol/L per minute but <0.17 mmol/L per minute	Glucose rapidly rising ≥ 0.16mmol/L per minute	N/A
↑	Glucose rising at rate ≥ 0.06mm0l/L per minute but <0.11 mmol/L per minute	Glucose rising 0.11 -0.16mmol/L per minute	Very rapidly rising glucose levels, rising at a rate >0.11 mmol/L per minute
↗	N/A	Glucose slowly rising 0.06 -0.11 mmol/L per minute	Moderately rising glucose level, rising at a rate between 0.06 and 0.11mmol/L per minute

→	N/A	Steady, glucose increasing/decreasing > 0.06 mmol/L per minute	Gradually rising or falling glucose levels, falling or rising at a rate between 0-0.06 mmol/L
↘	N/A	Glucose slowly falling 0.06 -0.11 mmol/L per minute	Moderately falling glucose level, falling at a rate between 0.06-0.11mmol/L per minute
↓	Glucose falling at rate of ≥ 0.06mm0l/L per minute but <0.11	Glucose falling 0.11 -0.16mmol/L per minute	Very rapidly falling glucose levels, falling at a rate > 0.11 mmol/L per minute
↓ ↓	Glucose falling at rate of ≥ 0.11mmol/L per minute but <0.17 mmol/L per minute	Glucose rapidly falling ≥ 0.16mmol/L per minute	N/A
↓ ↓ ↓	Glucose falling at rate of ≥ 0.17mmol/L per minute	N/A	N/A

Continuous Glucose Monitoring Report

Name: (Patient Gum Label)
ID:
Sex:
DOB: Patient's contact:

Type of CGM:_____

Date of CGM (On) :_____

Date of CGM (Off):_____

Background Information:

Type of DM: Type 1 _____ Type 2 _____ Gestational _____ Pre-existing GDM_____

Year of Diagnosis: _____

Current Therapy: Diet Control_____ OAD_____ Insulin_____ GLP1-RA_____

Current Regimen: _____

Meal Patterns: Main meal time _____ Snack time_____

Notes: _____

Physical Activity & Exercise: Types _____ Frequency_____

Indication for Monitoring:

Elevated HbA1c_____ Fluctuation of glucose_____ Hypoglycemia_____

Hypoglycemic unawareness _____ Nocturnal Hypoglycemia_____ GDM_____

Discrepancy between Records and HbA1c _____ Others_____

Report Interpretation:

Quality of Data:

Days of data available: _____ Calibrations done:_____times/ day

Data Information:

Average glucose: _____

Time in Range

Target Range: _____

Above Target (%): _____

In Target (%): _____

Below Target (%): _____

Hypoglycemia/Hyperglycemia Pattern:

Nocturnal Glucose

*Hypoglycemia: _____ **Hyperglycemia: _____

Duration and possible causes:_____

_____

Pre-Prandial Glucose

Pre-Breakfast

Hypopglycemia: _____ Hyperglycemia: _____

Pre-Lunch

Hypopglycemia: _____ Hyperglycemia: _____

Pre - Dinner

Hypopglycemia: _____ Hyperglycemia: _____

Post-Prandial Glucose

Post-Breakfast

Hypopglycemia: _____ Hyperglycemia: _____

Post-Lunch

Hypopglycemia: _____ Hyperglycemia: _____

Post - Dinner

Hypopglycemia: _____ Hyperglycemia: _____

Identify the possible causes

1. _____
2. _____
3. _____

Action Plan:

1. _____
2. _____
3. _____

Treatment Recommendation:

Drug

Treatment:_____

_____

_____

Continue SMBG / CGM: _____

DM Nurse / Clinic FU:_____

Others: _____

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Conclusion

CGM is a useful tool to provide data for health care professionals and people with diabetes to better manage diabetes. The development of CGM technology has progressed rapidly in recent years including accuracy, simple procedures of sensor insertion, and reduced frequency of sensor calibration. As CGM becomes more affordable and easily accessible, there is rapidly increasing trend for its use by individuals with diabetes and health care professionals and mounting demand for diabetes nurses in Hong Kong to acquire the new knowledge and skills on different models of CGM. Through literature search, an EBP question was set as "How to enhance patient outcomes through training and practical guide on continuous glucose monitoring (CGM) for diabetes nurses?"

By adopting the Johns Hopkins Nursing Evidence-Based Practice (JHKEBP) Appraisal Tool, the evidence, evidence levels and qualities of the findings have been appraised in writing this AHKDN Guidebook , which clearly illustrates the indications for CGM; information on different CGM models; nursing practice guide for CGM, education materials for people with diabetes; and interpretation of CGM results and reporting.

It is envisaged that this informative practice guide will facilitate our diabetes nurses to prepare and supervise their patients for CGM, thus enabling individuals with diabetes to gain the most benefits while minimizing the risk in using CGM, and ultimately improving their clinical outcomes.