Country Health SA Local Health Network

# Protocol (Clinical)

## Title: Continuous Glucose Monitoring (CGM) and Flash Glucose Monitoring (FGM) Ambulatory Service

**Protocol developed by:** CHSALHN Diabetes Service

**Protocol Sponsor:** CHSALHN, Executive Director, Medical Services

**Approved by:** CHSALHN, [Clinical Governance Committee] on: 31/10/2018

**Next review due**: 31/10/2021


**Summary** This protocol provides process, structural and governance support for the CHSA Diabetes Service Continuous Glucose Monitoring (CGM) and Flash Glucose Monitoring (FGM) Service.


**Policy reference** This protocol supports the Nursing and Midwifery Board of Australia: Nurses Code of Professional Conduct for Nurses in Australia (2016), Code of Ethics (2013) and Standards for Practice (2014), the SA Health Policy Directive: The Governance Framework for Advanced Scope of Practice (2013), and the CHSA Care Continuum Foundation Policy (2011).


**Keywords** Protocol, CHSA, diabetes, nurse practitioner, credentialled diabetes educator, diabetes educator, diabetes link nurse, dietitian, continuous glucose monitor, flash glucose monitor, subcutaneous insulin infusion, insulin pump.


**Protocol history** Is this a new protocol? **Y**
Does this protocol amend or update an existing protocol? **N**
Does this protocol replace an existing protocol? **N**

**Applies to** This protocol applies to all staff who are involved in the provision of CGM and FGM Services to CHSA Diabetes Service patients.

## Version control and change history

| Version | Date | Amendment | Amended by: |
|---|---|---|---|
| 1.0 | 31/10/2018 | Orignal version | Jane Giles |
| | | | |
| | | | |

## Table of Contents

# Protocol | Continuous Glucose Monitoring (CGM) and Flash Glucose Monitoring (FGM) Ambulatory Service

The aim of the CHSA Diabetes Service Continuous Glucose Monitoring (CGM) and Flash Glucose Monitoring (FGM) Service is to facilitate access to CGM and FGM for people with diabetes with complex diabetes education and management needs. The service will be delivered face to face, via videoconferencing or audioconferencing, with supplement information via email as needed. Any CHSA site will have access. The service will be accessible, clinically appropriate and evidence based. This protocol aims to articulate the systems and processes by which the Diabetes Service will fulfil the objectives of the service.

## 1. Areas of Responsibility

2.1 **CHSA Executive** are responsible for overall patient care.

2.2 **CHSA Directors of Medical Services/Community Health Managers/Nursing Directors** are responsible for ensuring that this protocol is made known to all staff who are affected by its contents and for supporting the far end operational requirements for the service.

2.3 **CHSA Diabetes Educators and Dietitians** remain responsible for the patient service and are responsible for assisting patients with diabetes to have access to the CGM service, and for providing the ongoing and local educational support.

2.3 **CHSA Diabetes Service** is responsible for providing the advanced clinical and educational support required to ensure a safe and quality service.

## 2. Background

Continuous Glucose Monitoring (CGM) and Flash Glucose Monitoring (FGM) can be used continuously and/or intermittently as a management tool and diagnostic instrument for people with diabetes and/or their healthcare providers. CGM and FGM can identify glucose trends during various forms of dietary intake, physical activity, stress, illnesses, steroid medications or menstrual cycles.

There is evidence to support the benefit of continuous and intermittent use of CGM and FGM as an educational motivational tool in those challenged by diabetes management and those who have poor glycaemia control as a consequence.

### Real-time CGM

Real-time CGM tracks the glucose concentrations in the body's interstitial fluid, providing near real-time glucose data.

Some CGM systems can be linked to blood glucose meters, smart phones and/or insulin pumps which can display the glucose result, recent history and alert the patient and/or carer of the glucose excursion (trend) moving above or below the glucose target.

Some CGM systems can be linked to insulin pump therapy providing sensor augmented pump technology (SAPT). SAPT can be programmed to automatically suspend insulin delivery if the glucose falls below target.

Real-time CGM (also known as Personal CGM) is most commonly used by the person with diabetes and/or their family.

### Retrospective CGM

Retrospective CGM uses similar methodology, however, the glucose levels are 'masked' until the device is removed, the data uploaded and a report is generated.

Retrospective CGM systems are owned by healthcare services and loaned to patients with diabetes intermittently and can be worn for up to 6 days.

Retrospective CGM *(also known as Professional CGM*) is most commonly used by credentialled diabetes educators (CDE) and diabetes educators (DE) in CHSA.

### Flash Glucose Monitoring

FGM also tracks the glucose concentrations in the body's interstitial fluid. FGM can provide a current glucose reading, the last 8 hours of glucose history, and a trend arrow showing if glucose is going up, down, or changing slowly. Information is not automatically displayed but only after physically scanning the sensor with the reader.

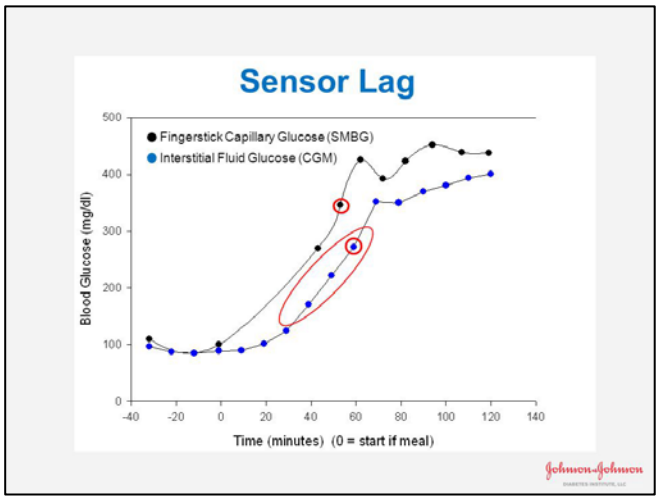
FGM is most commonly used by the person with diabetes and/or their family.

Both CGM and FGM can offer the potential to:

- improve time in target glucose range
- reduce hypoglycaemia
- reduce hyperglycaemia
- and improve HbA1c.

CGM and FGM systems are accurate but the level of glucose in interstitial fluid reacts slower than the level of glucose in the blood. This is because the interstitial glucose result lags approximately 10 minutes behind the blood glucose result. Figure 1 identifies the variance between blood glucose and interstitial glucose.

**Figure 1: Interstitial Glucose Sensor Lag Time**



Although CGM and FGM can reduce frequency, ***capillary blood glucose monitoring*** is recommended:

- for calibration of the CGM. Four blood glucose results are required for calibration for each day the CGM is insitu. The FGM requires no calibration.
- when glucose levels are rapidly changing (eg hypoglycaemia and hyperglycaemia)
- when results do not correspond to symptoms
- to use the rapid acting bolus insulin calculation function (FGM only)
- where the reader indicates a low glucose result (FGM only)
- to meet driving a vehicle licensing authority requirements
- when unwell
- on presentation to an emergency department
- during hospital admission.

Patients with diabetes who wear CGM or FGM systems in the community setting can continue to wear their personal system when admitted to hospital. However, hospital blood glucose meter results will be used to make changes to their inpatient diabetes management (eg management of hypoglycaemia, management of hyperglycaemia, insulin dose titration).

Apart from minor discomfort at the time of the insertion of the sensor, there is no expected discomfort when wearing the CGM or FGM. When applied, the CGM and FGM systems are to be worn 24 hours a day and if the sensor is removed, it cannot be reinserted and data collection will cease.

There is a small risk of infection but this risk is reduced by using a sterile technique when inserting the electrode and protecting the skin site with the dressing.

Mechanical faults can occur.

## 3. Types of CGM and FGM available in Australia

The CGM and FGM devices currently available for both personal and professional use and their specifications are identified on Appendix 1.

## 4. Access to CGM and FGM

### Personal CGM and FGM

Personal CGM and FGM offers real-time data collection for regular or intermittent use for individual patients with diabetes.

In Australia, children and young adults with type 1 diabetes under the age of 21 years can access CGM products for personal use. These products are fully subsidised and are available through the National Diabetes Services Scheme. For further information, visit the NDSS Website https://www.ndss.com.au/CGM Currently, FGM products are not subsidised.

In CHSA, Diabetes Services accept referrals and facilitate acquisition and training of CGM and FGM products for children and young adults with diabetes who meet the above criteria or adults whom purchase these systems.

### Professional CGM

Professional CGM offers intermittent real-time or retrospective data collection for diagnostic use and is available at no cost to young adults and adults unable to access the subsided CGM products through the NDSS.

In CHSA, some Diabetes Services accept referrals and facilitate training of loan CGM systems and products for short-term use to people with diabetes who are unable to access the NDSS selection criteria and who met the following criteria:

- hypoglycaemia seizures
- frequent severe hypoglycaemia
- impaired awareness of hypoglycaemia
- inability to recognise hypoglycaemia due to age, cognitive or neurological disabilities
- anxiety regarding to hypoglycaemia
- high levels of physical activity are undertaken and risk of hypoglycaemia is high
- hyperglycaemia - to reduce HbA1c, improve glycaemic control or reduce glycaemic variation.

Currently, Professional FGM products are not offered.

## 5. Protocol details

### Referral

5.1 All referrals should be directed to the CHSA Community Referral Unit at www.sahealth.sa.gov.au/countryreferralunit.

5.2 Referrals can also be received directly from endocrinologists, specialist physicians and/or paediatricians, allied health professionals, patients with diabetes and/or their carers or from external agencies (eg government and non-government). Further information may be requested.

5.3 All patients referred for consideration of Personal CGM or FGM must be assessed by a multi-disciplinary team either at the service site or in a shared care arrangement with regional and/or metropolitan diabetes services. This team is to include an:

- endocrinologist, specialist physician and/or paediatrician
- credentialled diabetes educator (CDE) and/or diabetes educator (DE) and
- dietitian.

5.4 All patients referred for consideration of Professional CGM must be assessed using the CHSA Patient Selection Criteria.

5.5 Details of all patients utilising CGM or FGM and their progress are to be accessible to local and regional staff.

### Appointment, bookings and confirmation

5.6 The CDE or DE to determine CGM or FGM service required:

- **Personal CGM** to support children and young adults to access the fully subsidised CGM products through the National Diabetes Services Scheme (NDSS).

  A number of appointments for resource acquisition, training and ongoing support will be required.

- **Professional CGM** which provides a 6 day period for retrospective and/or real-time data collection for young adults and adults unable to access the subsided CGM products.

  An sensor application and removal appointment will be required.

5.7 The CDE or DE will confirm appointments. Patient requiring **Professional CGM** are provided with CHSA Diabetes CGM and FGM Fact Sheet and the Medtronic iPro2 System Patient Guidelines.

5.8 Consolidated Country Client Management Engine (CCCME) booking is reported by CDE or DE providing the service.

**Personal CGM or FGM assessment appointment**

5.9 Patients referred for CGM or FGM are provided with an information package. This package is prepared by the Diabetes Service CDE / DE and includes information pertaining to which CGM devices are currently available in Australia, NDSS criteria and registration and training required. CGM and FGM information can be sourced from:

- Animas: www.amsl.com.au
- Medtronic: www.medtronic-diabetes.com.au
- Abbott: http://www.aus.abbott/products/diabetes-care.html

5.10 The CDE/DE is to inform the patient and/or carer of any financial cost of CGM or FGM including initial set up costs and ongoing subsidised costs of consumables via the NDSS or if not eligible for the subsidised products (eg does not have type 1 diabetes, over 21 years of age). The patient and/or carer are to seek further information from their Private Health Insurer.

5.11 A CDE will conduct an assessment of diabetes self-management with the patient and/or carer using the CHSA Diabetes Assessment Form (MR-DAF) or CHSA Diabetes in Pregnancy Assessment Form (MR-DIP). If the patient is identified as not having the diabetes self-management skills or the patient is unable to manage the CGM or FGM safely, the CDE must inform the referring endocrinologist, specialist physician or paediatrician, and document issues and outcomes of discussion in the patient's medical record.

5.12 The CDE may refer the patient and/or carer to the Dietitian for assessment of diabetes self-management. If the patient is identified as not having the diabetes self-management skills or the patient is unable to manage the CGM or FGM safely, the Dietitian must inform the referring endocrinologist, specialist physician or paediatrician and CDE/DE, and document issues and outcomes of discussion in the patient's medical record.

5.13 Once the patient and/or carer has undertaken the recommended assessments, the patient and/or carer is to inform the Diabetes Service whether they want to continue with the process.

If the patient and/or carer choose not to proceed, the CDE or DE is to document the patient and/or carer's decision and reasoning in the patient's medical record and send a letter to the referring endocrinologist, specialist physician or paediatrician to inform.

If patient and/or carer choose to commence CGM or FGM, the CDE will assist the patient and/or carer to complete the NDSS CGM Registration Form available via https://static.diabetesaustralia.com.au/s/fileassets/diabetes-australia/28d97e06-9248-42cf-baaa-526d039b3f12.pdf or access the order form on the relevant website.

The CDE or DE will arrange the second appointment.

**Subsequent Personal CGM or FGM education and application appointment/s**

5.14 Additional investigations may be requested, and these should be coordinated by the CDE or DE (eg blood glucose and/or blood ketone test, assessment of monitoring and/or injecting technique and/or administration site, foot assessment).

5.15 The CDE or DE and dietitian will provide further education in relation to diabetes self-management as required, installation of software and education on CGM or FGM requirements in accordance to the CGM and FGM Product Training Guides.

5.16 The patient and/or carer should be encouraged to install CGM of FGM computer software on their home computer and make these reports available to the endocrinologist, specialist physician or paediatrician. The reports can be printed or sent as a pdf prior to appointments.

5.17 The patient and/or carer is to continue appointments with the CDE until assessed as safe to obtain apply the CGM or FGM, remove the CGM or FGM , upload data and identify instructions on data analysis and insulin titration have been outlined by the referring endocrinologist, specialist physician or paediatrician.

5.18 Information provided by the Women's and Children's Hospital to the child, young person and/or carer may be referred to and may include 'Getting started with your Medtronic Continuous Glucose Monitor' (Appendix 2) and 'Getting started with your Dexcom Continuous Glucose Monitor' (Appendix 3).

5.19 All education provided by the CDE or DE should be documented in the patient's medical record. If issues are identified that impact on the patient's diabetes self-management or ability to manage the CGM or FGM safely, the CDE or DE must inform the referring endocrinologist, specialist physician and paediatrician, and document issues and outcomes of discussion with the in the patient's medical record.

5.20 Additional information relating to CGM system use during physical activity, at school and when driving can be accessed in the Association of Children's Diabetes Clinicians (2017) A Practical Approach to the Management of Continuous Glucose Monitoring (CGM)/Real-Time Flash Glucose Scanning (FGS) in Type 1 Diabetes Mellitus in Children and Young People Under 18 years Guideline available at http://www.a-c-d-c.org/wp-content/uploads/2012/08/CGM-FGS-Practical-Approach-ACDC-Guideline-April-2017.pdf

5.21 Ordering and acquisition of the ongoing CGM of FGM consumables is the responsibility of the patient and/or carer.

The patient and/or carer is to be informed that the subsidised CGM consumables may not be routinely available at all NDSS community pharmacies. Patients should notify their local pharmacy about their supply needs in order to ensure supplies are in stock and available.

The CDE or DE is not responsible for the purchase the CGM of FGM or related consumables for personal use.

5.21 The CDE is responsible for ensuring the patient and/or carer has an emergency backup plan and emergency contact details (eg endocrinologist, specialist physician, emergency department and CGM or FGM Technical Support).

The patient and/or carer will require a follow up appointment with the Endocrinologist or Specialist Physician to discuss insulin titration.

### Personal CGM Upgrade

5.22 Patients and/or carers have the option of upgrading their CGM at the end of the warranty period and if eligible to do so with the NDSS.

To ensure that patients and/or carers do not experience any out of pocket expenses, the CDE or DE will recommend that they check the warranty period and the NDSS eligibility.

For those patients who do not meet the NDSS CGM criteria or use FGM, upgrade can occur but at the individual's expense. The process for upgrade is as described in assessment and subsequent appointments.

### Professional CGM assessment and application appointment

5.23 Patients referred for Professional CGM provided with an information package. This package is prepared by the Diabetes Service CDE/DE and includes information pertaining to the CGM Diabetes Service and Medtronic iPro2 CGM device currently available in CHSA. The information will include:

- CHSA CGM and FGM Fact Sheet
- Medtronic iPro2 System Patient Instructions
- Medtronic iPro2 System Patient Log Sheet.

5.24 A CDE will conduct an assessment of diabetes self-management with the patient and/or carer using the CHSA Diabetes Assessment Form (MR-DAF) or CHSA Diabetes in Pregnancy Assessment Form (MR-DIP).

If the patient is identified as not having the diabetes self-management skills or the patient is unable to manage the CGM safely, the CDE must inform the referring endocrinologist, specialist physician or paediatrician, and document issues and outcomes of discussion in the patient's medical record.

5.25 Once the patient and/or carer has undertaken the recommended assessments, the patient and/or carer is to inform the Diabetes Service whether they want to continue with the process.

If the patient and/or carer choose not to proceed, the CDE or DE is to document the patient and/or carer's decision and reasoning in the patient's medical record and send a letter to the referring endocrinologist, specialist physician or paediatrician to inform.

If the patient and/or carer choose to commence Professional CGM, the patient and/or carer is required to complete the CHSA Consumer Consent to Specified Use/Disclosure of Information Form (MR82CH) including Section 4: Consent to Procedures/Treatments.

The CDE or DE will apply the CGM according to the Medtronic iPro2 CGM Product Training Guides and reiterate the Medtronic iPro2 System Patient Instructions (eg calibration and maintenance requirements) and use of the Medtronic iPro2 System Patient Log Sheet for documentation of blood glucose, carbohydrate intake, physical activity, medications and event (eg hypoglycaemia).

The CDE or DE will ensure that the patient and/or carer have access to an accurate blood glucose monitor and is competent in the techniques required.

The Patient Log Sheet may not be required if the Professional CGM is linked to the patient's own insulin pump.

5.26 The CDE or DE is responsible for ensuring the patient and/or carer has an emergency backup plan and emergency contact details (eg Diabetes Service and CGM Technical Support) and will provide the second CGM removal and data report appointment in 6 days.

### Professional CGM removal and data report appointment

5.27 The CDE or DE will discuss with the patient and/or carer the Professional CGM and previous 6 days with reference to the Medtronic iPro2 System Patient Log Sheet for documentation of blood glucose, carbohydrate intake, physical activity, medications and event (eg hypoglycaemia).

5.28 The CDE or DE will remove the iPro2 CGM and dispose of the used sensor in an Australian Safety Standards approved sharps container which is puncture proof and has a secure lid.

5.29 Additional investigations may be requested, and these should be coordinated by the CDE or DE (eg assessment of monitoring and/or injecting technique and/or administration site, dietary assessment and understanding of carbohydrate identification).

5.30 The CDE or DE will be responsible for the uploading of data accordance to the iPro2 CGM Product Training Guide from the Medtronic iPro2 System Patient Log Sheet to the Medtronic CareLink® iPro2 Software in available at https://carelink.minimed.eu/ipro/hcp/login

5.31 The CDE or DE will review the CGM report and assess glycaemic control using the following key metrics:

- mean glucose
- percentage of time in target range: 3.9-10.0 mmol/L (default); 3.9-7.8 mmol/L (secondary); individual targets closer to the physiological range can be defined, depending on age, comorbidities, and/or patient adherence
- episodes of hypoglycaemia using a standard definition of episodes and percentage of time in hypoglycaemic range (less than 4.0 mmol/L or individual target)
- episodes of hyperglycaemia using a standard definition of episodes and percentage of time in hyperglycaemic range (greater than10.0 mmol/L (default) greater than 7.8mmol/L (secondary) or individual target
- glycaemic variability, reported as CV (primary) and SD (secondary)
- estimated HbA1c
- data for glucose metrics (reported in three time blocks (sleep, wake, 24 h) with the default times for the sleep (12:00A.M.– 6:00A.M.) and wake (6:00A.M.–12:00A.M.)
- data sufficiency (eg minimum 2 weeks of data and 70-80% of possible Personal CGM readings over a 2 week period, maximum of 6 days of data for Professional CGM)
- area under the curve (eg for research purposes)
- indexed risk of hypoglycaemia and hyperglycaemia.

5.32 The CDE or DE is responsible for the identification of hypoglycaemia, investigation of causes and discussion of prevention strategies and hypoglycaemia action plan (including instructions for insulin titration outlined by the referring endocrinologist, specialist physician or paediatrician).

5.33 The CDE or DE is to take urgent action and make contact the referring endocrinologist, specialist physician and paediatrician in the event of clinically significant and/or severe hypoglycaemia (eg recurrent hypoglycaemia, hypoglycaemia unawareness) and if instructions for insulin titration are unavailable.

5.34 The CDE or DE is responsible in the identification of hyperglycaemia, investigation of causes and discussion of prevention strategies and hyperglycaemia (sick day) action plan (including instructions for insulin titration outlined by the referring endocrinologist, specialist physician or paediatrician).

5.35 The CDE or DE is to take urgent action and make contact the referring endocrinologist, specialist physician or paediatrician in the event clinically significant and/or severe hyperglycaemia

(eg generalised hyperglycaemia, risk of diabetic ketoacidosis, hyperglycaemia hyperosmolar state) and if instructions for insulin titration are unavailable.

5.36 In the event that the CDE or DE is not required to make urgent contact with the referring endocrinologist, specialist physician and paediatrician, the CDE or DE will ensure that the patient and/or carer has a follow up appointment to discuss the data report.

5.37 The CDE or DE is responsible for providing a copy of the Professional CGM data reports to the referring endocrinologist, specialist physician or paediatrician and to the patient and/or carer. A copy of the data report generated should also be included into the patient's medical record and may be sent to the local general practitioner if requested.

5.38 The CDE or DE is responsible for ensuring the patient and/or carer has an emergency backup plan and emergency contact details (eg endocrinologist, specialist physician, emergency department and diabetes service).

5.39 Additional information relating to CGM system use during physical activity, at school and when driving can be accessed in the Association of Children's Diabetes Clinicians (2017) A Practical Approach to the Management of Continuous Glucose Monitoring (CGM)/Real-Time Flash Glucose Scanning (FGS) in Type 1 Diabetes Mellitus in Children and Young People Under 18 years Guideline available at http://www.a-c-d-c.org/wp-content/uploads/2012/08/CGM-FGS-Practical-Approach-ACDC-Guideline-April-2017.pdf

5.40 All actions (including referrals to dietitian), education and recommendations provided by the CDE or DE should be documented in the patient's medical record. If, the CDE or DE makes urgent contact with the referring endocrinologist, specialist physician or paediatrician, the issues and outcomes of the discussion are to be included in the patient's medical record.

5.41 The CDE or DE is responsible for the purchase the Professional CGM related consumables and maintenance in accordance to the iPro2 CGM Product Training Guide.

5.42 The Professional CGM Service is provided free of charge to people with diabetes who met the CHSA CGM Selection Criteria. Repeat Professional CGM for diagnostic use can be offered.

## 6. Evaluation criteria

Compliance with this protocol will be monitored by CHSA Diabetes Service via the following mechanisms:

- bi-annual review of this protocol
- regular review of feedback from service sites.

## Linked Documents

| Document Name |
|---|
| CHSALHN Diabetes Assessment Form (MR-DAF) (order via the SA Distribution Centre) |
| CHSALHN Diabetes in Pregnancy Assessment Form (MR-DIP) (order via the SA Distribution Centre) |
| CHSA Consumer Consent Form - MR82CH |
| CHSA Diabetes - Continuous Glucose Monitoring and Flash Glucose Monitoring Factsheet https://www.chsa-diabetes.org.au/consumer/CGM%20&%20FGM_FINAL_Feb%2018-2.pdf |
| Medtronic iPro2 System Patient Instructions and Patient Log Sheet https://hcp.medtronic-diabetes.com.au/sites/default/files/ipro_logsheets.pdf |

## Attachments

| Document Name |
|---|
| Available CGM and FGS Devices |
| Women's and Children's Hospital 'Getting started with your Medtronic Continuous Glucose Monitor' Information |
| Women's and Children's Hospital 'Getting started with your Dexcom Continuous Glucose Monitor' Information |

## References


| Document Name |
|---|
| Nursing and Midwifery Board of Australia: Nurses Code of Professional Conduct for Nurses in Australia (2016) |
| Nursing and Midwifery Board of Australia: Code of Ethics (2013) |
| SA Health Policy Directive: Governance Framework for Advanced Scope of Practice Roles and Extended Scope of Practice (2013). |
| CHSALHN Foundation Policy: Care Continuum 2012 |
| The National Institute of Clinical Excellence (2015) Guideline on management of children and young people with type I and type II diabetes (NG18) |
| The National Institute of Clinical Excellence (2016) Diagnostics Guideline regarding the use of SAPT (DG21). |
| Association of Children's Diabetes Clinicians (2017) A Practical Approach to the Management of Continuous Glucose Monitoring (CGM) / Real-Time Flash Glucose Scanning (FGS) in Type 1 Diabetes Mellitus in Children and Young People Under 18 years. |

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|---|
| Diabetes UK (2017) Consensus Guideline for Flash Glucose Monitoring |
| International Consensus on Use of Continuous Glucose Monitoring (2017) |

## Accreditation Standards

***National Safety and Quality Health Service Standards* (NSQHSS)**

| 1 ☒ | 2 ☐ | 3 ☐ | 4 ☒ | 5 ☐ | 6 ☒ | 7 ☐ | 8 ☐ | 9 ☒ | 10 ☐ |
|---|---|---|---|---|---|---|---|---|---|
| Governance for Safety and Quality in Healthcare | Partnering with Consumers | Preventing & Controlling Healthcare Associated Infections | Medication Safety | Patient Identification & Procedure Matchng | Clinical Handover | Blood & Blood Products | Preventing & Managing Pressure Injuries | Recognising & Responding to Clinical Deterioration | Preventing Falls & Harm from Falls |

***Evaluation and Quality Improvement Program* (EQuIP)**

| 11 ☒ | 12 ☒ | 13 ☐ | 14 ☒ | 15 ☒ |
|---|---|---|---|---|
| Service Delivery | Provision of Care | Workforce Planning and Management | Information Management | Corporate Systems and Safety |

## Consultation

| Version | Consultation |
|---|---|
| 1.0 | SA Metropolitan Diabetes Services, CHSA Director of Endocrinology, CHSA Diabetes Specialist Nurse Network. |

**Appendix 1: Available CGM and FGS Devices**

| | Medtronic Guardian 2 Link and MiniLink | Medtronic Guardian Connect and iPro2 | AMSL Dexcom G4 | AMSL Dexcom G5 | Abbott Freestyle Libre |
|---|---|---|---|---|---|
| **Sensor Augmented with Insulin Pump** | MiniMed 640G Pump with Smart Guard  Paradigm VEO with Smart Guard  and the X22. | No | Animas VIBE  | No | No |
| **Stand Alone Systems** | No | Medtronic Guardian Connect  iPro2  | Dexcom G4 PLATINUM Receiver  | Dexcom G5 and Smart Phone or Receiver  Compatible Smart Phones (Applae and Android) at https://www.dexcom.com/ous-compatibility-page | Abbott Freestyle Libre  |
| **Description** | Personal Use - An integrated system where the insulin pump acts as a receiver of CGM data. The auto suspend feature helps in suspending the pump if glucose level is predicted to hit a threshold in the next 30 minutes (640G). The 640G has superseded the VEO. | Personal Use - The Guardian Connect system sends data wirelessly to a smart device and can predict future glucose values up to 60 minutes in advance. Professional Use -The iPro2 CGM is a diagnostic CGM device that patients can wear for up to 6 days, without seeing the outcomes. | Personal Use. An integrated system with the insulin pump (VIBE) which acts as a receiver of real-time CGM data. Can also be used as a stand alone with G4 Platinum Receiver. Also available for trial use. | Personal Use - Can be used alone and can send data wirelessly to a compatible smart phone. It is FDA and TGA approved to make treatment decisions upon its results. Dexcom G5 Mobile is a newer version compared to Dexcom G4 PLATINUM. | Personal Use - Reader needs to scan the Sensor to capture the current glycaemic data. The Reader can store approximately 90 days of glucose and clinical notes. |
| **Accuracy Mean Absolute Relative Difference** | Guardian 2 Link 9.10% MiniLink 14.20% | Guardian Connect 11.40% iPro2 10.6% Paediatrics 10.8% Adults | 15% Paediatrics 13% Adults | 10% Paediatrics 9% Adults | 13.9% Paediatrics 11.4% Adults Verses Blood Glucose Monitors |

| | Medtronic Guardian 2 Link and MiniLink | Medtronic Guardian Connect and iPro2 | AMSL Dexcom G4 | AMSL Dexcom G5 | Abbott Freestyle Libre |
|---|---|---|---|---|---|
| **Approved Age** | No age restriction | No age restriction | Age 2 years and over | Age 2 years and over | Age 4 years and over |
| **Sensor Glucose Measurement** | Every 5 minutes | Every 5 minutes | Every 5 minutes | Every 5 minutes | Every 1 minute, plotted at 15 minute intervals |
| **Duration of Wear** | 6 days | 6 days | 7 days | 7 days | Up to 14 days |
| **Calibration Required** | Yes | yes | Yes – one blood glucose every 12 hours | Yes – one blood glucose every 12hours | No – Factory Calibrated |
| **Alarms** | Yes - 640G and X22<br>No -VEO | Yes - Guardian Connect<br>No - iPro2 | Yes | Yes | No |
| **Trend Arrows** | Yes - 640G<br>No – VEO and X22 | No | Yes | Yes | Yes |
| **Predictive Low Glucose Suspend** | Yes | Not Applicable | No | No | No |
| **Power and Recharge** | Transmitter should be charged after 6 days of use. Requires 20mins to recharge. | Transmitter should be charged after 6 days of use. Requires 20mins to recharge. | Receiver to be charged every 3 days or as required. Transmitter battery lasts minimum 6months. | Transmitter battery lasts minimum 3months. | Rechargeable - 7 days of typical use. |
| **Transmission** | Sensor and transmitter to be worn together with pump. Sensor to be inserted 2.5cm from pump infusion site. | Sensor and transmitter to be worn together on abdomen. | Receiver has to be within 6 metres of the transmitter. | Receiver and/or smart phone device has to be within 6 metres of the transmitter. | When Reader is scanned near the Sensor. |
| **Blood Glucose Compatible** | Bayer Meter is compatible with pump and transmitter. Blood glucose result will automatically be entered for calibration. | Bayer Meter is compatible with pump and transmitter. Blood glucose result will automatically be entered for calibration. | Blood glucose must be manually entered. | Blood glucose must be manually entered. | Reader can be used to test blood glucose or blood ketone using Freestyle Optium blood glucose or blood ketone test strips. |
| **Waterproof** | Pump waterproof up to 3.6metres for up to 24hours. Transmitter is waterproof up to 2.4metres for up to 30minutes. | Transmitter is waterproof up to 2.4metres for up to 30minutes. | Receiver is not waterproof. Pump, sensor and transmitter is for up to 2.44metres for up to 24hours. | Receiver or smart phone is not waterproof. Sensor and transmitter is for up to 2.44metres for up to 24hours. | Reader is not waterproof. Sensor is water-resistant up to 1metre for up to 30minutes. |

| | Medtronic Guardian 2 Link and MiniLink | Medtronic Guardian Connect and iPro2 | AMSL Dexcom G4 | AMSL Dexcom G5 | Abbott Freestyle Libre |
|---|---|---|---|---|---|
| **Ability to share data** | No | The Guardian Connect system allows the wearer and up to 5 care partners to receive SMS alerts. | No | Yes | Yes |
| **Software** | CareLink® Personal Software and/or dock wired to PC with CareLink® iPro | CareLink® Personal Carelink iPro® | diasend®, web-based diabetes management system<br>Dexcom Clarity clarity.dexcom.eu | diasend®, web-based diabetes management system<br>Dexcom Clarity clarity.dexcom.eu | Libre Freestyle software |
| **Cost** | Products are fully subsidised by the NDSS for children and young adults (under 21 years of age).<br>For those over 21 years, costs vary.<br>Guardian 2 Link Transmitter and 12 months of Enlite Sensors $3000.00<br><br>Enlite Sensors $75.00 each. | Products are fully subsidised by the NDSS for children and young adults (under 21 years of age).<br>For those over 21 years, costs vary.<br>Guardian Connect Transmitter and 12 months of Enlite Sensors $3000.00<br>Cost of smart devices vary.<br><br>Enlite Sensors $75.00 each. | Products are fully subsidised by the NDSS for children and young adults (under 21 years of age).<br>For those over 21 years, costs as below.<br>Dexcom G4 Platinum Receiver $810.00<br>Dexcom G4 Platinum Transmitter $580.00<br>Dexcom G4 PlatinumSensor $92.50 each. | Products are fully subsidised by the NDSS for children and young adults (under 21 years of age).<br>For those over 21 years, costs as below.<br>Dexcom G5 Receiver $650.00<br>Dexcom G5 Mobile Transmitter Only $540.00<br>Dexcom G5 Sensor $92.50 each.<br>Cost of smart phones vary. | Products are not subsidised by the NDSS.<br>Libre Reader $95.00.<br>Libre Sensor $92.50. |

**Appendix 2: Women's and Children's Hospital 'Getting started with your Medtronic Continuous Glucose Monitor' Information**

## Getting Started with your Medtronic Continuous Glucose Monitor

Women's & Children's Hospital

The extra information provided by your Continuous Glucose Monitor (CGM) can help you to understand and better manage your diabetes, but it is important not to over-react to all the extra information initially.
Spend the first few days observing the patterns and trends, for example

- What is your trend overnight?
- How do your insulin doses work with meals?
- How much does the timing of your insulin bolus affect your glucose levels after meals?
- What is the effect of exercise?
- What is the effect of hypo treatment?

Studies have shown that to get most benefit from your CGM it needs to be worn at least 70% of the time.

### Setting your goals

Think about your personal goals with CGM. For example, do you want to improve diabetes control, reduce hypos or manage exercise better?

### Recommended Sensor Glucose and HbA1c targets

| | Ideal target range | Good range but not in target | Glucose and HbA1c high | Glucose and HbA1c extremely high |
|---|---|---|---|---|
| HbA1c | Less than 7% | 7.0 - 7.9% | 8.0 – 9.0% | Above 9.0% |
| Average Sensor Glucose | Less than 8.6mmol/L | 8.6 – 10mmol/L | 10.1 - 11.8mmol/L | Above 11.8mmol/L |

### Reviewing your CGM data

- We recommend downloading and reviewing your CGM data every 1-2 weeks at home. This will allow you to identify patterns and make adjustments if needed
  - Look at your average sensor glucose (SG) – aim to keep this below 10mmol/L
  - Look for patterns of high or low glucose levels at the same time each day and try to understand why these are occurring
- If SG readings are high, consider factors other than pump settings/insulin doses first
  - If your SG is rising after meals, try giving your insulin dose earlier (10-15 mins before you start eating)
  - If your SG readings are high overnight, make sure you are checking your blood glucose before bed each night and giving a correction dose if needed
  - Is your carb counting accurate?
  - Are you avoiding lumpy injection sites and if on a pump changing your sets every 2-3 days?
- Once these basics are addressed, consider adjusting your pump settings or insulin doses
  - Refer to *Interpreting Pump Downloads and Adjusting Settings* for more information

### Trend arrows

Your CGM not only tells you what your sensor glucose is, but where it is going and how fast it is going there. The trend arrows can help you to prevent hypos and correct high blood glucose levels earlier and more effectively.

| Rate of fall in sensor glucose | | Rate of rise in sensor glucose | |
|---|---|---|---|
| ↓ | SG falling 1-2mmol/L in 20mins | ↑ | SG rising 1-2mmol/L in 20mins |
| ↓↓ | SG falling 2-3mmol/L in 20 mins | ↑↑ | SG rising 2-3mmol/L in 20mins |
| ↓↓↓ | SG falling more than 3mmol/L in 20 mins | ↑↑↑ | SG rising more than 3mmol/L in 20 mins |

## Preventing Hypoglycaemia

### For those using a Medtronic 640G pump with suspend BEFORE low activated

Your pump will do the work to prevent hypoglycaemia most of the time

- **Your low limit will be set at 3.4mmol/L initially**
- **If suspend BEFORE low is activated**
  - Your pump will temporarily suspend basal insulin delivery if your SG is approaching your low limit. (i.e. when your SG is predicted to be below 4.5mmol/L within the next 30 mins)
  - Basal insulin delivery will automatically resume when your SG is above 4.5mmol/L and trending upwards or after a maximum suspend time of 2 hours
  - You have the option of resuming basal insulin manually at any time
  -
- When your pump suspends BEFORE low, first check if active insulin is present

| Active insulin | Action |
|---|---|
| **If minimal or no active insulin** | • **Let the pump do the work to prevent hypoglycaemia**<br>• **No hypo treatment is required**<br>• **Monitor SG closely** |
| **If more active insulin (eg. recent bolus excessive)** | • **Your pump suspending before low may not be enough to prevent hypoglycaemia**<br>• **Give rapid acting carbohydrate (without bolusing) and resume basal insulin manually**<br>• **The amount of carbohydrate required will depend on the amount of active insulin**<br>  ○ **Use your carb ratio to calculate the carbs required to cover the active insulin OR**<br>  ○ **Try giving 10 gms of carbohydrate, monitor SG response and adjust from there** |

- When you receive an Alert on Low your SG has reached your low limit (3.4mmol/L)
  - Give rapid acting carbohydrate (without bolusing) and resume basal insulin manually
  - If no active insulin, try giving 10 gms of carbohydrate initially, watch SG response and adjust from there
  - If active insulin present, use your carb ratio to calculate the extra carbs required to cover the active insulin
- Exceptions
  - **Remember if you are exercising, you may need to take more rapid acting carbs**
  - If you have an alternative basal pattern set to cover recess / lunch carbohydrate at school, discuss the implications of this with your Diabetes Educator or Doctor

### For those using a Medtronic VEO pump with Suspend ON Low activated

- **Your low limit will be set at 4.0mmol/L initially**
- **If suspend ON low is activated**
  - Your pump will temporarily suspend basal insulin delivery if your SG has reached or fallen below your low limit (4.0mmol/L). Basal insulin delivery will automatically resume after 2hrs
  - **If your low limit is reached with arrows still trending downwards** give rapid acting carbohydrate (without bolusing) and resume basal insulin manually. Try giving 10 gms of carbohydrate initially, watch SG response and adjust from there

## Practical Tips for Medtronic CGM Users

- Difference between SG and BG (lag time 6-12mins)
- Calibration:
  - Required with every sensor change at 2hrs, repeated within 6 hrs and then at least every 12 hrs
  - Best times to calibrate are before meals and before bed
- When is a BG check required?
  - to calibrate your CGM
  - to make insulin dosing decisions
  - to confirm a low or high SG
  - if SG readings don't match your clinical symptoms
- Change sensor every 6 days
- Recharge transmitter every 6 days, transmitter can be reused for up to 1 year (1 year warranty)
- Pump and transmitter must be within 1.8m to see data, data stored for up to 10 hrs if out of range
- Use good quality batteries in your pump when using CGM or vibrate settings
- The importance of regular downloads and review every 1-2 weeks at home and before each clinic visit
  - If problems with management software contact Medtronic on 1800 777 808
- CGM at School
  - Blood glucose monitoring and the treatment of low and high blood glucose levels, as outlined in your Diabetes Care Plan, should not change at school
  - School staff are not required to manage or use CGM data
- Special circumstances:
  - Remove CGM for MRI Scans
- Your sensor and transmitter are waterproof
- More information on your Medtronic CGM (including travel tips) is available at www.medtronic.com.au

*Last updated October 2017 Dr Jan Fairchild*

**Appendix 3: Women's and Children's Hospital 'Getting started with your Dexcom Continuous Glucose Monitor' Information**

## Getting Started with your Dexcom Continuous Glucose Monitor

The extra information provided by your Continuous Glucose Monitor (CGM) can help you to understand and better manage your diabetes, but it is important not to over-react to all the extra information initially.
Spend the first few days observing the patterns and trends, for example

- What is your trend overnight?
- How do your insulin doses work with meals?
- How much does the timing of your insulin bolus affect your glucose levels after meals?
- What is the effect of exercise?
- What is the effect of hypo treatment?

Studies have shown that to get most benefit from your CGM it needs to be worn at least 70% of the time.
Note: Sensor data is less accurate if your CGM is not calibrated every 12 hours and on the first and last (7th) day

### Setting your goals

Think about your personal goals with CGM. For example, do you want to improve diabetes control, reduce hypos or manage exercise better?

### Recommended Sensor Glucose and HbA1c targets

| | Ideal target range | Good range but not in target | Glucose and HbA1c high | Glucose and HbA1c extremely high |
|---|---|---|---|---|
| HbA1c | Less than 7% | 7.0 - 7.9% | 8.0 – 9.0% | Above 9.0% |
| Average Sensor Glucose | Less than 8.6mmol/L | 8.6 – 10mmol/L | 10.1 - 11.8mmol/L | Above 11.8mmol/L |

### Reviewing your CGM data

- We recommend downloading and reviewing your CGM data every 1-2 weeks at home. This will allow you to identify patterns and make adjustments if needed
  - Look at your average sensor glucose (SG) – aim to keep this below 10mmol/L
  - Look for patterns of high or low glucose levels at the same time each day and try to understand why these are occurring
- If SG readings are high, consider factors other than insulin doses/pump settings first
  - If your SG is rising after meals, try giving your insulin dose earlier (10-15 mins before you start eating)
  - If your SG readings are high overnight, make sure you are checking your blood glucose before bed each night and giving a correction dose if needed
  - Is your carb counting accurate?
  - Are you avoiding lumpy sites and if on a pump changing your sets every 2-3 days?
- Once these basics are addressed, consider adjusting your insulin doses or pump settings

### Trend arrows

Your CGM not only tells you what your sensor glucose is, but where it is going and how fast it is going there. The trend arrows can help you to prevent hypos and correct high blood glucose levels earlier and more effectively.

| Rate of fall in sensor glucose | | Rate of rise in sensor glucose | |
|---|---|---|---|
| ↘ | SG falling 1-2mmol/L in 20mins | ↗ | SG rising 1-2mmol/L in 20mins |
| ↓ | SG falling 2-3mmol/L in 20 mins | ↑ | SG rising 2-3mmol/L in 20mins |
| ↓↓ | SG falling >3mmol/L in 20 mins | ↑↑ | SG rising >3mmol/L in 20 mins |

## Practical Tips for Dexcom CGM Users

- Difference between SG and BG (lag time 6-12mins)
- Calibration:
  - Required with every sensor change and every 12 hrs to ensure accuracy
  - Best times to calibrate are before meals and before bed
- When is a BG check required?
  - to calibrate your CGM and for 2 hours after new sensor inserted
  - to make insulin dosing decisions
  - to confirm a low or high SG
  - if SG readings don't match your clinical symptoms
- Sensor data is less accurate:
  - on the first and last day (7th day) of wearing
  - if your CGM is not calibrated every 12 hours
- Change sensor every 7 days
- Transmitter may be used for up to 3 months
- Keep smart device charged to receive information/ CGM uses approximately 1Mb of data per day
- Receiver and transmitter must be within 6m to see data, data stored for up to 3 hrs if out of range
- Use good quality batteries in your pump when using CGM or vibrate settings
- The importance of regular downloads and review every 1-2 weeks at home and before each clinic visit
  - If problems with management software contact **AMSL Helpline on 1300 226 207**
  - **Remember to store your Diasend and Dexcom usernames and passwords in a safe place**
- School
  - Blood glucose monitoring and the treatment of low and high blood glucose levels, as outlined in your Diabetes Care Plan, should not change at school
  - School staff are not required to manage or use CGM data
- Special circumstances:
  - **Do not rely on SG readings if paracetamol has been taken within the last 6-8 hours**
  - Remove CGM for MRI Scans
- The sensor and transmitter are waterproof
- More information on your Dexcom CGM (including travel tips) is available at www.amsldiabetes.com.au

*Last updated October 2017: Dr Jan Fairchild*