D. DOT CGM

Continuous Glucose Monitoring System

Sensor, Transmitter and D DOT Mobile Application

USER MANUAL

India Executive Version

Full Stop to Diabetes Guesswork.

Document Item	Details
Product Name	D. DOT CGM Continuous Glucose Monitoring System
Model	D3
App Name	D DOT
IFU Number	Not Available as of now
Version Number	01
Document Date	25 June 2026
Effective Date	To be updated after regulatory approval
Sensor Wear Duration	Up to 14 days
Glucose Reading Interval	Every 3 minutes

Imported and Marketed by
Dexvia Healthcare Private Limited
3rd Floor, Sreshta Primus, Road No 36, Jubilee Hills, Hyderabad, Telangana - 500033, India
Customer Support: +91 800 800 2041 | support@ddot.health | www.ddot.health

Manufactured by
Infinovo Medical Co., Ltd.
3rd Floor, 6th Building, No.888, Zhujiang Road, Rudong, 226400 Jiangsu, P.R. China

Important before final printing

- This manual is a final executive draft for review and release preparation. Regulatory license numbers, import license details, UDI and final approved labeling must be inserted before commercial printing.
- The IFU, outer box, pouch label, sensor package, app screens and customer support documents should match the CDSCO-approved documents exactly.
- Do not add diabetes reversal, insulin dose, medicine change, diagnosis, cure, or AI doctor claims unless approved.

Document Control and Release Notes

Field	Details
Document owner	Dexvia Healthcare Private Limited
Document type	User Manual / Instructions for Use
Territory	India
Product basis	OEM D3 continuous glucose monitoring system manufactured by Infinovo Medical Co., Ltd.
Release status	Final executive draft, pending regulatory number insertion and label artwork verification
Required approval before print	Regulatory, Quality Assurance, Legal, Customer Support, App/Product Owner

What changed from the OEM manual

- Branding localized to D. DOT CGM and D DOT App.
- India importer, customer support, warranty and replacement process added.
- India regulatory placeholders added for CDSCO license, import license, importer license and UDI.
- Serious incident reporting localized to D. DOT Customer Support and MvPI/CDSCO channels.
- D DOT App features added, including reports, event logging, health timeline, AI Reports, evidence references, Family Sharing, Doctor Sharing and connected care controls.
- AI and app feature disclaimers added to reduce medical claim risk.

Pre-release Checklist

Item	Status
CDSCO import license number inserted	Pending
Importer license details inserted	Pending
UDI details inserted where applicable	Pending
Box, pouch, sensor and IFU content matched	Pending

Manufacturer technical specifications verified	Pending final QA
App store wording matched to approved claims	Pending
Warranty process approved by operations	Pending
Customer support scripts aligned with IFU	Pending

Table of Contents

Note: Final page numbers should be updated in Microsoft Word before printing or PDF export.

1. How to Use This Manual

Read this manual completely before using D. DOT CGM for the first time. This manual explains the sensor, applicator, D DOT App, warnings, precautions, app features, troubleshooting, reporting and warranty process for India.

Read first	Keep available
• Safety information • Contraindications • Warnings and precautions • Sensor application steps • When to verify with a blood glucose meter	• Customer support contact • Lot number and serial number • Warranty request form • Adverse event reporting instructions • App permissions checklist

Emergency and medical decision notice

- D. DOT CGM is intended to support glucose monitoring. It is not a substitute for emergency care, a blood glucose meter when symptoms do not match readings, or advice from a qualified healthcare professional.
- If you feel symptoms of severe hypoglycemia, hyperglycemia, dehydration, illness, infection, chest pain, fainting, confusion or any emergency condition, seek medical help immediately.

2. Terminology

Term	Meaning
CGMS	Continuous Glucose Monitoring System. In this manual, CGMS refers to the D. DOT CGM system consisting of the disposable applicator, sensor with built-in transmitter and D DOT App.
Applicator	Single-use sterile component used to apply the sensor onto the skin.

Sensor	Single-use component intended to measure glucose in interstitial fluid and transmit sensor glucose readings to the app.
Sensor electrode	The component inserted under the skin that reacts with interstitial fluid and converts biological signals into electrical signals.
Transmitter	Built into the sensor. It converts electrical signals into glucose readings and sends readings wirelessly to the app.
D DOT App	The mobile application that receives and displays sensor glucose readings, trends, alerts, reports and permitted app features.
Sensor glucose reading	The glucose value estimated by the CGM from interstitial fluid. It may differ from a fingerstick blood glucose value.
Blood glucose meter	A medical device used to measure glucose in blood from a fingerstick sample.
Calibration	A blood glucose value measured by a glucose meter and entered into the app if calibration is permitted or requested by the app workflow.
Data receiving range	The communication distance between the app and sensor. The expected range is within 6 m without obstruction.
Repeat prompt	A repeated notification if the first notification is not confirmed.
AGP	Ambulatory Glucose Profile, a summary view used to review glucose patterns over time.
TIR	Time in Range, the percentage of time glucose readings are within a selected target range.
Health timeline	A chronological view of important app events such as glucose highs/lows, medication entries, symptoms, exercise, wellness logs and report uploads, where supported.
Evidence-based insight	An app-generated explanation that references the data used, such as CGM data, logs, reports or user-entered events, where supported.
D DOT Health Score	A wellness-style score, where supported, summarizing selected app signals. It is not a diagnosis or clinical risk score unless separately validated and approved.

3. Product Overview

D. DOT CGM is a Continuous Glucose Monitoring System designed to continuously monitor glucose levels in interstitial fluid and provide real-time glucose information through the D DOT mobile application. The system consists of a disposable sensor, integrated transmitter and D DOT App.

After activation and warm-up, the sensor measures glucose every 3 minutes and can provide up to 480 readings per day. Each sensor is designed for up to 14 days of continuous wear, subject to proper application, adhesion, storage, phone setup and system operation.

- View real-time glucose readings and trend arrows.
- Review glucose graphs and historical trends.
- Receive high and low glucose alerts, subject to phone settings and app permissions.
- Generate reports, including time in range and AGP-style summaries where supported.

- Record meals, diet logs, hydration, medication, insulin events, activity, sleep, mood, stress, energy level, symptoms, menstrual logs and notes where supported.
- Upload medical reports in PDF or image formats where supported and permitted by user consent.
- View a health timeline of important events such as glucose highs/lows, missed medication, symptoms, exercise and report uploads.
- Share selected data with family members, caregivers, loved ones or healthcare professionals after consent.
- Access AI-generated report explanations, evidence-linked insights, trend summaries and health timeline summaries where supported.

[Insert approved product image: D. DOT CGM applicator, sensor and D DOT App screen.]

4. Working Principle

The sensor electrode is inserted into interstitial fluid under the skin. Glucose in the interstitial fluid reacts with the sensor chemistry and generates an electrical signal. The built-in transmitter processes this signal and transmits sensor glucose readings to the D DOT App through Bluetooth.

Interstitial fluid readings may lag blood glucose

- CGM readings are not direct blood measurements.
- During rapid glucose changes after meals, exercise, insulin, illness or hypoglycemia, sensor glucose may differ from blood glucose meter values.
- When symptoms do not match the app reading, use a fingerstick blood glucose meter and follow medical advice.

5. Product Components

Component	Type	Description
Applicator	Disposable, sterile, single-use	Used to apply the sensor onto the abdomen or back of the upper arm. Do not reuse.
Sensor	Single-use, up to 14 days	All-in-one sensor with adhesive patch, sensor electrode and built-in transmitter.
Integrated transmitter	Built into sensor	Wirelessly sends sensor glucose readings to the D DOT App via Bluetooth.
D DOT App	Mobile application	Displays glucose values, trends, alerts, logbook, reports and permitted sharing/AI features.

[Insert approved component images: applicator closed state, applicator open state, sensor front side and sensor reverse side.]

6. D DOT Application Overview

The D DOT App is a mobile medical application used with D. DOT CGM. It receives sensor data, processes glucose readings and displays readings, trend curves, trend arrows, sensor status, alerts, reports and supported app features.

Requirement	Details
Operating system	Android 9.0 and above / iOS 13.2 and above, or as updated in the app store compatibility list.
Connection	One app/device should connect to one active sensor at the same time unless a permitted sharing feature is used.
Data transmission	Sensor and app transmit data via Bluetooth protocol.
Data export	Excel, PDF or other formats depending on app version and released functionality.
Internet	May be required for login, cloud backup, sharing, AI reports, app updates and document upload features.

6.1 D DOT Health Intelligence Platform Features

In addition to glucose display, the D DOT App may combine CGM data, user-entered logs, uploaded medical reports and sharing permissions to provide a broader health-intelligence experience. Feature availability may vary by app version, regulatory release stage and user permissions.

Feature area	What it may support
CGM glucose data	Real-time sensor glucose, glucose trends, alerts, glucose history and CGM status.
Medication adherence	Medication schedules, taken doses, missed doses and adherence percentage where supported.
Insulin tracking	Insulin event logging where supported. The app does not recommend insulin dose changes.
Activity tracking	Steps, exercise sessions, activity consistency and movement-related context where supported.
Diet and meal logs	Meal notes, food entries, photos or carbohydrate context where supported. Not a medical nutrition prescription.
Hydration monitoring	Water intake logs and dehydration-risk context where supported. Not a diagnosis of dehydration.
Sleep tracking	Sleep duration, quality, consistency and recovery context where supported.
Mood, stress and energy	Mood logs, stress logs and energy level records to support pattern review.
Symptom tracking	Symptom frequency, timing, severity and relationship to glucose patterns where supported.
Menstrual tracking	Menstrual cycle logs where supported, to help users review health context over time.
Medical reports	PDF/image report upload, OCR-assisted reading and plain-language explanation where supported.
AI reports and evidence	AI-generated summaries may cite the source data used, such as CGM, medication, sleep, activity, hydration, symptoms and uploaded reports.
Health timeline	Chronological view of important glucose, medication, lifestyle, symptom and report events.

6.2 Feature Availability and Claim Boundary

Boundary	User meaning
Available only where released	Some app features may be disabled, limited, in beta, or released in phases. The app store listing and approved app version control actual availability.
Not a diagnosis tool	The platform can organize and explain data but must not be used to diagnose disease or confirm a medical condition.
Not treatment automation	The app must not automatically change medication, insulin, treatment, diet or emergency response.
Evidence is not medical approval	Evidence references show what data the AI used. They do not mean a doctor has reviewed or approved the output.
Consult healthcare professional	Users should discuss glucose reports, health scores, medication adherence and AI insights with qualified healthcare professionals.

7. Safety Information

Incorrect use of the system may lead to inaccurate readings, missed alerts or wrong interpretation of glucose data. Always follow this manual, the app instructions and guidance from your healthcare professional.

Safety area	Instruction
Do	Read this manual, prepare the skin properly, keep the phone within range, keep alerts enabled and verify with a blood glucose meter when symptoms do not match readings.
Do not	Do not reuse the sensor, use expired sensors, use damaged packaging, modify the device, ignore severe symptoms, or make medication/insulin decisions based only on app or AI output.
Ask your doctor	How to set alert thresholds, how to respond to low/high glucose alerts, when to use a blood glucose meter and how to use CGM reports in your care plan.

8. Intended Use, Users and Environment

8.1 Intended use

D. DOT CGM is intended for continuous or periodic recording of glucose levels in interstitial fluid for adults with diabetes aged 18 years or older. The information is intended to detect glucose trends and track glucose patterns to provide reference information to patients and healthcare professionals for diabetes management.

The system provides real-time sensor glucose values through the D DOT App. It is not intended to diagnose diabetes, replace professional medical judgment, or independently determine treatment decisions.

8.2 Intended users

Intended users include healthcare professionals, patients and family members or caregivers of patients aged 18 years and above. Users must be able to understand the instructions, maintain hygiene, identify body parts and operate the app safely. Patients with disabilities may need assistance.

8.3 Intended environment

The system is intended for use in home healthcare environments and professional healthcare facility environments.

8.4 Indications

- Type 1 and Type 2 diabetes mellitus.
- Special types of diabetes, excluding monogenic diabetes syndromes, diseases of the exocrine pancreas, and drug or chemical induced diabetes unless specifically advised by a healthcare professional.
- Abnormal glucose levels requiring monitoring.
- Patients requiring improved glycemic control.
- People requiring frequent or continuous monitoring of glucose.

8.5 Application site and reuse

Approved application sites are the abdomen and the back of the upper arm. D. DOT CGM sensor and applicator are single-use products. Do not reuse, re-sterilize or share the sensor or applicator.

9. Contraindications, Warnings and Precautions

9.1 Contraindications

- Because part of the sensor pierces the skin, people with delicate skin should use the device cautiously and seek medical advice if needed.

· Remove the sensor before MRI, CT scan or diathermy treatment unless the healthcare provider and approved device instructions specifically confirm safe use.
· Taking higher than the maximum recommended dose of acetaminophen/paracetamol may affect CGM readings and may make readings appear higher than they really are.
· The system was not evaluated for pregnant women, peritoneal dialysis patients, patients with implanted pacemakers, patients with coagulation disorders or those taking anticoagulant drugs.

9.2 Warnings

· Do not use the system if you have diffuse subcutaneous nodules at the intended application site.
· Read instructions thoroughly before use. Incorrect use may lead to misunderstanding of the information or missed low/high glucose events.
· Talk to a healthcare professional about how to use CGM glucose information for diabetes management.
· If alerts or readings do not match symptoms or expectations, use a fingerstick blood glucose meter to make treatment decisions and seek medical attention when appropriate.
· After restarting the phone or enabling airplane mode, confirm that Bluetooth is turned on and the D DOT App can communicate with the sensor.
· Do not use if sterile packaging is damaged, opened or expired.
· Keep small parts away from children. Small parts may cause choking if swallowed.
· Keep the system away from strong electromagnetic fields that may interfere with Bluetooth communication.

9.3 Precautions

· No modifications are allowed. Unauthorized modification may cause malfunction and may void warranty.
· Read this manual or receive training before use.
· Rapid glucose changes may cause sensor glucose to differ from fingerstick blood glucose.
· Severe dehydration or excessive water loss may result in inaccurate readings.
· If the sensor becomes loose, readings may be unavailable or unreliable.
· The product is waterproof to 1 meter for up to 120 minutes. Do not exceed this limit.
· Clean and dry skin before application. Do not apply until alcohol has fully dried.
· Change the insertion site each time to reduce irritation and allow the skin to heal.
· Intense exercise, sweat, friction or impact may loosen the sensor.
· Users are responsible for securing their phone and app account to prevent unauthorized access.

10. Risks and Clinical Benefits

10.1 Potential risks

Risk	Description
Inaccurate readings	May occur due to rapid glucose changes, dehydration, compression, medication interference, sensor issue, expired product or improper storage.
Skin reaction	May include redness, itching, rash, bleeding, discomfort, adhesive allergy or infection at the insertion site.
Missed alerts	May occur if phone battery is low, Bluetooth is off, app permissions are disabled, phone is out of range, Do Not Disturb is active or the app is closed.
Sensor detachment	May occur due to poor skin preparation, friction, sweat, impact, swimming beyond specifications or adhesive issue.
Broken sensor tip	Rarely, the sensor tip may break and remain under the skin. Do not attempt to remove it yourself. Seek medical help.

10.2 Potential clinical benefits

- Improved visibility of glucose trends and patterns.
- Better review of time in range and glucose variability with healthcare professionals.
- Reduced time spent in hypoglycemia or hyperglycemia when alerts and treatment plans are used appropriately.
- More informed diabetes management discussions with doctors, diabetes educators and caregivers.

Benefit depends on proper use

• CGM benefit is strongest when users respond appropriately to alerts, verify readings when needed and review reports with healthcare professionals.
• The system cannot prevent glucose events by itself. User action and clinical guidance are still required.

11. Installation Requirements

Before using D. DOT CGM, confirm that you have a compatible smartphone, the D DOT App, stable Bluetooth, notification permissions, a clean application site and a blood glucose meter available for verification when needed.

Requirement	Instruction
Phone battery	Keep the phone charged. Low battery may cause missed alerts or disconnection.
Bluetooth	Keep Bluetooth enabled during sensor use.

Distance	Keep the phone within 6 m of the sensor without major obstruction whenever possible.
Notifications	Allow app notifications and critical alerts where supported.
Background activity	Allow the app to run in the background. Do not force close the app during sensor use.
Internet	Required for features such as login, sharing, cloud sync, AI reports and app updates where enabled.
Blood glucose meter	Keep a meter available to confirm readings when symptoms do not match CGM values.

12. Smartphone and App Setup

12.1 App installation

1. Download the D DOT App from Google Play Store or Apple App Store, as applicable.
2. Install the app and complete account setup and personal information fields as requested.
3. Select the glucose unit: mmol/L or mg/dL.
4. Set the target glucose range and alarm/alert preferences in consultation with your healthcare professional.
5. Allow Bluetooth, notification, camera, background refresh and other permissions requested by the app where required for operation.
6. Review consent settings before enabling sharing, cloud backup, document upload or AI features.

12.2 Phone settings checklist

Setting	Recommended status
Bluetooth	On
Notifications	Allowed for D DOT App
Background refresh / background data	Allowed
Battery optimization / deep sleep	Disabled for D DOT App where possible
Do Not Disturb	Disabled or configured to allow critical glucose alerts
Silent / mute mode	Avoid relying only on sound if phone settings may block sound
Operating system update	After every update, reopen the app and verify Bluetooth and notification permissions

Warning

- If phone settings are not configured correctly, you may miss high or low glucose alerts.
- No app can guarantee delivery of every alert under all phone, operating system, battery, network or Bluetooth conditions.

13. Sensor Application

13.1 Check sensor before use

- Check the package, expiration date, batch/lot number, serial number and tamper-evident label.
- Do not use if the applicator, cap, packaging or tamper-evident label is damaged or opened.
- Do not use if expired.
- Keep the package closed until ready to apply.

13.2 Select application site

The D. DOT CGM can be worn on the back of the upper arm or abdomen. Select a flat area less likely to be pressed, rubbed or bumped.

- Avoid a site where a CGM was recently worn.
- Avoid loose skin, muscle areas, bony areas or areas with insufficient fat.
- Avoid areas within 5 cm of insulin injection or infusion sites.
- Avoid damaged skin, irritation, scars, tattoos, moles or excessive hair.
- Avoid the waistline, belt area or places likely to be pressed during sleep.
- Keep abdomen placement at least 5 cm away from the navel.
- If pregnant, avoid abdomen placement unless specifically advised by a healthcare professional.

13.3 Clean application site

1. Wash your hands with soap and water and dry them.
2. Clean the selected application site with soap and water if needed and dry fully.
3. Wipe the site with an alcohol wipe.
4. Allow the skin to dry completely before applying the sensor.
5. Make sure the site is free of lotions, perfumes, oils, medication, sweat or moisture.

13.4 Apply sensor

1. Rotate/open the product casing according to the applicator design.
2. Do not touch the sensor needle or inside of the applicator.
3. Place the applicator on the selected site.
4. Press downward with firm vertical force.
5. After hearing a click, wait 3 to 5 seconds.
6. Gently remove the applicator vertically.
7. After application, gently press the sensor and surrounding adhesive tape to improve adhesion.
8. Dispose of the used applicator safely.

Minor bleeding may occur during application. Minor bleeding does not always affect monitoring. If bleeding is heavy, painful, persistent or concerning, remove the sensor and seek medical advice.

[Insert approved step images: open applicator, position applicator, press, remove applicator, press adhesive.]

14. Starting Monitoring

1. Open the D DOT App.
2. Follow app instructions to scan the sensor QR code or pair the sensor.
3. Keep the phone near the sensor during pairing.
4. Wait for warm-up to complete. Expected warm-up period is about 60 minutes.
5. After warm-up, sensor glucose readings will be displayed in the app.

During warm-up

- No sensor glucose reading or glucose alert may be available during warm-up.
- Use a blood glucose meter if you feel symptoms of low or high glucose during warm-up.
- If the app shows System stopped, please change sensor, remove and replace the sensor or contact customer support.

15. Understanding Glucose Readings

The D DOT App displays current sensor glucose value, trend arrow, glucose curve and CGM status. The exact screen layout may vary by app version.

15.1 Sensor glucose range

The sensor glucose display range is 2.2 to 22.2 mmol/L. Values below or above this range may be displayed as out-of-range readings or handled by the app according to design, while records may still appear in logbook depending on app behavior.

15.2 Trend arrows

Trend arrow	Definition
Stable	Glucose is stable, no more than 0.06 mmol/L rise or fall per minute.
Slow increase	Glucose increases by 0.06 to 0.11 mmol/L per minute.
Increase	Glucose increases by 0.11 to 0.17 mmol/L per minute.
Rapid increase	Glucose increases by more than 0.17 mmol/L per minute.
Slow decrease	Glucose decreases by 0.06 to 0.11 mmol/L per minute.
Decrease	Glucose decreases by 0.11 to 0.17 mmol/L per minute.
Rapid decrease	Glucose decreases by more than 0.17 mmol/L per minute.
No arrow	The app cannot calculate rate of change because of synchronization, disconnection or insufficient recent data.

15.3 When to verify with a blood glucose meter

- When symptoms do not match the app reading.
- When glucose is changing quickly.
- During warm-up or system recovery.
- When the app shows no reading, link lost or sensor error.
- Before making treatment decisions when readings are unexpected.
- Any time your healthcare professional advises meter confirmation.

16. Alerts and Notifications

The app provides urgent low, low and high glucose alerts using sounds, vibration, display and notifications depending on phone settings, app permissions and operating system behavior.

Alarm	Introduction	Threshold setting	Default
Low Alarm	If sensor glucose is lower than this value, the app gives a hypoglycemia alarm.	3.3 to 5.6 mmol/L (60 to 101 mg/dL)	3.9 mmol/L (71 mg/dL)
Urgent Low	If sensor glucose is at or below this value, the app gives an urgent hypoglycemia alarm.	3.1 mmol/L (56 mg/dL)	3.1 mmol/L (56 mg/dL)
High Alarm	If sensor glucose is higher than this value, the app gives a hyperglycemia alarm.	7.9 to 22.2 mmol/L (143 to 400 mg/dL)	13.0 mmol/L (234 mg/dL)

Snooze: Users may turn off the current alarm or snooze the alarm according to app settings. Do not ignore repeated alarms. Confirm glucose with a blood glucose meter if needed.

16.1 Alert reliability responsibilities

Area	Instruction
User responsibility	Keep phone charged, Bluetooth enabled, app running in background and notifications allowed.
App limitation	Alerts may not be delivered if phone, app, Bluetooth, operating system, battery or permission settings block operation.
Clinical responsibility	Discuss alert thresholds and response plans with a healthcare professional.

17. Event Logging and Health Timeline

The app may allow users to record events that help explain glucose patterns. Event entries are user-provided and may be inaccurate, incomplete or delayed. They should be used as context, not as medical advice.

Event type	Purpose and limitation
Meals / carbohydrates	Record meal timing, food notes, photos or carbohydrate information where supported.
Medication	Record medication schedules, taken doses, missed doses and adherence percentage. The app does not recommend medicine changes.
Insulin	Record insulin events where supported. The app does not recommend insulin doses.
Exercise / activity	Record exercise type, timing, duration, steps or activity consistency where supported.
Hydration	Record water intake and hydration context where supported. Hydration scores are wellness indicators, not diagnoses.
Sleep	Record sleep duration, sleep quality, sleep consistency or recovery context where supported.
Mood, stress and energy	Record mood, stress and energy levels to help review lifestyle context.
Symptoms	Record symptoms such as dizziness, sweating, fatigue, nausea or other user-selected symptoms where supported.
Menstrual tracking	Record menstrual cycle context where supported.
Medical report upload	Upload lab reports, prescriptions, discharge summaries or imaging reports where supported. OCR and AI explanation may be available.
Health profile	Store basic profile data to support display and report personalization where supported.

17.1 Health Timeline

The health timeline may show important events in one place so that users and healthcare professionals can review glucose and lifestyle context together.

Timeline item	Purpose
Glucose highs and lows	High or low glucose events shown in chronological order where supported.
Medication adherence events	Taken doses, missed doses and adherence changes where supported.
Symptoms and wellness logs	Symptoms, stress, mood, energy, hydration and sleep entries where supported.
Exercise and activity	Exercise sessions, step trends and activity events where supported.
Report uploads	Medical report uploads and AI-generated summaries where supported.
Pattern context	The app may help connect events such as poor sleep, stress, missed medication or exercise with glucose changes. These are associations for review, not proof of medical cause.

18. Reports, AGP, Health Score and Time in Range

Reports may include daily glucose reports, Ambulatory Glucose Profile (AGP), time in range, trend summaries, glucose variability and exportable summaries. Reports require sufficient valid data. Some charts may require at least 24 hours of valid sensor data.

Report type	Description
Time in Range	Shows the percentage of time sensor glucose readings are within a selected target range.
AGP-style report	Summarizes glucose patterns over time to support review with healthcare professionals.
Daily / weekly / monthly reports	May show glucose curves, alerts, event context, weekly summaries and monthly summaries where supported.
Glucose performance	May include time in range, high glucose episodes, low glucose episodes, daily variability, weekly trends, best control days and worst control days.
Medication impact	May include adherence score, missed days, taken doses, correlation with glucose control and potential risk periods where supported.
Sleep impact	May include average sleep quality, sleep consistency, sleep debt and possible relationship to glucose patterns where supported.
Stress and mood impact	May include stress trends, high-stress periods and glucose changes during stress where supported.
Activity impact	May include average steps, exercise frequency and activity consistency where supported.
Hydration insights	May include water intake, dehydration-risk context and wellness impact where supported.
Symptom intelligence	May include common symptoms, severity trends and possible relationship to glucose where supported.
D DOT Health Score	A wellness-style score from 0 to 100 may combine glucose control, medication adherence, sleep, activity, hydration, stress and mood. It is not a medical diagnosis or treatment score.
Data export	May export data in Excel, PDF or other formats depending on app version.

Report use limitation

- Reports are intended to support review and discussion. They should not be used alone to diagnose, prescribe or change treatment.
- Users should consult qualified healthcare professionals before making medical decisions based on reports.

19. AI Health Coach, AI Reports and Evidence-Based Insights

The D DOT App may provide AI Health Coach-style conversations, AI-generated reports, trend summaries and plain-language explanations based on available glucose data, user-entered events and uploaded documents where supported. AI outputs are intended to make data easier to understand, not to replace a doctor.

AI feature	User manual description
AI Health Coach	May answer questions about the user's own glucose readings, medication logs, lifestyle habits, wellness logs and uploaded records where supported. It must not be positioned as a doctor.
Example questions	Why was my glucose high yesterday? Is stress affecting my glucose? What habits appear linked with better control? These answers are informational and should be verified clinically.
Evidence-based reports	Insights may include traceable references to CGM data, medication logs, sleep logs, activity data, hydration logs, symptoms, menstrual logs or medical reports where supported.
Medical report understanding	The app may use OCR and AI to explain lab reports, prescriptions, discharge summaries or imaging reports in simple language. It must not provide diagnosis or treatment changes.
Health correlation engine	The app may identify associations such as poor sleep with glucose spikes, stress with hyperglycemia, exercise with glucose stability, hydration with wellness scores, or medication adherence with glucose outcomes.
Risk pattern detection	The app may highlight patterns such as high glucose, low glucose or missed medication events. This is not an emergency response service or guaranteed prevention system.

AI area	User manual wording
May do	Explain app-generated reports in plain language; summarize glucose trends; identify possible patterns; explain user-uploaded documents using available evidence; provide general wellness context; answer supported questions about user data.
Must not do	Diagnose disease; prescribe treatment; recommend insulin doses; recommend medication changes; act as an emergency monitoring service; replace doctor consultation; present itself as a personal AI doctor.
Exercise content	Any exercise-related suggestion, if present, should be general wellness information and should not override medical restrictions or doctor advice.
Food content	The app should not provide medical nutrition therapy or personalized food prescriptions unless approved and clinically validated for that use.
Review status	AI outputs are not reviewed by healthcare professionals before delivery unless the app specifically states otherwise.

AI disclosure

- AI-generated insights, report explanations, glucose interpretations and wellness summaries are for informational and educational purposes only.
- AI-generated content does not diagnose disease, prescribe treatment, recommend insulin doses or replace medical advice.
- Do not change medicine, insulin, diet, treatment plan or emergency response based only on AI output.
- Evidence references show the source data used by the app. They do not prove medical causation and do not mean a clinician reviewed the result.
- Always verify important information with a qualified healthcare professional.

20. Family, Caregiver and Loved-One Sharing

Users may authorize selected family members, caregivers, loved ones, friends or healthcare providers to view selected health information through approved application features. Sharing may include current glucose values, alerts, trends, wellness updates, reports, AI summaries and selected events depending on app version and consent settings.

Sharing area	Instruction
Consent required	Sharing should be enabled only after user authorization in the app.
Access control	Users should review who has access and revoke access when no longer needed.
Live view where supported	Recipients may view live glucose readings, glucose trends, critical high/low glucose events, medication adherence, wellness updates, AI reports and emergency alerts where supported.
Not emergency monitoring	Family sharing is supportive only and should not be relied on as an emergency monitoring service.
Recipient responsibility	Family members/caregivers should not change treatment unless instructed by the user’s healthcare professional.

21. Doctor Collaboration and Report Sharing

Users may securely share glucose reports, medical records, health timelines, medication adherence summaries, AI-generated summaries and historical data with healthcare professionals. Shared information may assist healthcare professionals in reviewing glucose patterns and supporting treatment discussions.

- Share reports only with trusted healthcare professionals.
- Confirm recipient identity before sharing.
- Review what data is being shared and for what time period.
- Shared data may include CGM trends, medication adherence reports, AI-generated health summaries, medical records, lifestyle insights and progress reports where supported.
- Doctor sharing can make consultations more informed, but it does not guarantee faster treatment, real-time review or emergency response.
- Treatment decisions remain between the user and qualified healthcare professionals.

22. Data Privacy and Consent in the App

The D DOT App may process sensitive personal information and health data. Users should read the D DOT User Agreement, Privacy Policy, Consent for Health Data Processing, Doctor Data Sharing Consent, Family/Caregiver Sharing Consent and AI Disclosure Statement before enabling optional features.

Data area	Instruction
Core CGM use	Glucose data, sensor details, alerts and logbook information required for device operation.
Optional app features	Family sharing, doctor sharing, AI reports, document upload, meal tracking and other app features may require separate permissions or consent.
User control	Users should be able to manage permissions, sharing and account settings in the app where supported.
Security responsibility	Users must secure the phone, account, password, OTP and app access. Do not share login credentials.
Policy reference	This manual is not a full privacy policy. The privacy policy and consent documents control data processing terms.

23. Calibration and Blood Glucose Meter Verification

The D. DOT CGM is factory calibrated. The app workflow may allow or request meter-based calibration in specific circumstances. Follow the app instructions and this manual.

Topic	Instruction
Calibration range	2.2 to 22.2 mmol/L.
Timing	Enter the exact blood glucose meter value within the permitted app time window.
Do not calibrate	During rapid glucose change, system recovery, sensor warm-up, syncing or when app does not allow calibration.

Meter verification	Use a blood glucose meter when symptoms do not match CGM readings or when readings appear unexpected.
Treatment decisions	When unsure, follow healthcare professional guidance and confirm with a meter.

24. Sensor Removal and Disposal

24.1 Sensor removal

1. Remove the sensor when the 14-day session ends, when instructed by the app, when advised by a healthcare professional, or if severe skin irritation occurs.
2. Carefully peel the adhesive patch from the edge.
3. Do not pull suddenly. Remove slowly to avoid skin injury or discomfort.
4. If adhesive residue remains, gently clean with soap and water or an alcohol swab.
5. Check the site. Contact a healthcare professional if redness, swelling, pain, discharge, fever or signs of infection occur.

24.2 Disposal

Dispose of the used sensor and applicator according to local rules for electronic waste and medical waste. Since parts of the sensor may contact bodily fluids, wipe the removed sensor with alcohol or disinfectant before disposal. Do not incinerate the sensor. The sensor contains a non-removable battery and burning it may be hazardous.

25. Troubleshooting

Issue	Possible cause	Solution
Sensor adhesive not sticky or sensor fallen off	Skin not clean/dry, hair, lotion, sweat, wrong site, friction or adhesive intolerance.	Clean skin with soap/water and alcohol wipe before application. Allow skin to dry fully. Avoid tattoos, scars, oily skin and waistline. Use approved overpatch or tape around the adhesive if recommended.
System stopped, please change sensor	Sensor failure, expired sensor, improper activation or end of session.	Check expiry and app instructions. Remove and replace sensor if instructed. Contact support with lot number, serial number and screenshots.
Connecting, please wait	Bluetooth off, phone too far, app closed, compatibility issue or interference.	Turn Bluetooth on, move phone within 6 m, reopen app, restart phone if needed and remove sources of interference.
System recovering, please wait	Temporary sensor/system recovery period.	Use a blood glucose meter during this period. If it does not recover after about 4 hours, contact support.
Calibration error	Syncing, recovery, first 24 hours, rapid glucose fluctuation or invalid meter value.	Wait until glucose is stable and app allows calibration. Enter exact meter value within the permitted time.

25. Troubleshooting, Continued

Issue	Possible cause	Solution
No reading during warm-up	Normal warm-up behavior.	Wait about 60 minutes. Use a blood glucose meter if you have symptoms.
Reading does not match symptoms	Rapid glucose change, compression, dehydration, medication interference or sensor issue.	Check with a fingerstick blood glucose meter. Treat according to medical advice, not sensor reading alone.
Allergy, redness, swelling or itching	Adhesive reaction, skin irritation or infection.	Remove sensor if severe or worsening. Clean site. Seek medical advice for pain, swelling, discharge, fever or persistent irritation.
Phone battery drains quickly	Bluetooth, background refresh and notifications increase battery use.	Keep phone charged. Do not disable critical permissions required for CGM alerts.
Unable to share data	Internet issue, consent not completed, account issue or recipient setup incomplete.	Check internet, app permissions, consent settings and recipient details. Contact support if unresolved.
AI report seems incorrect	Incomplete data, incorrect event entries, app limitations or AI interpretation error.	Do not act on AI output alone. Verify with original report and healthcare professional.
Skin pain after removal	Skin irritation, adhesive reaction or insertion site issue.	Clean gently and monitor. Seek medical advice if severe, worsening, infected or persistent.

26. Maintenance and Travel

26.1 Maintenance

The D. DOT CGM sensor has no serviceable parts and requires no maintenance. Do not attempt to repair, open, modify, recharge, re-sterilize or reuse the sensor or applicator.

26.2 Travel

Wearing the sensor is generally safe while passing through metal detectors. If concerned, inform security personnel that you are wearing a continuous glucose monitoring sensor and request visual inspection or alternative screening where permitted. Carry extra sensors, blood glucose meter supplies, charging accessories and relevant medical documents when traveling.

27. Product Performance

Item	Specification
Model	D3
Measurement range	2.2 to 22.2 mmol/L
Effective working time	Up to 14 days
Sensor size	24 mm diameter x 3.5 mm
Sensor weight	1.7 g
Data receiving range	Up to 6 m without obstruction
Calibration method	Factory calibration. App workflow may allow or request meter-based calibration as applicable.
Calibration range	2.2 to 22.2 mmol/L
Storage and transport conditions	Temperature: 2 °C to 30 °C. Relative humidity: 15% to 85%.
Working conditions	Temperature: 10 °C to 40 °C. Relative humidity: 10% to 95%.
Atmospheric pressure	70 kPa to 106 kPa
Sterile state	Sterile
Sterilization method	Irradiation sterilization, gamma ray
Validity period	12 months
Display interval	3 minutes
Rated voltage	d.c. 1.5 V
Classification	Type BF applied part
Power support	Internal power supply
Protection grade	IP28, waterproof to 1.0 meter for up to 120 minutes
Wireless	Bluetooth 5.0, 2402 to 2480 MHz, GFSK, 0 dBm

28. EMC Statement

The D. DOT CGM is suitable for use in the specified electromagnetic environments and has met applicable emission and immunity requirements listed below. Higher interference levels may cause essential performance to be lost or degraded.

28.1 Electromagnetic emissions

Phenomenon	Home healthcare or professional healthcare facility environment
Conducted and radiated RF emissions	CISPR 11, Group 1, Class B
Harmonic distortion	N/A

Voltage fluctuations and flicker	N/A

28.2 Electromagnetic immunity

Phenomenon	Basic EMC standard	Immunity test level
Electrostatic discharge	IEC 61000-4-2	+/- 8 kV contact; +/- 2, +/- 4, +/- 8, +/- 15 kV air
Radiated RF EM fields	IEC 61000-4-3	10 V/m, 80 MHz to 2.7 GHz, 80% AM at 1 kHz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	See RF wireless communication equipment table.
Rated power frequency magnetic fields	IEC 61000-4-8	30 A/m; 50 Hz or 60 Hz
Electrical fast transients/bursts	IEC 61000-4-4	N/A
Surges	IEC 61000-4-5	N/A
Conducted disturbances induced by RF fields	IEC 61000-4-6	N/A
Voltage dips / interruptions	IEC 61000-4-11	N/A

28.3 Recommended Minimum Separation Distances

Test freq. MHz	Band MHz	Service	Modulation	Max W	Distance m	Level V/m
385	380 to 390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27
450	430 to 470	GMRS 460 / FRS 460	FM, +/- 5 kHz deviation	2	0.3	28
710 / 745 / 780	704 to 787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9
810 / 870 / 930	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28
1720 / 1845 / 1970	1700 to 1990	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1/3/4/25, UMTS	Pulse modulation 217 Hz	2	0.3	28
2450	2400 to 2570	Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
5240 / 5500 / 5785	5100 to 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9

EMC warnings

- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation.
- Use of accessories, transducers or cables other than those specified may increase electromagnetic emissions or reduce immunity.
- Portable RF communications equipment, including antenna cables and external antennas, should be used no closer than 30 cm to any part of the system.

29. Regulatory Information, India

Regulatory / labeling item	Information
Medical device licensed under CDSCO	Not Available as of now
Import license number	Not Available as of now
Device classification	Class C Medical Device
UDI details	Not Available as of now
Importer license details	Not Available as of now
Lot / batch number	Refer to product packaging
Serial number	Refer to product packaging
Imported and marketed by	Dexvia Healthcare Private Limited, 3rd Floor, Sreshta Primus, Road No 36, Jubilee Hills, Hyderabad, Telangana - 500033, India
Customer care	+91 800 800 2041 / support@ddot.health

Regulatory release requirement

- Your regulatory consultant should provide the exact CDSCO license, import license, importer license and UDI details.
- Do not print or distribute this manual commercially with placeholders unless legally permitted by the applicable approval stage.
- IFU, labels, app wording and carton content should match the approved regulatory submission.

30. Technical Support and Customer Service

Contact item	Details
D. DOT Customer Support	+91 800 800 2041
Email	support@ddot.health
Website	www.ddot.health
Company	Dexvia Healthcare Private Limited
Address	3rd Floor, Sreshta Primus, Road No 36, Jubilee Hills, Hyderabad, Telangana - 500033, India
Manufacturer	Infinovo Medical Co., Ltd.
Manufacturer address	3rd Floor, 6th Building, No.888, Zhujiang Road, Rudong, 226400 Jiangsu, P.R. China
Manufacturer telephone	+86 (513) 81900808

31. Reporting Serious Incidents

In the event of a serious incident involving D. DOT CGM, report it immediately to D. DOT Customer Support. Where applicable, medical device adverse events may also be reported through the Materiovigilance Programme of India and applicable CDSCO reporting channels.

Reporting contact	Details
D. DOT Customer Support	+91 800 800 2041
Email	support@ddot.health
Company	Dexvia Healthcare Private Limited
India reporting route	Materiovigilance Programme of India and applicable CDSCO medical device adverse event reporting channels

A serious incident includes any occurrence that has caused, might have caused or could potentially cause death, serious injury, hospitalization, significant temporary or permanent deterioration in health, permanent impairment, or serious device malfunction.

31.1 Information to provide when reporting

- Product name and model.
- Sensor lot number, serial number and expiry date.
- Date of purchase and seller details.
- Date and time of incident.
- Description of the event or malfunction.
- App screenshots, error messages or photos of the sensor/packaging where available.
- Medical outcome and whether healthcare support was required.
- Customer name and contact details.

32. Warranty and Indian Replacement Process

32.1 Warranty period

Recommended warranty period: 12 months from date of purchase for manufacturing defects in materials and workmanship under normal use conditions, subject to the final warranty policy approved by Dexvia Healthcare Private Limited.

The D. DOT CGM sensor is a single-use consumable product intended for up to 14 days of wear. Replacement eligibility may apply to confirmed device malfunction, defective applicator, sensor failure before completion of intended wear, or other verified manufacturing defect.

32.2 Indian replacement process

1. Contact D. DOT Customer Support at support@ddot.health or +91 800 800 2041.
2. Provide customer name, phone number, purchase invoice, seller name, purchase date, product model, batch/lot number, serial number and app screenshots where relevant.
3. Describe the fault clearly, including when it occurred, whether the sensor was applied, whether warm-up completed and whether an app error message appeared.
4. Do not discard the product until customer support confirms whether return, photo evidence or additional checks are required.
5. Customer support will review the issue and may request photos, app logs, packaging details or the used/unused device for inspection.
6. If eligible, a replacement may be provided according to the company replacement policy.
7. If not covered, the customer will be informed of the reason and available options.

32.3 Warranty exclusions

- Use outside this manual or approved labeling.
- Use after expiry date.
- Damage caused by accident, misuse, abuse, neglect, improper storage, improper application or unauthorized modification.
- Opening, tampering, repairing, reusing or re-sterilizing the product.
- Loss of data due to phone damage, app deletion, account misuse, user error or failure to maintain backups where applicable.
- Use with unsupported phones, rooted/jailbroken phones or phones with unauthorized operating system modifications.
- Cosmetic damage that does not affect product performance.
- Sensor detachment caused by improper skin preparation, excessive friction, excessive sweating, impact, swimming beyond specifications or failure to follow instructions.
- Adverse skin reaction not caused by product quality defect, unless replacement is approved by customer support as a policy exception.

32.4 Limitation of liability

Except where prohibited by law, Dexvia Healthcare Private Limited and/or the manufacturer will not be liable for special, indirect, incidental or consequential damages arising from misuse, unsupported use, unauthorized modification, or failure to follow this user manual. This warranty does not limit statutory consumer rights that cannot be excluded by law.

33. Label Symbols

Symbol description	Meaning
Refer to instructions for use	Read the user manual before using the product.
Do not reuse	Single-use product. Do not reuse.
Do not use if package is damaged	Do not use if sterile packaging is damaged or opened.
Type BF applied part	Applied part classification.
Medical device	Indicates the product is a medical device.
Temperature limit	Store within specified temperature range.
Humidity limitation	Store within specified humidity range.
Non-ionizing radiation	Wireless communication symbol.
Sterilized using irradiation	Sterilization method is irradiation.
Date of manufacture	Manufacturing date.
Keep dry	Protect from moisture.
Keep away from sunlight	Protect from direct sunlight.
Manufacturer	Manufacturer information.
Caution	Read warnings and precautions.
Batch code	Batch or lot number.
Use-by date	Expiry date.
Unique device identifier	UDI, to be updated once available.
Model number	Product model.
Country of manufacture	Country where manufactured.
Do not re-sterilize	Do not re-sterilize the product.
Dustproof and waterproof class	Ingress protection grade.
Catalogue number	Product catalogue/reference number.
Serial number	Product serial number.
Environmental protection	Dispose according to local e-waste and medical waste rules.

[Insert approved label symbols exactly as printed on the packaging.]

34. Appendix: Warranty Card and Replacement Request Form

Field	Customer / support entry
Customer name	
Contact number	
Email address	
Contact address	
Product name	D. DOT CGM
Product model	D3
Date of purchase	
Seller / pharmacy / platform name	
Invoice number	
Sensor LOT / batch number	
Serial number	
Date of issue / malfunction	
App error message, if any	
Fault description	
Photos / screenshots attached	Yes / No
Support ticket number	
Replacement status	

Customer declaration: I confirm that the information provided above is accurate to the best of my knowledge and that the product was used according to the D. DOT CGM User Manual.

Customer signature: _____ Date: _____

35. Quick Reference Card for Users

This quick reference card is a user-facing summary only. It does not replace the complete manual. Read the full manual before first use.

Situation	What to do
Before applying	Check expiry, packaging, lot number and app compatibility. Wash hands. Select a flat site on abdomen or back of upper arm.
Skin preparation	Clean skin with soap/water if needed. Use alcohol wipe. Let skin dry fully. Do not apply over lotion, oil, sweat, scars, tattoos or irritated skin.
After applying	Press the sensor and adhesive gently. Pair in the D DOT App. Wait for warm-up. Keep phone close.
During use	Keep Bluetooth on, phone charged, app running and notifications allowed. Keep phone within 6 m when possible.
Verify with meter	Use a blood glucose meter if symptoms do not match app readings, during warm-up, system recovery, link lost or unexpected readings.
Get help	Contact D. DOT Customer Support at +91 800 800 2041 or support@ddot.health.

Never ignore symptoms

- If you feel severe low/high glucose symptoms, confusion, fainting, persistent vomiting, infection, severe dehydration or any emergency condition, seek medical help immediately.
- Do not wait for the app, AI report, family member or customer support to respond during an emergency.

36. Skin Care and Adhesion Guide

Good skin preparation is one of the most important factors for reliable sensor wear. Poor adhesion can lead to sensor movement, missing readings or early detachment.

Topic	Guidance
Choose the right site	Flat skin, enough soft tissue, away from waistline, injection sites, scars, tattoos, moles and heavy hair.
Prepare skin	Wash, dry, wipe with alcohol and wait until fully dry before applying.
Avoid products	Do not apply over lotion, oil, perfume, sunscreen, talcum powder, sweat or moisture.
Hair	Trim excessive hair if required. Avoid shaving immediately before application if it irritates the skin.
After application	Press adhesive gently around the sensor. Avoid pulling or twisting the sensor.
Exercise and sweating	Check adhesion before and after intense activity. Use approved overpatch/tape only if recommended.
Water exposure	The sensor is waterproof up to 1 meter for up to 120 minutes. Avoid long soaking, high-pressure water and rubbing with towel.
Skin reaction	Mild redness can occur. Remove sensor and seek medical advice if severe pain, swelling, discharge, fever, spreading redness or persistent itching occurs.

37. App Feature Boundaries and Safe Use

The D DOT App may include multiple features beyond glucose display. These features should be described and used within clear boundaries to reduce medical risk and user misunderstanding.

Feature	Permitted use	Boundary
Glucose monitoring	Displays sensor glucose, trends and alerts.	Not a diagnosis. Verify with meter when symptoms do not match readings.
Reports and AGP	Helps summarize glucose patterns for review.	Not a prescription, treatment plan or replacement for doctor review.
AI Health Coach	Answers supported questions about user data and explains patterns where supported.	Does not act as a doctor, diagnose, prescribe or replace clinician advice.
AI Reports	Explains reports, trends, timeline events and uploaded documents in plain language where supported.	Does not diagnose, prescribe, change medication, recommend insulin dose or act as AI doctor.
Evidence references	Shows which data sources were used for an insight where supported.	Evidence reference is not proof of medical causation or clinician approval.
Health Score	Summarizes selected wellness signals in a 0 to 100 style score where supported.	Not a clinical risk score unless validated and approved for that use.
Medication tracking	Allows users to record medication events and adherence.	Does not recommend medicine changes.
Insulin tracking	Allows users to log insulin events where supported.	Does not recommend insulin doses.
Meal tracking	Allows users to log meals, notes or photos where supported.	Does not replace dietitian advice or prescribe a medical diet.
Sleep, stress, mood, energy	Allows wellness context tracking where supported.	Does not diagnose mental health, sleep disorders or fatigue causes.
Hydration tracking	Allows water intake and wellness context tracking where supported.	Does not diagnose dehydration or kidney issues.
Symptom tracking	Allows symptom frequency and severity logging where supported.	Does not diagnose illness.
Menstrual tracking	Allows cycle context logging where supported.	Does not diagnose reproductive or hormonal conditions.
Family sharing	Allows selected data to be shared with approved family/caregivers/loved ones.	Not emergency monitoring and not guaranteed real-time response.
Doctor sharing	Allows reports/data to be shared with healthcare professionals.	Does not guarantee immediate review or emergency action.

38. Connected Care Ecosystem Guide

The D DOT App may support a connected care model where the user controls who can access selected health information. This section is intended to explain sharing boundaries to users, caregivers and support teams.

Connected care role	Access purpose
Patient / user	Owns the account, controls permissions and decides what data can be shared.

D DOT AI Platform	Organizes CGM data, wellness logs, medical reports and AI summaries where supported.
Family / caregiver	May view permitted glucose readings, trends, alerts, wellness updates and reports where supported.
Doctor / healthcare provider	May review shared CGM trends, adherence reports, medical records, lifestyle insights and progress reports.
Loved ones / friends	May receive selected updates only if the user gives permission and the app supports the role.

Privacy-first sharing

- The user should be able to decide who can access data, what data can be viewed, how long access remains active and whether access is read-only or collaborative where supported.
- Sharing should use consent, access controls and privacy settings. Users should revoke access when it is no longer needed.
- Connected care features are supportive. They are not a replacement for emergency services or medical supervision.

39. Report Review Worksheet

Users may use this worksheet before a doctor visit to discuss CGM patterns. Do not use this worksheet to self-adjust medicine or insulin without medical advice.

Review item	Notes
Report period reviewed	
Average glucose shown in app/report	
Time in Range	
Time below range	
Time above range	
Frequent low glucose timing	
Frequent high glucose timing	
Meals linked to spikes	
Exercise linked to lows/highs	
Medication events to discuss	
Symptoms that did not match CGM readings	
Questions for healthcare professional	

Doctor discussion reminder

- Take app reports, logbook entries and blood glucose meter readings to your doctor when reviewing diabetes management.
- Do not change prescription medicines or insulin doses unless advised by a qualified healthcare professional.

40. Customer Support Triage Checklist

This checklist helps customer support and users collect the right information quickly for troubleshooting, warranty or adverse event review.

Triage item	Details
Customer name and phone	
Product model	D3
Sensor lot / batch number	
Serial number	
Expiry date	
Date and time sensor was applied	
Application site	Abdomen / Back of upper arm
Phone model and operating system	
D DOT App version	
Error message shown	
Was warm-up completed?	Yes / No
Was Bluetooth on?	Yes / No
Was phone within 6 m?	Yes / No
Photos/screenshots received?	Yes / No
Blood glucose meter verification done?	Yes / No / Not applicable
Medical symptoms or injury?	Yes / No
Adverse event escalation needed?	Yes / No

41. Final Release Approval Page

This page is for internal release control before commercial printing or PDF publication. Remove this page from consumer-facing print copies if your Quality/Regulatory team prefers a separate approval record.

Approval area	Name / signature	Date
Regulatory review		
Quality Assurance review		
Legal review		
Medical/clinical review		
App/Product owner review		
Customer Support review		
Final print approval		

Final check	Status
IFU matches approved CDSCO submission	Pending
All placeholder values removed or approved	Pending
All app feature descriptions verified against released app	Pending
All claims checked against approved labeling	Pending
All artwork and symbols inserted	Pending
Final PDF generated and archived	Pending

Final Document Placeholders

Placeholder	Current value
IFU Number	Not Available as of now
CDSCO Registration / License Number	Not Available as of now
Import License Number	Not Available as of now
Importer License Details	Not Available as of now
UDI Details	Not Available as of now
Final Release Date	To be updated

End of document