Evaluation of the Performance of CONTOUR NEXT® and CONTOUR PLUS ELITE® Blood Glucose Monitoring Systems in Neonates using Capillary Blood Samples

Protocol/Clinical Investigation Plan:

GCA-PRO-2021-003-01

Amendment 1: 14 October 2022

Sponsor: Ascensia Diabetes Care
100 Summit Lake Drive
Valhalla, NY 10595

[redacted] Date

[redacted] Date

[redacted] Date

[redacted] Date

[redacted] Date

[redacted] Date

Investigator Statement

I have read this protocol and agree to conduct the clinical performance study according to the protocol. I understand and agree that before seeking approval from an Institutional Review Board (IRB), the Ascensia Diabetes Care study manager must approve any changes to the protocol. I also agree to protect the rights, safety, dignity, and well-being of the subjects.

Principal Investigator (PI):	Dennis Dietzen, PhD
Site:	St. Louis Children's Hospital, Washington University
Address:	1 Children's Place St. Louis, MO 63110

_____	_____	_____
PI Sgnature	Printed Name	Date

This protocol and the data obtained from the study are confidential and may not be disclosed without the prior written consent of Ascensia Diabetes Care (ADC).

Table of Contents

Abbreviations

ADC	Ascensia Diabetes Care
AE	Adverse Event
ADE	Adverse Device Effect
BG	Blood Glucose
BGMS	Blood Glucose Monitoring System
CIP	Clinical Investigation Plan (Protocol)
CRF	Case Report Form
EDC	Electronic Data Capture
GCP	Good Clinical Practice
HCP	Health Care Professional
ICF	Informed Consent Form
IRB	Institutional Review Board
LAR	Legally Authorized Representative
NICU	Neonatal Intensive Care Unit
PI	Principal Investigator
POC	Point Of Care
SAE	Serious Adverse Event
SADE	Serious Adverse Device Effect
SCN	Special Care Nurseries
SIV	Site Initiation Visit
UG	User Guide

1.0 Identification of the Protocol/ Clinical Investigation Plan (CIP)

1.1 Title of the clinical investigation: Evaluation of the Performance of CONTOUR NEXT® and CONTOUR PLUS ELITE® Blood Glucose Monitoring Systems in Neonates using Capillary Blood Samples

1.2 Protocol Number: GCA-PRO-2021-003-01

1.3 Date: October 14, 2022

1.4 Revision Status

Date	Revision History
30Jun2022	Initial Release version
14Oct2022	1. Amendment 1 Sections 3.0, 8.2, and 10.1.1: Changed "up to 150 subjects may be enrolled to obtain the required number of samples" to "up to 200 subjects may be enrolled to obtain the required number of samples." Section 13.1.2: Changed "meter results will be 2*120 = 240" to "meter results will be at least 2*120 = 240." Section 13.10: Added "or valid" to the following statements: "Samples with no associated or valid hematocrit value." "Samples with no associated or valid Cobas 6000 value." Appendix D: Added "Ensure the tube setting on the HemataStat II™ is set to 0.5 mm ID (inner diameter)."

2.0 Contact Information

2.1 Sponsor : Ascensia Diabetes Care
100 Summit Lake Drive
Valhalla, NY, 10595

Clinical Trial Manager contact:

[redacted]

2.2 Principal Investigator (PI): Dennis Dietzen, PhD

2.2.1 Name, address, emergency contact details: St. Louis Children's Hospital
1 Children's Place
St. Louis, MO 63110
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2.2.2 Professional position, roles, responsibilities and qualifications:

Professor of Pathology & Immunology, and Pediatrics, Washington University
Medical Director, Laboratory Services, St. Louis Children's Hospital
Medical Director, Laboratory Services, Children's Specialty Care Center, St. Louis
PhD, Biochemistry and Molecular Biology, Indiana University School of Medicine

2.3 Name and address of the investigation site: Site address is the same as in 2.2.1.

Business address of the site: Washington University
One Brookings Drive
Campus Box 1054
St. Louis, MO 63130

2.4 Name(s) and address(es) of other institutions involved: Not Applicable

2.5 Description of study financing and the agreement between the sponsor/site.

Separate document: Clinical Trial Agreement between Ascensia Diabetes Care and Washington University, St. Louis.

3.0 Synopsis of the Clinical Study

Design Type:	Open Label, prospective, single arm study
Investigational Devices:	CONTOUR NEXT ® Blood Glucose Monitoring System (BGMS) CONTOUR PLUS ELITE® Blood Glucose Monitoring System
Trial objective	The purpose of this study is to extend the intended use of two BGMSs to include testing of neonatal blood by Health Care Professionals in a clinical setting for the quantitative measurement of glucose levels in neonates. This trial will evaluate the performance of both the CONTOUR NEXT BGMS and CONTOUR PLUS ELITE BGMS using blood from neonates within a hospital ward, e.g. routine/newborn nurseries, Special Care Nurseries, Neonatal Intensive Care Unit (NICU). The investigational BGMSs will be tested by a Point-of-Care operator using residual heel-stick capillary blood samples from neonates who underwent routine prescribed testing.
Reference Analyzer	Cobas® 6000
Sample size:	A total of 120 blood samples tested in duplicate with N=240 evaluable results are required for this study. Therefore, at least 120 subjects will be enrolled. Up to 200 subjects may be enrolled to obtain the required number of samples. A sub-group of at least 5 capillary whole blood samples will be tested in neonates who are less than 24 hours of age. A sub-group of at least 5 capillary whole blood samples will be tested in neonates from the NICU.
Inclusion and Exclusion criteria:	**Inclusion Criteria** • Residual capillary (heel-stick) blood samples collected from neonates (less than 28 days of age) after birth as part of prescribed testing. • Sample blood volume must be sufficient to complete investigational testing in addition to routine prescribed clinical laboratory testing. **Exclusion Criteria** • Samples from subjects who are ≥ 28 days of age. • Samples from subjects who have previously been enrolled into this study.

Objectives and Endpoints:	The primary objective of the study is to evaluate the performance of CONTOUR NEXT and CONTOUR PLUS ELITE BGMSs with residual neonatal blood samples. The performance of the BGMSs will be analyzed according to the following objectives: Primary Objective: • At least 95% of all blood glucose results shall fall within ±12.5% of reference values (laboratory method) for glucose concentration ≥100 mg/dL (5.55 mmol/L) and within ±12 mg/dL (±0.67 mmol/L) at glucose concentrations <100 mg/dL (5.55 mmol/L). • At least 98% of values shall be within ±20% of reference values (laboratory method) for glucose concentration ≥75 mg/dL (4.16 mmol/L) and within ±15 mg/dL(±0.83 mmol/L) at glucose concentrations < 75 mg/dL (4.16 mmol/L).
Number of study sites	1 site
Proposed start date	July 2022
Study Duration	The study duration is expected to be approximately 4 months. The duration of each subject's participation is not applicable because the study uses residual samples.

4.0 Identification and description of the investigational device

4.1 Name of the investigational device:

- CONTOUR NEXT blood glucose monitoring system (Meter, CONTOUR NEXT Test Strips, Control solutions)
- CONTOUR PLUS ELITE blood glucose monitoring system (Meter, CONTOUR PLUS Test Strips, Control solutions)

4.2 Intended purpose of investigational devices

4.2.1 The CONTOUR NEXT and CONTOUR PLUS ELITE blood glucose monitoring systems (BGMS) are investigational BGMSs comprised of the blood glucose meter, the compatible test strips, and control solutions. They are automated systems intended for the quantitative measurement of glucose in fresh capillary whole blood drawn from the fingertip or palm, arterial blood, and venous blood. Its use in this trial is for the quantitative measurement of glucose levels in neonates from fresh capillary whole blood drawn from the heel.

4.2.2 The system is intended to be used for self-testing by lay persons with diabetes and for near-patient testing by Health Care Professionals (HCP) to monitor the effectiveness of diabetes control.

4.2.3 The BGMS can only be used for monitoring blood glucose levels and is not for diagnosis or screening of diabetes. The system is intended for *in vitro* diagnostic use only.

4.3 Ascensia Diabetes Care (ADC) is the manufacturer of the device.

4.4 Traceability of the devices is achieved by serial numbers on the meters and lot numbers of the test strips and controls.

4.5 The population for which the device is intended in this study is residual blood sampled from neonates in a hospital setting.

4.6 No contact between the devices and the patients is required since all testing will be performed on blood sampled from a tube.

4.7 The technical and functional features of the investigational devices, CONTOUR NEXT and CONTOUR PLUS ELITE BGMSs, can be found in the User Guides (UG) in Attachments 1 and 2.

4.8 The instructions for use for the devices are found in the UGs (Attachments 1 and 2).

4.9 Training and experience required for use of the device is Good Clinical Practice (GCP) training, and laboratory experience. The study staff will be provided specific device training as part of the Site Initiation Visit (SIV) by the sponsor.

5.0 Justification for the Design of the Clinical Study

Hypoglycemia is the most common metabolic disturbance occurring in the neonatal period, which can lead to neonatal morbidity and developmental sequelae. Screening at-risk infants and the management of low blood glucose levels in the first hours to days of life is a frequent issue in the care of newborn infant. Transitional neonatal hypoglycemia usually resolves within 2 or 3 days of age. Severe prolonged neonatal hypoglycemia can cause seizures, brain damage, and neurodevelopmental impairment. Signs of neonatal hypoglycemia are non-specific, and babies with hypoglycemia are frequently asymptomatic. Therefore, it is common to screen babies considered at high risk for neonatal hypoglycemia with repeated blood glucose measurements. Usually, plasma or serum samples are used for routine blood glucose estimation in a hospital laboratory. However, such an approach using a laboratory-based testing method is not practical in acute situations due to the delayed turnaround time. Therefore, BGMS are frequently used for the bedside estimation of blood glucose levels. Rapid measurement time, smaller volume of required blood samples, and enhanced usability are the main benefits of using BGMS compared with laboratory-based testing. Most BGMS that are currently used are initially developed for monitoring blood glucose levels in adult patients with diabetes. Neonatal blood differs from adult blood in two major aspects—it has lower concentrations of blood glucose and a wider range of hematocrit levels (Adamkin 2011; BAPM 2017; Harris et al 2012; Lucas et al 1988; Movalia and Ogino 2006; Nuntnarumit et al 2011; Roth-Kleiner et al 2010; Rozance 2006).

The CONTOUR NEXT and CONTOUR PLUS ELITE BGMSs are investigational BGMSs comprised of the blood glucose meter, the compatible test strips, and control solutions. They are automated systems intended for the quantitative measurement of glucose in neonatal blood, venous blood, fresh capillary whole blood drawn from the fingertip or palm. The system is intended to be used for self-testing by lay persons with diabetes and for near-patient testing by HCPs to monitor the effectiveness of diabetes control. Its use in this trial is for the quantitative measurement of glucose levels in neonates from fresh capillary whole blood drawn from the heel by HCPs in a clinical setting.

This investigational clinical trial will evaluate the performance of two BGMSs, CONTOUR NEXT BGMS and CONTOUR PLUS ELITE BGMSs, in neonates within a hospital ward, e.g. routine/newborn nurseries, Special Care Nurseries (SCN), Neonatal Intensive Care Units (NICU). The BGMS will be used by a POC operator in a clinical setting using residual heel-stick capillary blood samples from neonates who underwent routine prescribed testing. The residual blood no longer needed for clinical purposes will be used for this study.

6.0 Risks and benefits of the investigational device and clinical investigation

Risks

This is a low risk study. Residual blood samples will ONLY be tested for the study if the neonate is having prescribed blood tests done as ordered by their physician. Therefore, there will be no additional blood samples collected for this study. All testing procedures with the investigational device will be perfomed by the study staff in a laboratory setting and at no point will the neontate come in contact with the Investigational device or any other study-related material. There is no discomfort to the neonate as only residual blood will be collected.

There are no risks to patients associated with this study except for the potential for loss of confidentiality. Measures will be taken to minimize this risk by de-identifying study samples. Without the identification list that is exclusively stored at the site, connection between personal data and study data is not possible.

Benefits

There are no direct benefits to the subject (neonate) for donation of residual blood samples for this study except to contribute to a study that provides information on the performance of two BGMSs when measuring glucose in capillary blood by HCPs within a clinical setting. Subjects will not receive compensation.

There are no anticipated adverse device effects.

7.0 Objectives and Hypotheses

The primary objective of the study is to evaluate the performance of CONTOUR NEXT and CONTOUR PLUS ELITE BGMSs with residual heel-stick capillary blood samples from neonates, i.e. babies who are less than 28 days old. The performance of the BGMS will be analyzed according to the following objectives:

7.1 **Primary Objective**: The accuracy criteria below are taken from CLSI. *Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities; Approved Guideline – Third Edition*. CLSI document POCT12-A3. Wayne, PA: Clinical and Laboratory Standards Institute; 2013.

7.1.1 At least 95% of all blood glucose results shall fall within ±12.5% of reference values (laboratory method) for glucose concentration ≥100 mg/dL (5.55 mmol/L) and within ±12 mg/dL (±0.67 mmol/L) at glucose concentrations <100 mg/dL (5.55 mmol/L).

Note: Satisfying Criterion 7.1.1 would also satisfy the ISO 15917:2013 criteria of obtaining the ±15% of reference values (laboratory method) for glucose concentration ≥100 mg/dL (5.55 mmol/L) and within ±15 mg/dL (±0.83 mmol/L) at glucose concentrations <100 mg/dL (5.55 mmol/L).

7.1.2 At least 98% of values shall be within ±20% of reference values (laboratory method) for glucose concentration ≥75 mg/dL (4.16 mmol/L) and within ±15 mg/dL (±0.83 mmol/L) at glucose concentrations < 75 mg/dL (4.16 mmol/L).

7.2 Other Objectives:

- Evaluate the performance of both BGMSs for neonates who are <24 hours old. Compute differences between BGMS and laboratory blood glucose measurements and plot them against hematocrit results.
- Evaluate the performance of both BGMSs with blood samples from babies in the NICU.
- Compute differences between BGMS and laboratory blood glucose measurements and plot them against bilirubin results, for those subjects where bilirubin measurements were recorded (when available).

8.0 Clinical Study Design

8.1 This is an open label, prospective, single arm study. The results of the study devices will be compared to the laboratory analyzer results from the same blood sample.

8.2 For each BGMS, 120 evaluable samples (N=240 evaluable results due to duplicate testing) are required. Therefore at least 120 subjects will be enrolled. Up to 200 subjects may be enrolled to obtain the required number of samples.

8.3 Randomization:

8.3.1 Since two BGMSs will be tested in the study, the order of testing the study devices will be randomized.

8.3.2 Three strip lots (per BGMS) will be tested, with each sample tested with one lot. The strip lots will be randomized.

8.4 The results from these two BGMSs will not be compared to each other.

8.5 The study design follows CLSI- POCT12-A3:2013 and ISO 20916:2019(E) to ensure it is scientifically robust and valid.

8.6 Subjects with non-evaluable data will be replaced as needed to obtain N=120 samples, and N= 240 results (duplicate results) for each BGMS.

9.0 Investigational device(s) and comparator(s)

9.1 Materials and Methods

9.1.1 Resources Supplied by Investigator - Staffing

- Principal Investigator / and, if applicable, Sub-Investigators
- HCP to collect blood samples
- Laboratory professionals to perform meter testing, hematocrit, and laboratory analyzer testing

9.1.2 Resources Supplied by Investigator - Other

- Hospital IRB and/or Central IRB approval of the protocol.
- Facility with adequate laboratory resources for conducting all tests (including blood glucose laboratory analyzer, hematocrit measurement instrument).
- Facility with adequate neonatal population for at least 120 study-appropriate samples within the desired course of the trial.
- Cobas® 6000 (Roche Diagnostics Corp., Indianapolis, IN) Laboratory Analyzer, to measure glucose in plasma.
- Print-outs of the Cobas 6000 results for Quality Control (QC) checks during study days.

9.1.3 Resources Supplied by Ascensia - Materials

- Protocol and sample Case Report Forms (CRF)
- CONTOUR NEXT® meters
- CONTOUR NEXT® strips (3 lots) with inserts
- CONTOUR NEXT® UGs

- CONTOUR PLUS ELITE® meters
- CONTOUR PLUS® strips (3 lots) with inserts
- CONTOUR PLUS ELITE® UGs
- CONTOUR NEXT® and CONTOUR PLUS® Low, Normal and High Control solutions with inserts
- Hematocrit instrument and testing supplies
- Thermometer/hygrometers for measuring environmental conditions at the meter testing location, if needed. The site may use its calibrated measuring devices with approval of ADC.
- Disinfectant (see Appendix A for procedure and detail)
- Serum controls for the laboratory glucose analyzer
- Atomic clock(s)

9.2 Note that the subjects will not be exposed to the study devices since residual blood samples will be collected in a tube and used for all study procedures.

9.3 All meters will have Bluetooth® ON.

9.4 The meters, test strips, and CONTOUR NEXT and PLUS control solutions must be stored at 9-30C. See Appendix C for serum control storage.

10.0 Subjects

10.1 Recruitment and Enrollment

10.1.1 A total of at least 120 blood samples with evaluable results (N=240) are required for this study. Up to 200 subjects may be enrolled into the study to obtain the required number of samples. See section 13.10 for the definition of evaluability.

10.1.2 The subject population will consist of neonates from hospital wards (e.g. routine/newborn nurseries, SCN, NICU) of the clinical investigational site.

10.1.3 There will be a sub-group of at least 5 samples collected from neonates who are less than 24 hours of age.

10.1.4 There will be a sub-group of at least 5 samples collected from neonates from the NICU.

10.1.5 The samples in these two sub-groups are permitted to overlap.

10.1.6 The study staff will document subject demographics, including age and gender.

10.1.7 Unused residual blood samples collected for study testing procedures will be discarded according to hospital Laboratory Safety Guidance (Occupational Safety and Health Administration) procedures.

10.2 Inclusion Criteria

10.2.1 Residual capillary (heel-stick) blood samples from neonates (less than 28 days of age) after birth as part of prescribed testing.

10.2.2 Sample blood volume must be sufficient to complete investigational testing in addition to routine prescribed clinical laboratory testing.

10.3 Exclusion Criteria

10.3.1 Samples from subjects who are ≥ 28 days of age.

10.3.2 Samples from subjects who have previously been enrolled into this study.

10.4 Study Duration

10.4.1 The total expected duration to complete the clinical investigation is ~4 months.

10.4.2 The expected duration of each subject's participation is not applicable since there is no direct subject participation. Only residual blood samples from subjects will be tested per the study procedures only on the day of sample collection.

11.0 Procedures

11.1 Summary

Laboratory professionals will test the glucose concentration of residual capillary whole blood samples, collected (into a tube) from neonatal heel-sticks only, using the CONTOUR NEXT and CONTOUR PLUS ELITE BGMSs. The investigational site will enroll neonates from hospital wards (e,g, routine/newborn nurseries, SCN, NICU). For subject safety and ethical reasons, only those neonates already scheduled to have blood samples obtained for prescribed testing (by the hospital staff), will be enrolled into this study. No neonate will have heel-stick blood collected solely for the purpose of this study.

A minimum of 10 capillary whole blood samples (from residual neonatal heel-stick) will be tested in duplicate on both BGMSs. A sub-group of at least 5 of these blood samples will be from neonates who are less than 24 hours of age. A sub-group of at least 5 blood samples will be from neonates in the NICU. These two sub-groups' samples are permitted to overlap.

Up to 50uL of whole blood will be removed from the subject's sample tube, and will be used for completing a total of 4 tests using both BGMSs (two tests with CONTOUR NEXT BGMS and two tests with CONTOUR PLUS ELITE BGMS), and a hematocrit measurement. Each subject sample will be tested using both BGMS as per the randomization schedule. After completion of the BGMS testing, each meter will be cleaned and disinfected as per the procedures in Appendix A.

The site staff will use their Laboratory Glucose Analyzer (approved by the Sponsor) for the laboratory assessment of blood glucose samples tested in duplicate as part of prescribed testing of the same sample. The laboratory duplicate results will be averaged. In cases where the prescribed test for the sample is a bilirubin analysis, the results of this test will be recorded as part of the study data.

During the study, three test strip lots will be used for each BGMS. The test strip lots will be arbitrarily designated as green, blue, or red to easily identify the bottles during the study. See Table 1 for the description of test strip distribution during the study. Blood samples will be assigned to one of three test strip lots. The assignment will be made in a rotating order following the random order in which samples are received. For each sample, the order of testing each of the two BGMSs will also be randomized.

Table 1. Strip Lot Assignments Per Meter Type

Meter System & Test Strips	**Green Lot**	**Red Lot**	**Blue Lot**
CONTOUR NEXT Meter (CONTOUR NEXT Test Strips)	~40 Samples ~80 tests	~40 Samples ~80 tests	~40 Samples ~80 tests
CONTOUR PLUS ELITE Meter (CONTOUR PLUS Test Strips)	~40 Samples ~80 tests	~40 Samples ~80 tests	~40 Samples ~80 tests

11.2 Study Staff Training

The site study staff will be given copies of the protocol and meter instructional material (UG). They will participate in a training session conducted by the Ascensia Study team or designee. The training will be documented, and the following will be reviewed:

11.2.1 Protocol & CRFs

11.2.2 Meter Instructions for Use (UG)

11.2.3 Meter control solution testing

11.2.4 Error messages and troubleshooting

11.2.5 GCP

11.2.6 Practice using the CONTOUR NEXT and CONTOUR PLUS ELITE BGMSs

11.2.7 Practice preparing and reading hematocrit samples

11.3 Meter Control Solution Testing

Control testing on the study BGMS will occur after they arrive at the site and before the trial starts.

11.3.1 The site staff will equally distribute (approximately) the strip lots for control testing.

11.3.2 The site staff will perform 3 control tests (one each of low, normal, and high) on each BGMS assigned for the study.

11.3.3 Results will be recorded and compared to the control ranges listed on the test strip bottle.

11.3.4 If results are out of range, troubleshooting will be performed (see UG), and the test will be repeated for a total of up to 3 attempts.

11.3.5 If the meter tests are out of range after troubleshooting is complete, the meter will be removed from the study, and the Ascensia Study Manager will be notified. Additionally, this will be documented on the 'Device Deficiency Reporting Form'.

11.4 Blood Glucose Testing

11.4.1 No blood will be taken from study subjects solely for this study. Neonatal blood will be collected for prescribed testing and residual blood from the sample will be used for this study. Blood will be collected following HCP's orders by nursing/phlebotomy staff using standard heel puncture techniques. All samples will be transported to the laboratory per standard practice and submitted for prescribed clinical testing. Samples will be collected according to hospital standards and procedures and will be collected into a tube containing anticoagulants (lithium heparin).

11.4.2 Neonatal blood samples will be inspected to verify if the volume drawn was sufficient to complete both prescribed clinical and investigational testing by laboratory personnel. Samples that do not have sufficient volume to complete the required investigational testing will not be used for the clinical trial.

11.4.3 If sufficient volume is available, this is the time of enrollment. No more than the agreed amount (50 uL) of capillary whole blood will be removed from the original sample to perform blood glucose testing on two investigational BGMSsand a hematocrit measurement.

11.4.4 The collected samples will be used within a maximum of 5 h of sample collection time, and will be kept at room temperature (23 ± 5 °C) before evaluation.

11.4.5 Each blood sample for the study will be assigned an ID that is not traceable to the identity of the subject. The first digit will indicate the site ID followed by three digits indicating the sample ID as follows: X-001, X-002, X-003, and so on.

11.4.6 Strip lot (color code) will be determined via a randomization schedule provided by the Sponsor. The testing order of the meter will also be based on a randomization schedule. Note that one CONTOUR NEXT and one CONTOUR PLUS ELITE BGMS per subject will be used and the meters will be disinfected after use as per procedures listed in Appendix A.

11.4.7 For each subject, a CONTOUR NEXT BGMS, and a CONTOUR PLUS ELITE BGMS will be brought to the testing area. A test strip (as assigned for the given BGMS) will be inserted into each of the 2 meters (same color code strip lot for both meters).

11.4.8 A drop of blood will be placed on a piece of Parafilm (or other non-absorbent material) and immediately tested with the first and second meter.

11.4.9 The test strips in the two meters will then be replaced, to prepare the meters for duplicate testing.

11.4.10 A new drop of blood will be placed on the Parafilm and immediately tested with the first and second meter.

11.4.11 A hematocrit measurement (%) will also be performed. (See Section 11.6.)

11.4.12 The blood (from the same sample as used in meter testing) will be centrifuged within 10 minutes of BG testing for separation into plasma.

11.4.13 The start time of centrifugation will be recorded. Centrifugation must be performed within 10 minutes of the first-meter assay.

11.4.14 The plasma will be tested in duplicate with the laboratory analyzer within 60 minutes of the meter test. If greater than 60 minutes of the meter test, plasma samples may be refrigerated.

11.5 Errors

11.5.1 If the meter reports an error code during blood glucose testing, the instructions shown in the UG should be followed. Re-testing is recommended (per the UG). The reason for the repeated test will be documented in the comments section of the form. No more than a total of 3 attempts are allowed.

11.5.2 The study staff will record all meter error codes as appropriate for the meter tests as it occurs.

11.6 Hematocrit

11.6.1 At least one hematocrit tube, but preferably two, will be filled with the residual whole blood and then centrifuged.

11.6.2 The hematocrit will be measured from only one tube; the second tube will be collected as a backup in case the first tube is not measurable (i.e., tube spun out, broken tube, clay seal compromised, etc.). Additional details regarding hematocrit measurements are found in Appendix D.

11.7 Testing Schematic

Table 2. Sample Testing Schematic

Step	Test/action	Description
1	Sample prep	▪ Ensure collection of residual neonatal sample in collection tube containing anticogulant (lithium/heparin). ▪ Confirm sufficient blood volume to perform all testing procedures. ▪ If so, then aliquot up to 50 uL into microtube and cover.
2	Testing prep	Assign one CONTOUR NEXT meter and one CONTOUR PLUS ELITE meter to the patient sample. ▪ Follow the strip lot randomization (red, green, blue) and get the test strip bottle for the respective meter. ▪ Get a piece of parafilm. ▪ For steps 3 and 4, follow meter test order per randomization schedule.
3	Meter Test 1	▪ Put a test strip into each meter. ▪ Immediately place 1 drop of blood on the parafilm and test with both meters. Record results. ▪ In case of error, may repeat 2 more times with a new blood drop. ▪ Record time of successful meter tests.
4	Meter Test 2	▪ Replace test strips, and place new blood drop on parafilm to repeat Step 3 for duplicate testing.
5	Hematocrit	▪ Using the blood from the same collection tube, fill up to 2 hematocrit tubes. ▪ Perform hematocrit measurement, and record results.
6	Centrifugation	▪ Centrifuge blood, and record start time. (The centrifugation start time must be within 10 min of meter tests).
7	Laboratory tests*	▪ Perform blood glucose testing of plasma sample on laboratory analyzer (Cobas) in duplicate. ▪ Record results.

* Pre-study and on-study serum control testing on Cobas: See 11.8 and Appendix C.

11.8 Accuracy and Precision of Cobas 6000

Performance of the Cobas 6000 will be tracked by two methods. The primary method will be the instrument QC check procedure regularly applied by the clinical site. In addition, serum controls will be provided by Ascensia for internal research purposes only, and will not impact the study data or data collection. See Appendix C for further details.

11.9 Bilirubin Data

Bilirubin data will be collected to assess potential interference with elevated bilirubin levels occurring in neonates. In cases where the prescribed test for the sample is a bilirubin analysis, the results of this test will be recorded as part of the study data from the hospital records.

No bilirubin test will be performed on study samples just for the purpose of this study. Thus, not all study samples may have bilirubin data.

11.10 Temperature and Humidity Logs

- The study staff will measure the temperature/humidity in the meter testing area once during the day that meter testing occurs and record the results on the appropriate log form.
- Study staff will maintain a temperature log for the storage of investigational materials including the meters, test strips, controls, and serum controls.

12.0 Monitoring Plan

12.1 A monitoring plan will be completed by the Study Manager/designee prior to the study.

12.2 The study manager or designee will conduct the SIV. The frequency of the number of monitoring visits by sponsor personnel or designee(s) will be based on the monitoring plan and will include at least 1-3 monitoring visits and a close-out visit.

12.3 Sponsor representatives may observe some study testing as part of study monitoring. This will be done under supervision of the Investigator.

12.4 Sponsor representatives will maintain subject confidentiality, and will not interfere with the rights of human subjects or safety, or bias study conduct.

13.0 Statistical Plan

13.1 Sample Size

13.1.1 The sample size requirement is based on the primary objective, section 7.0.

13.1.2 There will be a minimum of N = 120 study samples entered into the study. The meter results will be taken in duplicate, so that the total sample size of meter results will be at least 2*120 = 240.

13.1.3 With a sample size of n = 240 results, there is approximately a 95% chance that at least 228 of those results (95% of 240) will be "accurate" (errors within either ±12 mg/dL (±0.67 mmol/L) when the comparator result is < 100 mg/dL (5.55 mmol/L), or ±12.5% when the comparator result is ≥ 100 mg/dL (5.55 mmol/L) if the evaluation (meter) system has a 96.77% chance of yielding an "accurate" result.

13.1.4 Conversely, there is about a 95% chance of obtaining fewer than 228 "accurate" results if the system only has an approximately 92.03% chance of yielding an accurate result.

13.1.5 Note that each glucose result obtained with the evaluation devices will be considered either 'accurate' or 'not accurate', where accuracy depends on the particular test criterion as described in section 7.0 of this protocol.

13.2 Blood Glucose Measurements

Data analysis follows analyses and presentations described in CLSI. *Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities; Approved Guideline – Third Edition*. CLSI document POCT12-A3. Wayne, PA: Clinical and Laboratory Standards Institute; 2013.

The unit conversion formula for blood glucose is the following:

Xmmol/L = Ymg/dL / 18.016

13.3 Bland-Altman Plots

Modified Bland-Altman plots (the difference between each evaluation device results and reference results plotted against reference results) will be constructed.

13.4 Weighted Least Squares Regression

Weighted least squares regressions of meter results against comparator results will be performed. If *M* represents the meter result, and *C* the comparator result, the linear model can be expressed as:

$$\boldsymbol{M = \beta_0 + \beta_1 C + \varepsilon}$$

$$\boldsymbol{\varepsilon \sim N(0, cv * C)}$$

The parameter *cv* is the coefficient of variation, which is assumed to be constant across the glucose range. The weighting function will be:

$$\boldsymbol{w = C^{-2}}$$

This weighting function is used to account for the constant cv nature of glucose measurement (Draper and Smith, 1998).

13.5 Accuracy Analyses

13.5.1 Two sets of metrics will be calculated:

Relative (Percent) Difference (RD) for reference result ≥ threshold glucose:

$$\boldsymbol{RD = \frac{M - C}{C} 100\%}$$

where: *M* =strip/meter result and *C* =comparator or reference method result.

Difference (D) for reference result < threshold glucose:

$$\boldsymbol{D = M - C}$$

13.5.2 Primary objective:

The threshold glucose value is 100 mg/dL (5.55 mmol/L). Accuracy will be assessed using the CLSI. *Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities; Approved Guideline – Third Edition*. CLSI document POCT12-A3. Wayne, PA: Clinical and Laboratory Standards Institute; 2013.

i.e., D within ±12 mg/dL(±0.67 mmol/L) for comparator result < 100 mg/dL (5.55 mmol/L) and RD within ±12.5% for comparator result ≥ 100 mg/dL(5.55 mmol/L).

For RD, the percent of results within ±5%, ±10%, ±12.5%, ±15% and ±20% will be computed.

For *D,* the percent less than or equal to ±5 mg/dL (±0.28mmol/L), ±10 mg/dL (±0.56 mmol/L), ±12.0 mg/dL (±0.67 mmol/L), ±15 mg/dL (±0.83 mmol/L), and ±20 mg/dL (±1.11 mmol/L) will be computed.

The *RD* and *D* distribution tables will be constructed using a threshold of 100 mg/dL(5.55 mmol/L).

As discussed in section 13.1 (Sample Size), with n =240, the critical number (minimum) of accurate results is 228, which yields approximately 95% chance of satisfying the criterion if the actual probability that any result will be accurate is at least 96.77%. Symbolically, this criterion is equivalent to testing the hypothesis:

H_0 : *Prob{accurate}*<96.77% versus the alternative:

H_1 : *Prob{accurate }* ≥ 96.77%

This test has a power of about 95%, with n =240, to reject H_0 if the actual probability of obtaining an accurate result is 96.77%. Conversely, there is about a 95% chance that the null will NOT be rejected if the actual probability that a result with the evaluation device would satisfy this definition of accuracy is only about 92.03%.

13.5.3 The second part of the primary objective

The second part of the primary objective states that at least 98% of the n = 240 results must fall within ±15 mg/dL(±0.83 mmol/L) of the comparator result (comparator < 75 mg/dL/4.16 mmol/L)) or ±20% of the comparator result (comparator ≥ 75 mg/dL/4.16 mmol/L). Thus, with n = 240, there must be at least 236 BGMS results satisfying this requirement. This is equivalent to testing the hypotheses:

H_0: *Prob{accurate}*<98.33% versus the alternative:

H_1: *Prob{accurate }* ≥ 98.33%

There is approximately a 95% chance of rejecting H_0 in favor of H_1 if the actual probability that a meter measurement would satisfy the ±15mg/dL or 20% is 98.33%. Conversely, there is about a 95% chance that the null will NOT be rejected if the actual probability that a result with the evaluation device would satisfy this definition of accuracy is only about 96.23%. It is possible

that the sample size after the study is completed may not be exactly 240. The critical values will be approximately 95% or 98% of results (first and second parts of primary objective, respectively), and the associated hypotheses will be adjusted to reflect the change while maintaining no more than a 95% chance of rejecting the null hypotheses.

13.6 Neonates < 24 hrs. old and Neonates in NICU – Other Objectives

In addition to the neonates less than 28 days of age, additional analyses of data from neonatal subjects ≤ 24 hrs. old and neonates in NICU will be performed.

13.6.1 Specifically, differences in BG results between BGMS and reference laboratory instrument will be plotted against the laboratory instrument results (modified Bland-Altman plot).

13.6.2 There must be at least 5 subjects <24 hrs. old and 5 subjects in NICU enrolled to perform this analysis. These groups may have any or all subjects in common.

13.7 Hematocrit Analysis – Other Objectives

13.7.1 Hematocrit will be measured for each subject. Mean, median, minimum, maximum, and standard deviation, will be computed for hematocrit determinations.

13.7.2 The effect of hematocrit on meter results will be presented via regression of differences between the meter and laboratory BG measurements against hematocrit.

13.8 Bilirubin Analysis – Other Objectives

For neonates who would have bilirubin results, regression analysis will be used to assess the effects of bilirubin on the difference between meter and laboratory reference method blood glucose measurements.

There must be at least 3 subjects enrolled with bilirubin recorded to perform this analysis. If fewer than 3, then the results will be reported in a table.

13.9 Temperature and Humidity

Mean, median, standard deviation, minimum and maximum room temperature, and humidity will be computed.

13.10 Data Evaluability

Blood glucose data will be considered not evaluable for the following reasons:

- Samples with no associated or valid hematocrit value.
- Samples with no associated or valid Cobas 6000 value.

- Failure to begin to separate the plasma from the red cells within 10 minutes of obtaining the first meter test.
- The collected samples exceed a maximum of 5 h of sample withdrawal time, and will be kept at room temperature (23 ± 5 °C) before evaluation.
- For a given sample, the meter is missing a replicate.
- Results of the glucose analyzer blood sample are not within ±4% of each other, 100* (Rep2-Rep1)/Rep1, or ±4mg/dL (0.22mmol/L) of each other (Rep2-Rep1) if the average falls below 100mg/dL (5.5mmol/L).

14.0 Data Management

14.1 A unique number will identify each subject/sample. The unique number will be entered on the CRFs. The site will create a procedure to de-identify subjects from samples so that the staff members documenting subject names will not have access to sample results and the staff members testing the samples will not have access to subject names. A master list of subject names, with their subject IDs, will be kept by the Investigator at the study site until the study has been closed.

14.2 Study personnel will complete and sign all appropriate forms in compliance with GCP. CRFs should be completed legibly, in black or blue ink. If it is necessary to make corrections, a single line should be drawn through the original entry, the new entry is written in, and the correction initialed and dated by the individual correcting the CRF.

14.3 Study data will be primarily collected through an electronic data capture (EDC) system used by Ascensia. The data will be recorded on forms by designated study staff that will serve as source documents and entered into the EDC system. All source forms will be retained by the site.

14.4 In addition to data collection, the EDC system will be used for data cleaning as well as monitoring operations. Site users will be trained on this system before the start of the study and their access to EDC system will be contingent upon successful completion of training requirements.

15.0 Amendments to the Protocol

15.1 Any change to this protocol requires a protocol amendment (or revision) unless the IRB agrees to an administrative change (for minor changes).

15.2 Determine the justification(s) for the protocol revision, impact of the changes on subject safety, the clinical or statistical significance of the data, impact of changes on the clinical investigators and their staff, and impact on timely completion of the clinical trial.

15.3 Determine if the revision meets the criteria of a Substantial Amendment.

15.4 Substantial Amendments

15.4.1 Substantial amendments to the conduct of the clinical trial may arise from changes to the protocol or from new information relating to the scientific documents in support of the trial. Substantial changes require notification to the overseeing IRB before implementation. For any questions on whether a change would be considered substantial, consult with the respective IRB.

15.4.2 Amendments to the trial are regarded as "substantial" where they are likely to have a significant impact on the:

- Safety, health or rights or physical or mental integrity of the subjects,
- Scientific value of the trial including robustness or reliability of the data generated by the study,
- Conduct or management of the trial,
- Quality or safety of any investigational product used in the trial.

15.4.3 An amendment is only to be regarded as "substantial" when one or more of the above criteria are met but the IRB may have additional requirements that shall be considered.

15.4.4 Examples of substantial amendments may include (but are not limited to):

- New tests
- Increase in the number of visits due to safety issues associated with the ongoing trial
- Change of inclusion/exclusion criteria
- Change in the number of participants
- Updated PI
- Informed Consent Form (ICF)
- Updated investigator brochure with relevant safety information
- Change in the management of the study
- Temporary halt to the study or restart of the trial after a temporary halt

15.5 Once justified, the protocol changes can be drafted and the changes documented in the Revision History. The changes are to be incorporated directly into the body of the protocol document itself (revised protocol).

15.6 Once the drafted revision is approved internally and by the PI, it will be submitted to the IRB, where required. All subsequent, IRB-approved, revised protocols would be numbered sequentially.

15.7 The amended protocol will be approved by the original approvers, including the sponsor representatives or designee and the PI.

15.8 The sponsor must assure that each investigator (and his/her staff) is following the most recent IRB approved amendment or revised protocol as the study proceeds. The sponsor must ensure that the study monitors, investigator(s) and study staff have been trained with respect to any recent protocol amendments and revisions prior to implementation.

16.0 Deviations from the clinical protocol

16.1 A protocol deviation is any alteration or modification to the procedures described in the protocol. The investigator is not allowed to deviate from the protocol. The only exceptions to this are:

16.1.1 The deviation is necessary to protect the subject's rights, safety and well-being, or the scientific integrity of the clinical investigation without prior approval of the sponsor and IRB.

16.1.2 Prospective deviations that broaden the scope of the protocol (waivers of the protocol) are prohibited. Under emergency circumstances, these instances can proceed.

16.2 Procedures for recording, reporting and analyzing protocol deviations will include recording the deviation on a Protocol Deviation log form to be supplied by the Sponsor.

17.0 Device Accountability

17.1 Description of the procedures for the accountability of investigational devices as follows:

17.1.1 Access to investigational devices shall be controlled and the investigational devices shall be used only in the clinical investigation and according to the protocol.

17.1.2 The sponsor shall keep records to document the physical location of all investigational devices from shipment of investigational devices to the investigation sites until return or disposal.

17.1.3 Accountability: The PI or a delegate shall keep records documenting the receipt, use, return and disposal of the investigational devices, (including unused, expired or malfunctioning devices), which shall include:

- Date of receipt
- Identification of each device (serial number of meter or strip lot)
- The expiry date, if applicable
- Date(s) of use
- Subject number

- Date of return of unused, expired or malfunctioning investigational devices, if applicable

18.0 Regulatory

Ascensia (sponsor) has determined that according to IDE requirements of 21 CFR 812.2(c), this IVD study meets all conditions for IDE exemption and therefore submission of an IDE application to FDA is not required. Determination is based on the following:

The Contour Next and Contour Plus Elite Glucose Monitoring Systems (IVDs);

- are labeled in accordance with 21 CFR 809.10(c)
- are non-invasive
- do not require an invasive sampling procedure that presents significant risk
- do not by design or intention introduce energy into a subject
- are not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure.

18.1 IRB Approval

18.1.1 Before study initiation, an IRB must review this protocol, the ICF, and any other supporting study documents which impact subject safety. The IRB will determine if the Informed Consent is required according to local regulations and requirements or if consent is not required (ISO 20916:2019(E)).

18.1.2 The investigational site may not begin the study until the IRB has given its written and dated approval via a letter that identifies the version/date of the protocol and ICF, if applicable, or a notification that consent is not required.

18.1.3 A copy of the IRB approval letter must be provided to the Investigator and to sponsor prior to the SIV.

18.2 Study Documentation Procedures

18.2.1 The investigator will keep study records for a minimum of three years. Alternatively, other arrangements may be made with Ascensia for study document storage.

18.2.2 Study Investigational Devices will be labeled "For Investigational Use only. The performance characteristics of this product have not been established" for this study.

18.2.3 After study completion, all BGMSs will be disinfected before they are returned to Ascensia. A decontamination log will be completed for the used meters. The meters, unused strip vials, control solutions, and meter UGs will be accounted for at the site and returned to the Ascensia Study Manager upon completion of the trial.

18.3 Investigator's Report of Study Closure

18.3.1 Sponsor representatives will notify the site that the study is closed. The study will be considered closed when the data has been locked for data analysis.

18.3.2 The Investigator or designee will submit a report summarizing subject disposition and other study details, as appropriate, to the Study Manager and the IRB. This report will be completed within 3 months of the study closure date.

18.3.3 In addition, the Study Manager, or designee, will report the completion of the study to the IRB within 6 months of study closure.

19.0 Statements of compliance

19.1 This clinical investigation will be conducted in compliance with applicable requirements:

19.1.1 Protection of Human Subjects regulations in 21 CFR part 50.

19.1.2 IRB regulations in 21 CFR part 56.

19.1.3 Investigational Device Exemptions regulations in 21 CFR part 812.

19.1.4 Declaration of Helsinki.

19.1.5 CLSI. *Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities; Approved Guideline – Third Edition*. CLSI document POCT12-A3. Wayne, PA: Clinical and Laboratory Standards Institute; 2013.

19.1.6 International Standards: ISO20916:2019(E) – In vitro diagnostic medical devices – Clinical performance studies using specimens from human subjects – Good Study Practice and In Vitro Diagnostic Regulation 2017/746 Annex XIII, Part 2.

19.1.7 British Standard BS EN 13612:2002, "Performance evaluation of in vitro diagnostic medical devices."

19.2 The clinical study shall not begin until the required approval from the IRB or regulatory authority have been obtained.

19.3 Clinical trial insurance shall be provided as appropriate.

20.0 Informed Consent Process

The IRB will determine if the Informed Consent is required according to local regulations and requirements for use of residual blood samples for this study.

The following will only apply if Informed Consent is required by the IRB. If the IRB determines that consent is not required, this section will not apply.

20.1 Since the subject is a neonate, the subject's parent/guardian - Legally Authorized Representative (LAR) - will complete the informed consent process before performing any study procedures.

20.2 The LAR will be informed about the study objectives, investigational devices, study procedures, expected study duration, and risks of study participation.

20.3 Study participation is voluntary. The information will be given in written form (ICF) as well as verbally by the investigator.

20.4 The subject's LAR will sign and date the ICF. The ICF will then be dated and signed by the investigator.

20.5 The investigator will retain the original of the documents. The subject's LAR will receive a copy of the ICF and if applicable, insurance terms and conditions.

21.0 Adverse events and adverse device effects

The procedures to be performed under this protocol are considered to be of low risk since the glucose testing procedures will use residual samples which are remnants of neonatal blood collected as part of routine prescribed practice.

Due to the nature of this study, no adverse events (AE) are expected as per the following:

21.1 This study only includes residual ('left-over') samples of blood collected by standard, approved technique for prescribed tests.

21.2 No neonate will be exposed to any of the BGMS at any point; all study activities will be conducted in the institution's lab.

21.3 The samples will be de-identified in order to protect the confidentiality of the subjects. Confidentiality issues are mitigated due to the fact that the nursing staff overseeing the babies will not be informed of any study results, and samples will be de-identified prior to being given to the laboratory staff who perform study testing

21.4 Regardless of the above, any experience that the investigator considers to be an AE will be documented and reported immediately to Ascensia.

21.5 <u>Definition of Adverse Events</u>

21.5.1 <u>Adverse Event (AE):</u> Adverse event refers to any untoward medical occurrence, inappropriate patient management decision, unintended disease or injury, or untoward clinical signs in subjects, users, or other persons, with any connection to to study related activities, whether or not related to the IVD medical device under investigation.

21.5.2 Adverse Device Effect (ADE or Adverse Effect): Any AE resulting from insufficient or inadequate instructions for use, installation, operation, or any malfunction of the IVD medical Device under investigation. This includes any AE resulting from use error or from unintentional misuse of the device.

21.5.3 Serious Adverse Event (SAE): Refers to an AE that led to any of the following:

a) death,
b) serious deterioration in the health of the subject, users or other persons as defined by one or more of the following:
   1) a life-threatening illness or injury, or
   2) a permanent impairment of a body structure or a body function including chronic diseases, or
   3) in-patient or prolonged hospitalisation, or
   4) medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function,
c) fetal distress, fetal death, or a congenital abnormality or birth defect, including physical or mental impairment.

21.5.4 Serious Adverse Device Effect (SADE): Adverse device effect that has resulted in any of the consequences of an SAE.

21.6 Adverse Event Classification

Table 3. Classification of Adverse Events (ISO 20916: 2019)

<table>
<tr><th>Adverse Events</th><th>Non -device related</th><th colspan="2">Device related</th></tr>
<tr><td></td><td>Applies to :
• Interventional Studies
• Sampling procedure causes direct harm to the subject</td><td colspan="2">Applies to :
• Interventional Studies: inaccurate test result leads to indirect harm to the subject.
• Sampling procedure causes direct harm to the subject</td></tr>
<tr><td>Non-Serious</td><td>Adverse event (includes all categories)</td><td colspan="2">Adverse device effect</td></tr>
<tr><td rowspan="3">Serious</td><td rowspan="3">Serious Adverse event (includes all categories that are serious)</td><td colspan="2">Serious adverse device effect</td></tr>
<tr><td>Anticipated</td><td>Unanticipated</td></tr>
<tr><td>Anticipated Serious adverse device effect</td><td>Unanticipated Serious adverse device effect</td></tr>
</table>

21.7 Adverse Event Reporting

21.7.1 AEs will be documented during this study by completing the AE Form. The Investigator or designee will sign and date an AE Form for each AE that is observed.

21.7.2 AEs will be evaluated by a member of the study staff and the PI. The nature of each event and date of onset, outcome, course, maximum intensity and action taken for treatment should be established. Details of any corrective treatment should be recorded on the AE Form.

21.7.3 Investigators should follow up on the status of any AE until the event has been resolved, or until the condition has stabilized.

21.7.4 The Investigator or designee will notify the Study Manager or Study Monitor within 24 hours of any SAE that occurred during the study. Ascensia will promptly review all information relevant to the safety of the investigational device.

21.7.5 Upon the receipt of a report of an SAE by the Ascensia Study Manager or Monitor, the report will be immediately forwarded to:

[redacted]

22.0 Handling and Reporting of Device Deficiencies

22.1 Any functional problems with the investigational BGMS will be considered a device deficiency and will be documented by the study staff and reported timely to Ascensia.

22.2 The study staff should be specific about describing the problem and the sequence of events that led to it. All information will be documented on the Data Deficiency Form, including the meter type, serial number, and test strip lot.

22.3 Malfunctioning BGMs will be replaced and this will be documented for device tracking.

22.4 All device deficiencies related to the identity, quality, durability, reliability, safety or performance of an investigational medical device shall be documented throughout the clinical investigation and appropriately managed by the sponsor.

22.5 Device deficiencies that did not lead to an AE but could have led to a medical occurrence shall be reported to the sponsor without delay.

22.6 All device deficiencies are to be reviewed and documented in writing whether they could have led to a SADE.

23.0 Vulnerable population

23.1 While the samples will be taken from neonates, who are in the vulnerable population category, the procedure does not involve additional risk since the samples are residual with no additional sampling required.

23.2 If the IRB determines consent is required, then proxy consent by an LAR shall be provided to protect the rights of the subject.

24.0 Suspension/Premature termination and Subject Withdrawal Criteria

24.1 In the event the study is prematurely suspended or terminated, the sponsor shall be notified as well as the IRB.

24.2 The subject's sample may be withdrawn from the study at the discretion of the Investigator.

25.0 Results Handling

Results of the study will not be shared with subjects. There is no plan for treating or following up with subjects based on the investigational results from this study.

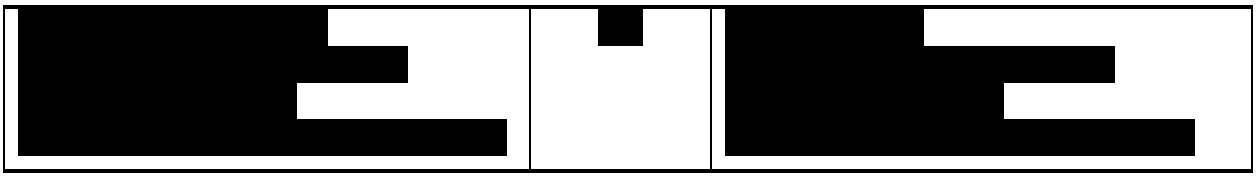
26.0 Publication policy

26.1 The results will be published in regulatory databases, Clinicaltrials.gov and EUDAMED.

26.2 In general, for publication of data, the principles of GCP and Good Scientific Practice are respected. All manuscripts, abstracts or other modes of presentation arising from the results of the study must be reviewed and approved in writing by the sponsor in advance of submission. The sponsor's intention is neither to influence nor to prevent the publication of the study results to the medical and scientific community. The review is exclusively aimed at protecting the sponsor's proprietary information existing either at the date of commencement of the study or generated during the study. Details of the publication policy and related sponsor and principal investigator responsibilities are included in the clinical investigation agreement.

27.0 Administration

All investigator and site staff communications regarding the study should be directed to the Ascensia Study Manager. If at any time questions or problems arise concerning the evaluation, please contact the Ascensia Study Manager at the telephone number listed below.



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Appendix A - Instructions for Cleaning and Disinfecting Meters

Study staff will clean and disinfect meters according to the UG instructions for HCPs.

Health Care Professionals

Health care professionals or persons using this system on multiple patients should follow the infection control procedure and the recommendations for prevention of blood-borne transmissible diseases approved by their facility.

The following disinfection solutions are recommended: 70% isopropyl alcohol, 6.0% sodium hypochlorite (full bleach), 0.6% sodium hypochlorite (diluted bleach), didecyldimethylammonium chloride (DDAC).

NOTE: Using cleaning and disinfecting solutions other than those recommended by the manufacturer could result in damage to system components. The cleaning and disinfecting directions provided should not cause any damage or degradation to the external case, buttons, or display.

CAUTION: Do not allow any solution to run into the meter through open areas, such as around the buttons or the meters test strip or data ports, such as USB port.

Blood glucose meters must be cleaned and disinfected by study staff before returning to Ascensia.

References

Protection of laboratory workers from occupationally acquired infections; approved guideline – third edition. CLSI document M29-A3. ISBN1-56238-567-4.

Rutala W, Weber D. Healthcare Infection Control Practices Advisory Committee. Guideline for disinfection and sterilization in healthcare facilities, 2008. Centers for Disease Control and Prevention.

Appendix B - Instructions for Processing of Blood for the glucose analyzer

Processing of Neonatal Blood for laboratory glucose analysis

Once collected, process the microtainer tube for laboratory glucose analysis as follows:

- Label all tubes with the subject number using a Sharpie®-like marker.
- Gently invert the microtainer tube several times to mix the anticoagulant.
- Centrifuge the whole blood immediately to separate the plasma from the red blood cells. The centrifugation start time must occur within 10 minutes of the first meter blood test. The timing of all meter testing/centrifugation will be recorded on the appropriate CRF.
- It is recommended that after centrifugation, the plasma is transferred from the microtainer tube to a small clean tube or container with a cap. Ensure the tube is labeled and the cap is secured, and proceed with the site's laboratory glucose analyzer procedures.
- The plasma will be tested in duplicate with the laboratory analyzer within 60 minutes of the meter test. If greater than 60 minutes of the meter test, plasma samples may be refrigerated.
- Insufficient (or suspected to be insufficient) samples, missing samples, and other sample issues should be recorded in the CRF and on the glucose analyzer printout, as appropriate. If a sample is hemolyzed, record it in the CRF.

Appendix C - Instructions for Tracking Accuracy and Precision of the Laboratory Glucose Analyzer

Procedure for Tracking Accuracy and Precision of Site Laboratory Analyzer

Performance of the Cobas 6000 will be assessed to ensure accuracy. Analyzer performance will be tracked by two methods: the Laboratory Analyzer QC procedure regularly applied by the clinical site, and the testing of serum controls provided by Ascensia.

The following are the procedures required for each method:

I. Laboratory Analyzer QC Procedure

The Cobas 6000 will be maintained and operated according to the instructions in the manufacturer's operating manual by the site's lab specifications/SOP previously reviewed by ADC. Before the study begins, the analyzer will be set up and the appropriate maintenance will be performed.

The site will perform glucose analyzer control tests in accordance with the site's quality control check procedures and requirements. Site staff will keep a log for the analyzer, including daily operational checks and maintenance.

II. Ascensia Serum Controls[1]

A set of three serum control levels will be provided to the investigator to document the performance of the Cobas 6000 at each BG level. These serum controls have been assayed by a method traceable to one proposed for use as a national glucose reference method.

Serum Control Testing Schedule:

- Pre-study: The controls will be assayed (singlet readings) on the Laboratory Analyzer for at least three runs prior to the assay of subject samples. The runs will occur over at least three days, if possible. The data will be sent to the Ascensia Study Manager, or designee, for review before the study begins.
- Once the study begins, serum control testing should be completed on each Analyzer on the Monday and Friday of the first week, and then on one day for each week that the study continues.
- Record all data on the CRF. One reading will be recorded for each control level (for a total of 3 readings per run).

[1] Caution: The serum glucose traceability controls are human serum-based and must be handled using universal precautions.

Proper Handling of Ascensia Serum Controls

Ascensia completed the characterization of serum controls purchased from Bio-Techne® (formerly Bionostics). During the characterization, staff observed that sample stratification during thawing can occur if the control vials are not handled judiciously. The recommended procedure is as follows.

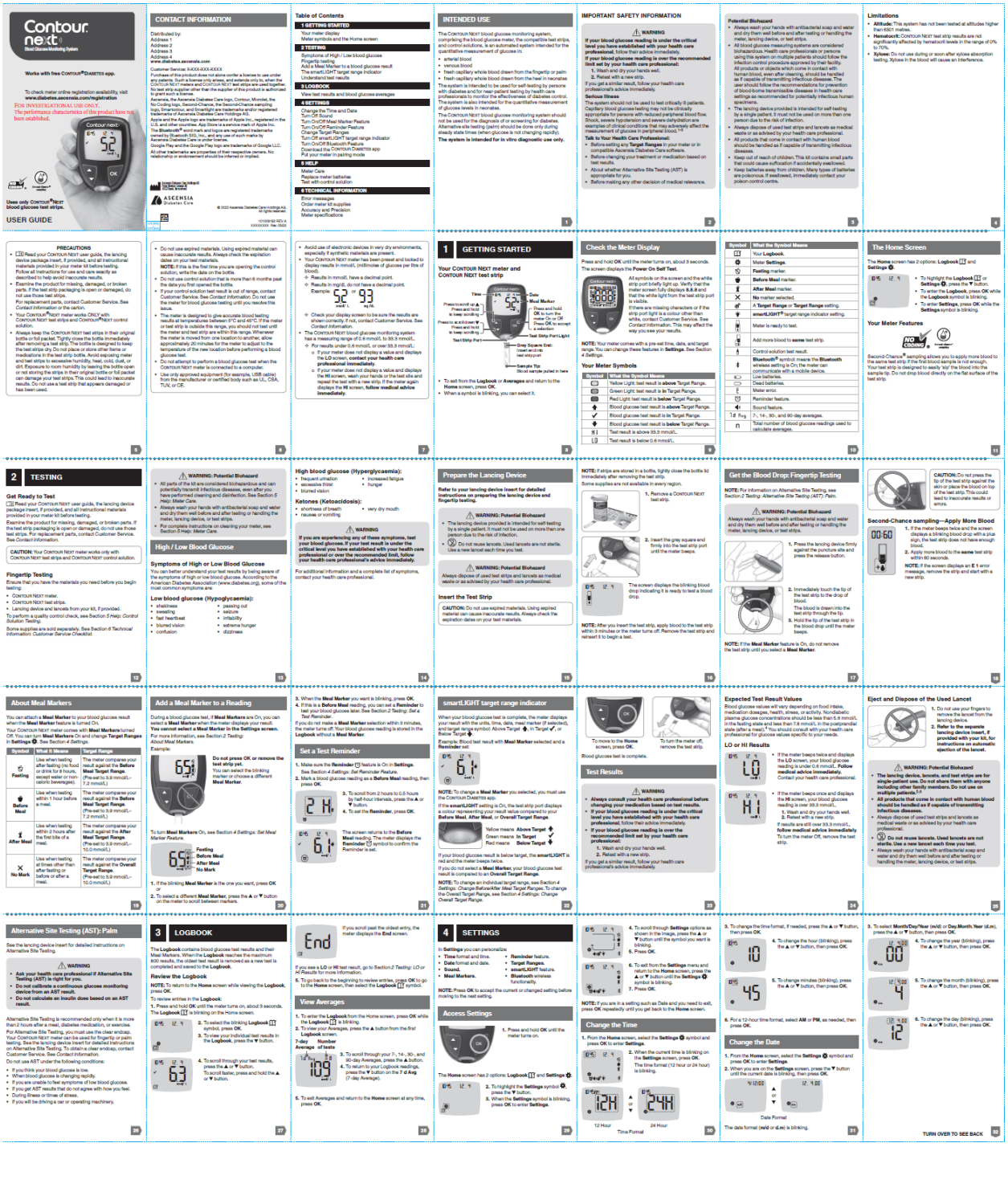
- Store the frozen controls in a -20C freezer upon arrival.
- Thaw the frozen control amber glass vials at 2-8ºC for 2-3 days in the refrigerator. Each vial holds approximately 2.0 mL.
- Before opening, mix the vials well by gently inverting them at least 10 times.
- Prepare an aliquot of each level in capped microcentrifuge tubes. Cap tightly. We prefer Fisherbrand™ Microcentrifuge 0.5mL tubes (PN 02-681-333) with O-ring seal caps (PN 02-681-358).
- Store any remaining control in the amber glass vials at 2-8ºC.
- Before running a control sample on the laboratory analyzer, mix the aliquot tubes by gently inverting them.
- At the beginning of each day, remix the amber glass vials and refill the aliquot tubes. When not in use, store the aliquots at 2-8ºC.
- The thawed control use life is two weeks. Discard all thawed control—aliquot tubes and amber glass vials—after two weeks.
- Since slow thawing for 2-3 days is recommended, it is advisable to keep an extra thawed set available for testing.

Appendix D - Instructions for Hematocrit Sample Preparation and Testing

Staff will follow the instructions in the hematocrit reader user manual.

1. At least one microhematocrit tube, but preferably two, will be filled with residual capillary blood from each subject sample. One tube will be measured, and the result recorded on the form. The second tube is a backup and will be measured only if the first tube was not adequate for measurement, or is broken.
    - Ensure the tube setting on the HemataStat II™ is set to 0.5 mm ID (inner diameter).
    - Samples collected from residual capillary blood (heel-stick) will be collected in treated micro-hematocrit tubes.
2. Place a microhematocrit tube against the surface of the blood drop.
3. Fill the microhematocrit tube about halfway. Do not over-fill. Then immediately place one of the microhematocrit tube openings in the clay sealant. Press into the clay 2-3 times to make sure enough sealant is transferred.
4. Place the sealed microhematocrit tube into the Hematastat II™ micro-centrifuge. Note: it is very important to place the microhematocrit tube in centrifuge rotor with clay side down. Balance the rotor with another hematocrit tube containing water.
5. Click run to spin for the preset 60 seconds.
6. Measure hematocrit using the Hematastat reader or other hematocrit reader approved by the sponsor.
7. Summary of Instructions for the Hematastat reader:
    - After collection and centrifugation of hematocrit, place tube in the reader slot, with clay side to the left. Press enter to read.
    - Slide the marker on the reader to the exact line where the clay and red blood cells meet. Press enter to “enter interface: sealant/RBCs.”
    - Then move the marker to the exact line where the red blood cells meet the plasma. Press enter to “enter interface: RBCs/plasma.”
    - Slide the marker to the exact line where the plasma ends. Press enter to “enter interface: plasma/air.”
    - The result in the display is the hematocrit percentage for that sample.
8. Record hematocrit result on the appropriate form.

Attachment 1 - CONTOUR NEXT User Guide



Contour next
Blood Glucose Monitoring System
Works with free CONTOUR®DIABETES app.
To check meter online registration availability visit www.diabetes.ascensia.com/registration
FOR INVESTIGATIONAL USE ONLY.
The performance characteristics of this product have not been established.
Uses only Contour®NEXT blood glucose test strips.
USER GUIDE

CONTACT INFORMATION
Distributed by:
Address 1
Address 2
Address 3
Address 4
www.diabetes.ascensia.com
Customer Service: XXXX-XXX-XXXX
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XXXXXXXX Rev. 05/22

Table of Contents

INTENDED USE
The CONTOUR®NEXT blood glucose monitoring system, comprising the blood glucose meter, the compatible test strips, and control solutions, is an automated system intended for the quantitative measurement of glucose in:
- arterial blood
- venous blood
- fresh capillary whole blood drawn from the fingertip or palm
- fresh capillary whole blood drawn from the heel in neonates

The system is intended to be used for self-testing by persons with diabetes and for near-patient testing by health care professionals to monitor the effectiveness of diabetes control. The system is also intended for the quantitative measurement of glucose levels in neonates.
The CONTOUR®NEXT blood glucose monitoring system should not be used for the diagnosis of or screening for diabetes. Alternative site testing (palm) should be done only during steady state times (when glucose is not changing rapidly).
The system is intended for in vitro diagnostic use only.

IMPORTANT SAFETY INFORMATION
⚠ WARNING
If your blood glucose reading is under the critical level you have established with your health care professional, follow their advice immediately.
If your blood glucose reading is over the recommended limit set by your health care professional:
1. Wash and dry your hands well.
2. Retest with a new strip.

If you get a similar result, follow your health care professional's advice immediately.
Serious Illness
The system should not be used to test critically ill patients. Capillary blood glucose testing may not be clinically appropriate for persons with reduced peripheral blood flow. Shock, severe hypotension and severe dehydration are examples of clinical conditions that may adversely affect the measurement of glucose in peripheral blood.[1,2]
Talk to Your Health Care Professional:
- Before setting any **Target Ranges** in your meter or in compatible Ascensia Diabetes Care software.
- Before changing your treatment or medication based on test results.
- About whether Alternative Site Testing (AST) is appropriate for you.
- Before making any other decision of medical relevance.

Potential Biohazard
- Always wash your hands with antibacterial soap and water and dry them well before and after testing or handling the meter, lancing device, or test strips.
- All blood glucose measuring systems are considered biohazardous. Health care professionals or persons using this system on multiple patients should follow the infection control procedure approved by their facility. All products or objects which come in contact with human blood, even after cleaning, should be handled as if capable of transmitting infectious diseases. The user should follow the recommendations for prevention of blood-borne transmissible diseases in health care settings as recommended for potentially infectious human specimens.
- The lancing device provided is intended for self-testing by a single patient. It must not be used on more than one person due to the risk of infection.
- Always dispose of used test strips and lancets as medical waste or as advised by your health care professional.
- All products that come in contact with human blood should be handled as if capable of transmitting infectious diseases.
- Keep out of reach of children. This kit contains small parts that could cause suffocation if accidentally swallowed.
- Keep batteries away from children. Many types of batteries are poisonous. If swallowed, immediately contact your poison control centre.

Limitations
- **Altitude:** This system has not been tested at altitudes higher than 6301 metres.
- **Hematocrit:** CONTOUR NEXT test strip results are not significantly affected by hematocrit levels in the range of 0% to 70%.
- **Xylose:** Do not use during or soon after xylose absorption testing. Xylose in the blood will cause an interference.

PRECAUTIONS
- Read your CONTOUR NEXT user guide, the lancing device package insert, if provided, and all instructional materials provided in your meter kit before testing. Follow all instructions for use and care exactly as described to help avoid inaccurate results.
- Examine the product for missing, damaged, or broken parts. If the test strip packaging is open or damaged, do not use those test strips. For replacement parts, contact Customer Service. See *Contact Information* or the carton.
- Your CONTOUR®NEXT meter works ONLY with CONTOUR NEXT test strips and CONTOUR®NEXT control solution.
- Always keep the CONTOUR NEXT test strips in their original bottle or foil packet. Tightly close the bottle immediately after removing a test strip. The bottle is designed to keep the test strips dry. Do not place or store other items or medications in the test strip bottle. Avoid exposing meter and test strips to excessive humidity, heat, cold, dust, or dirt. Exposure to room humidity by leaving the bottle open or not storing the strips in their original bottle or foil packet can damage your test strips. This could lead to inaccurate results. Do not use a test strip that appears damaged or has been used.

- Do not use expired materials. Using expired material can cause inaccurate results. Always check the expiration dates on your test materials.
NOTE: If this is the first time you are opening the control solution, write the date on the bottle.
- Do not use control solution that is more than 6 months past the date you first opened the bottle.
- If your control solution test result is out of range, contact Customer Service. See *Contact Information*. Do not use the meter for blood glucose testing until you resolve this issue.
- The meter is designed to give accurate blood testing results at temperatures between 8°C and 45°C. If the meter or test strip is outside this range, you should not test until the meter and test strip are within this range. Whenever the meter is moved from one location to another, allow approximately 20 minutes for the meter to adjust to the temperature of the new location before performing a blood glucose test.
- Do not attempt to perform a blood glucose test when the CONTOUR NEXT meter is connected to a computer.
- Use only approved equipment (for example, USB cable) from the manufacturer or certified body such as UL, CSA, TUV, or CE.

- Avoid use of electronic devices in very dry environments, especially if synthetic materials are present.
- Your CONTOUR NEXT meter has been preset and locked to display results in mmol/L (millimoles of glucose per litre of blood).
  - Results in mmol/L have a decimal point.
  - Results in mg/dL do not have a decimal point.
  Example: 5.2 mmol/L = 93 mg/dL
- Check your display screen to be sure the results are shown correctly. If not, contact Customer Service. See *Contact Information*.
- The CONTOUR NEXT blood glucose monitoring system has a measuring range of 0.6 mmol/L to 33.3 mmol/L.
  - For results under 0.6 mmol/L or over 33.3 mmol/L:
    - If your meter does not display a value and displays the LO screen, **contact your health care professional immediately.**
    - If your meter does not display a value and displays the HI screen, wash your hands or the test site and repeat the test with a new strip. If the meter again displays the **HI** screen, **follow medical advice immediately.**

1 GETTING STARTED

Your CONTOUR NEXT meter and CONTOUR NEXT test strip

- To exit from the **Logbook** or **Averages** and return to the **Home** screen, press **OK**.
- When a symbol is blinking, you can select it.

Check the Meter Display
Press and hold **OK** until the meter turns on, about 3 seconds. The screen displays the **Power On Self Test**.

All symbols on the screen and the white strip port briefly light up. Verify that the meter screen fully displays **8.8.8** and that the white light from the test strip port is visible.
If there are missing characters or if the strip port light is a colour other than white, contact Customer Service. See *Contact Information*. This may affect the way you see your results.

NOTE: Your meter comes with a pre-set time, date, and target range. You can change these features in **Settings**. See Section *4 Settings*.

Your Meter Symbols

Symbol	What the Symbol Means
	Yellow Light: test result is **above** Target Range.
	Green Light: test result is **in** Target Range.
	Red Light: test result is **below** Target Range.
	Blood glucose test result is **above** Target Range.
	Blood glucose test result is **in** Target Range.
	Blood glucose test result is **below** Target Range.
HI	Test result is above 33.3 mmol/L.
LO	Test result is below 0.6 mmol/L.

Symbol	What the Symbol Means
	Your **Logbook**.
	Meter **Settings**.
	Fasting marker.
	Before Meal marker.
	After Meal marker.
	No marker selected.
	A **Target Range** or **Target Range** setting.
	smartLIGHT® target range indicator setting.
	Meter is ready to test.
	Add more blood to **same** test strip.
	Control solution test result.
	Bluetooth® symbol means the **Bluetooth** wireless setting is On; the meter can communicate with a mobile device.
	Low batteries.
	Dead batteries.
	Meter error.
	Reminder feature.
	Sound feature.
7 d Avg	7-, 14-, 30-, and 90-day averages.
n	Total number of blood glucose readings used to calculate averages.

The Home Screen
The **Home** screen has 2 options: **Logbook** and **Settings**.

- To highlight the **Logbook** or **Settings**, press the ▼ button.
- To enter the **Logbook**, press **OK** while the **Logbook** symbol is blinking.
- To enter **Settings**, press **OK** while the **Settings** symbol is blinking.

Your Meter Features
Second-Chance® sampling allows you to apply more blood to the same test strip if the first blood sample is not enough. Your test strip is designed to easily 'slip' the blood into the sample tip. Do not drop blood directly on the flat surface of the test strip.

2 TESTING

Get Ready to Test
Read your CONTOUR NEXT user guide, the lancing device package insert, if provided, and all instructional materials provided in your meter kit before testing.
Examine the product for missing, damaged, or broken parts. If the test strip packaging is open or damaged, do not use those test strips. For replacement parts, contact Customer Service. See *Contact Information*.
CAUTION: Your CONTOUR NEXT meter works only with CONTOUR NEXT test strips and CONTOUR NEXT control solution.

Fingertip Testing
Ensure that you have the materials you need before you begin testing:
- CONTOUR NEXT meter.
- CONTOUR NEXT test strips.
- Lancing device and lancets from your kit, if provided.

To perform a quality control check, see Section *3 Help: Control Solution Testing*.
Some supplies are sold separately. See Section *6 Technical Information: Customer Service Checklist*.

⚠ WARNING: Potential Biohazard
- All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection. See Section *5 Help: Meter Care*.
- Always wash your hands with antibacterial soap and water and dry them well before and after testing or handling the meter, lancing device, or test strips.
- For complete instructions on cleaning your meter, see Section *5 Help: Meter Care*.

High / Low Blood Glucose
Symptoms of High or Low Blood Glucose
You can better understand your test results by being aware of the symptoms of high or low blood glucose. According to the American Diabetes Association (www.diabetes.org), some of the most common symptoms are:

Low blood glucose (Hypoglycaemia):
- shakiness
- sweating
- fast heartbeat
- blurred vision
- confusion
- passing out
- seizure
- irritability
- extreme hunger
- dizziness

High blood glucose (Hyperglycaemia):
- frequent urination
- excessive thirst
- blurred vision
- increased fatigue
- hunger

Ketones (Ketoacidosis):
- shortness of breath
- nausea or vomiting
- very dry mouth

⚠ WARNING
If you are experiencing any of these symptoms, test your blood glucose. If your test result is under the critical level you have established with your health care professional or over the recommended limit, follow your health care professional's advice immediately.

For additional information and a complete list of symptoms, contact your health care professional.

Prepare the Lancing Device
Refer to your lancing device insert for detailed instructions on preparing the lancing device and fingertip testing.
⚠ WARNING: Potential Biohazard
- The lancing device provided is intended for self-testing by a single patient. It must not be used on more than one person due to the risk of infection.
- Do not reuse lancets. Used lancets are not sterile. Use a new lancet each time you test.

⚠ WARNING: Potential Biohazard
Always dispose of used test strips and lancets as medical waste or as advised by your health care professional.

Insert the Test Strip
CAUTION: Do not use expired materials. Using expired material can cause inaccurate results. Always check the expiration dates on your test materials.

NOTE: If strips are stored in a bottle, tightly close the bottle lid immediately after removing the test strip.
Some supplies are not available in every region.

1. Remove a CONTOUR NEXT test strip.
2. Insert the grey square end firmly into the test strip port until the meter beeps.

The screen displays the blinking blood drop indicating it is ready to test a blood drop.

NOTE: After you insert the test strip, apply blood to the test strip within 3 minutes or the meter turns off. Remove the test strip and reinsert it to begin a test.

Get the Blood Drop: Fingertip Testing
NOTE: For information on Alternative Site Testing, see Section *2 Testing: Alternative Site Testing (AST): Palm*.
⚠ WARNING: Potential Biohazard
Always wash your hands with antibacterial soap and water and dry them well before and after testing or handling the meter, lancing device, or test strips.

1. Press the lancing device firmly against the puncture site and press the release button.
2. Immediately touch the tip of the test strip to the drop of blood.
   The blood is drawn into the test strip through the tip.
3. Hold the tip of the test strip in the blood drop until the meter beeps.

NOTE: If the **Meal Marker** feature is On, do not remove the test strip until you select a **Meal Marker**.

Second-Chance sampling—Apply More Blood

CAUTION: Do not press the tip of the test strip against the skin or place the blood on top of the test strip. This could lead to inaccurate results or errors.

1. If the meter beeps twice and the screen displays a blinking blood drop with a plus sign, the test strip does not have enough blood.
2. Apply more blood to the **same** test strip within 60 seconds.

NOTE: If the screen displays an **E 1** error message, remove the strip and start with a new strip.

About Meal Markers
You can attach a **Meal Marker** to your blood glucose result when the **Meal Marker** feature is turned On.
Your CONTOUR NEXT meter comes with **Meal Markers** turned Off. You can turn **Meal Markers** On and change **Target Ranges** in **Settings**. See Section *4 Settings*.

Symbol	What it Means	Target Range
Fasting	Use when testing after fasting (no food or drink for 8 hours, except water or non-calorie beverages).	The meter compares your result against the **Before Meal Target Range.** (Pre-set to 3.9 mmol/L–7.2 mmol/L)
Before Meal	Use when testing within 1 hour before a meal.	The meter compares your result against the **Before Meal Target Range.** (Pre-set to 3.9 mmol/L–7.2 mmol/L)
After Meal	Use when testing within 2 hours after the first bite of a meal.	The meter compares your result against the **After Meal Target Range.** (Pre-set to 3.9 mmol/L–10.0 mmol/L)
No Mark	Use when testing at times other than fasting or before or after a meal.	The meter compares your result against the **Overall Target Range.** (Pre-set to 3.9 mmol/L–10.0 mmol/L)

Add a Meal Marker to a Reading
During a blood glucose test, if **Meal Markers** are On, you can select a **Meal Marker** when the meter displays your result. **You cannot select a Meal Marker in the Settings screen.**
For more information, see Section *2 Testing: About Meal Markers*.
Example:

Do not press OK or remove the test strip yet.
You can select the blinking marker or choose a different **Meal Marker.**

To turn **Meal Markers** On, see Section *4 Settings: Set Meal Marker Feature*.

1. If the blinking **Meal Marker** is the one you want, press **OK** or
2. To select a different **Meal Marker**, press the ▲ or ▼ button on the meter to scroll between markers.

3. When the **Meal Marker** you want is blinking, press **OK**.
4. If this is a **Before Meal** reading, you can set a **Reminder** to test your blood glucose later. See Section *2 Testing: Set a Test Reminder*.

If you do not make a **Meal Marker** selection within 3 minutes, the meter turns off. Your blood glucose reading is stored in the **Logbook** without a **Meal Marker.**

Set a Test Reminder
1. Make sure the **Reminder** feature is On in **Settings**. See Section *4 Settings: Set Reminder Feature*.
2. Mark a blood glucose reading as a **Before Meal** reading, then press **OK**.

3. To scroll from 2 hours to 0.5 hours by half-hour intervals, press the ▲ or ▼ button.
4. To set the **Reminder**, press **OK**.

The screen returns to the **Before Meal** reading. The meter displays the **Reminder** symbol to confirm the Reminder is set.

smartLIGHT target range indicator
When your blood glucose test is complete, the meter displays your result with the units, time, date, meal marker (if selected), and target range symbol: Above Target ▲, In Target ✓, or Below Target ◆.
Example: Blood test result with **Meal Marker** selected and a **Reminder** set:

If the **smartLIGHT** setting is On, the test strip port displays a colour representing your result value compared to your **Before Meal**, **After Meal**, or **Overall Target Range**.

If your blood glucose result is below target, the **smartLIGHT** is red and the meter beeps twice.
If you do not select a **Meal Marker**, your blood glucose test result is compared to an **Overall Target Range.**
NOTE: To change an individual target range, see Section *4 Settings: Change Before/After Meal Target Ranges*. To change the Overall Target Range, see Section *4 Settings: Change Overall Target Range*.

To move to the **Home** screen, press **OK**.

To turn the meter off, remove the test strip.

Blood glucose test is complete.

Test Results
⚠ WARNING
- **Always consult your health care professional before changing your medication based on test results.**
- **If your blood glucose reading is under the critical level you have established with your health care professional**, follow their advice immediately.
- **If your blood glucose reading is over the recommended limit set by your health care professional:**
  1. Wash and dry your hands well.
  2. Retest with a new strip.

If you get a similar result, follow your health care professional's advice immediately.

Expected Test Result Values
Blood glucose values will vary depending on food intake, medication dosages, health, stress, or activity. Nondiabetic plasma glucose concentrations should be less than 5.6 mmol/L in the fasting state and less than 7.8 mmol/L in the postprandial state (after a meal).[3] You should consult with your health care professional for glucose values specific to your needs.

LO or HI Results

- If the meter beeps twice and displays the **LO** screen, your blood glucose reading is under 0.6 mmol/L. **Follow medical advice immediately.** Contact your health care professional.

- If the meter beeps once and displays the **HI** screen, your blood glucose reading is over 33.3 mmol/L.
  1. Wash and dry your hands well.
  2. Retest with a new strip.

If results are still over 33.3 mmol/L, **follow medical advice immediately.**
To turn the meter Off, remove the test strip.

Eject and Dispose of the Used Lancet

1. **Do not use your fingers to remove the lancet from the lancing device.**
2. **Refer to the separate lancing device insert, if provided with your kit, for instructions on automatic ejection of the lancet.**

⚠ WARNING: Potential Biohazard
- **The lancing device, lancets, and test strips are for single-patient use. Do not share them with anyone including other family members. Do not use on multiple patients.[1,2]**
- **All products that come in contact with human blood should be handled as if capable of transmitting infectious diseases.**
- Always dispose of used test strips and lancets as medical waste or as advised by your health care professional.
- ⊘ **Do not reuse lancets. Used lancets are not sterile. Use a new lancet each time you test.**
- Always wash your hands with antibacterial soap and water and dry them well before and after testing or handling the meter, lancing device, or test strips.

Alternative Site Testing (AST): Palm
See the lancing device insert for detailed instructions on Alternative Site Testing.
⚠ WARNING
- **Ask your health care professional if Alternative Site Testing (AST) is right for you.**
- **Do not calibrate a continuous glucose monitoring device from an AST result.**
- **Do not calculate an insulin dose based on an AST result.**

Alternative Site Testing is recommended only when it is more than 2 hours after a meal, diabetes medication, or exercise.
For Alternative Site Testing, you must use the clear endcap. Your CONTOUR NEXT meter can be used for fingertip or palm testing. See the lancing device insert for detailed instructions on Alternative Site Testing. To obtain a clear endcap, contact Customer Service. See *Contact Information*.
Do not use AST under the following conditions:
- If you think your blood glucose is low.
- When blood glucose is changing rapidly.
- If you are unable to feel symptoms of low blood glucose.
- If you get AST results that do not agree with how you feel.
- During illness or times of stress.
- If you will be driving a car or operating machinery.

3 LOGBOOK

The **Logbook** contains blood glucose test results and their Meal Markers. When the **Logbook** reaches the maximum 500 results, the oldest test result is removed as a new test is completed and saved to the **Logbook**.

Review the Logbook
NOTE: To return to the **Home** screen while viewing the **Logbook**, press **OK**.
To review entries in the **Logbook**:
1. Press and hold **OK** until the meter turns on, about 3 seconds. The **Logbook** is blinking on the Home screen.

2. To select the blinking **Logbook** symbol, press **OK**.
3. To view your individual test results in the **Logbook**, press the ▼ button.

4. To scroll through your test results, press the ▲ or ▼ button.
   To scroll faster, press and hold the ▲ or ▼ button.

If you scroll past the oldest entry, the meter displays the **End** screen.

If you see a **LO** or **HI** test result, go to Section *2 Testing: LO or HI Results* for more information.

5. To go back to the beginning to review entries, press **OK** to go to the **Home** screen, then select the **Logbook** symbol.

View Averages
1. To enter the **Logbook** from the Home screen, press **OK** while the **Logbook** is blinking.
2. To view your Averages, press the ▲ button from the first **Logbook** screen.

3. To scroll through your 7-, 14-, 30-, and 90-day Averages, press the ▲ button.
4. To return to your Logbook readings, press the ▼ button on the **7 d Avg** (7-day Average).

5. To exit Averages and return to the **Home** screen at any time, press **OK**.

4 SETTINGS

In **Settings** you can personalize:
- **Time** format and time.
- **Date** format and date.
- **Sound.**
- **Meal Markers.**
- **Reminder** feature.
- **Target Ranges.**
- **smartLIGHT** feature.
- **Bluetooth** wireless functionality.

NOTE: Press **OK** to accept the current or changed setting before moving to the next setting.

Access Settings

1. Press and hold **OK** until the meter turns on.

The Home screen has 2 options: **Logbook** and **Settings**.

2. To highlight the **Settings** symbol, press the ▼ button.
3. When the **Settings** symbol is blinking, press **OK** to enter **Settings**.

4. To scroll through **Settings** options as shown in the image, press the ▲ or ▼ button until the symbol you want is blinking.

5. To enter the **Settings** menu and return to the **Home** screen, press the ▲ or ▼ button until the **Settings** symbol is blinking.
6. Press **OK**.

NOTE: If you are in a setting such as Date and you need to exit, press **OK** repeatedly until you get back to the **Home** screen.

Change the Time
1. From the **Home** screen, select the **Settings** symbol and press **OK** to enter **Settings**.

2. When the current time is blinking on the **Settings** screen, press **OK**.
3. The time format (12 hour or 24 hour) is blinking.

12 Hour

24 Hour

Time Format

3. To change the time format, if needed, press the ▲ or ▼ button, then press **OK**.

4. To change the hour (blinking), press the ▲ or ▼ button, then press **OK**.

5. To change minutes (blinking), press the ▲ or ▼ button, then press **OK**.
6. For a 12-hour time format, select **AM** or **PM**, as needed, then press **OK**.

Change the Date
1. From the **Home** screen, select the **Settings** symbol and press **OK** to enter **Settings**.
2. When you are on the **Settings** screen, press the ▼ button until the current date is blinking, then press **OK**.

Date Format

The date format (**m/d** or **d.m**) is blinking.

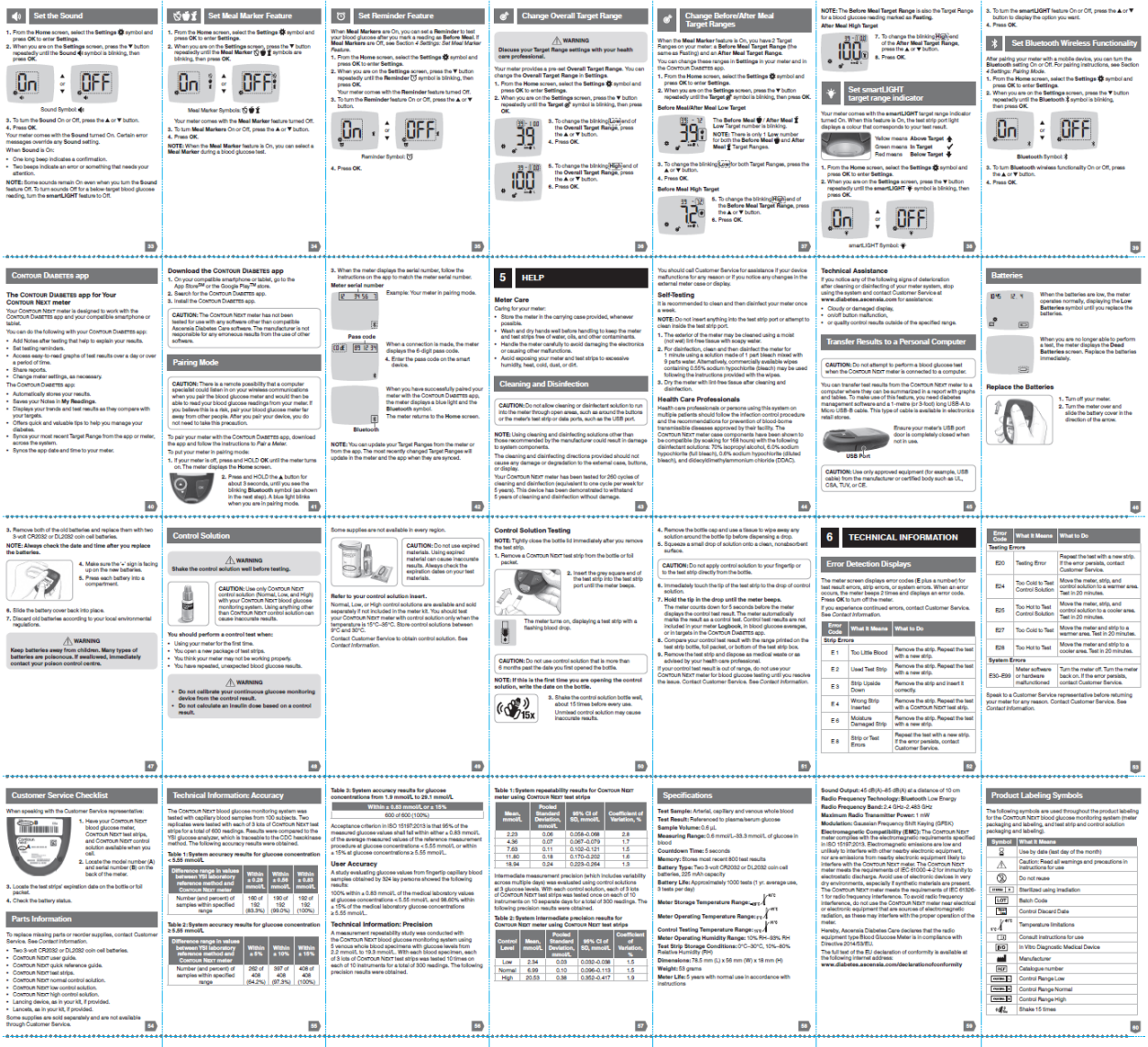
3. To select **Month/Day/Year** (**m/d**) or **Day.Month.Year** (**d.m**), press the ▲ or ▼ button, then press **OK**.

4. To change the year (blinking), press the ▲ or ▼ button, then press **OK**.

5. To change the month (blinking), press the ▲ or ▼ button, then press **OK**.

6. To change the day (blinking), press the ▲ or ▼ button, then press **OK**.

TURN OVER TO SEE BACK



Set the Sound

1. From the **Home** screen, select the **Settings** ⚙ symbol and press **OK** to enter **Settings**.
2. When you are on the **Settings** screen, press the ▼ button repeatedly until the **Sound** ◀) symbol is blinking, then press **OK**.

Sound Symbol ◀)

3. To turn the **Sound** On or Off, press the ▲ or ▼ button.
4. Press **OK**.

Your meter comes with the **Sound** turned On. Certain error messages override any **Sound** setting.

When **Sound** is On:

- One long beep indicates a confirmation.
- Two beeps indicate an error or something that needs your attention.

NOTE: Some sounds remain On even when you turn the **Sound** feature Off. To turn sounds Off for a below-target blood glucose reading, turn the **smartLIGHT** feature to Off.

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Set Meal Marker Feature

1. From the **Home** screen, select the **Settings** ⚙ symbol and press **OK** to enter **Settings**.
2. When you are on the **Settings** screen, press the ▼ button repeatedly until the **Meal Marker** symbols are blinking, then press **OK**.

Meal Marker Symbols

Your meter comes with the **Meal Marker** feature turned Off.

3. To turn **Meal Markers** On or Off, press the ▲ or ▼ button.
4. Press **OK**.

NOTE: When the **Meal Marker** feature is On, you can select a **Meal Marker** during a blood glucose test.

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Set Reminder Feature

When **Meal Markers** are On, you can set a **Reminder** to test your blood glucose after you mark a reading as **Before Meal**. If **Meal Markers** are Off, see Section 4 *Settings: Set Meal Marker Feature*.

1. From the **Home** screen, select the **Settings** ⚙ symbol and press **OK** to enter **Settings**.
2. When you are on the **Settings** screen, press the ▼ button repeatedly until the **Reminder** symbol is blinking, then press **OK**.

Your meter comes with the **Reminder** feature turned Off.

3. To turn the **Reminder** feature On or Off, press the ▲ or ▼ button.
4. Press **OK**.

Reminder Symbol

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Change Overall Target Range

⚠ WARNING

Discuss your Target Range settings with your health care professional.

Your meter provides a pre-set **Overall Target Range**. You can change the **Overall Target Range** in **Settings**.

1. From the **Home** screen, select the **Settings** ⚙ symbol and press **OK** to enter **Settings**.
2. When you are on the **Settings** screen, press the ▼ button repeatedly until the **Target** symbol is blinking, then press **OK**.

3. To change the blinking **Low** end of the **Overall Target Range**, press the ▲ or ▼ button.
4. Press **OK**.

5. To change the blinking **High** end of the **Overall Target Range**, press the ▲ or ▼ button.
6. Press **OK**.

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Change Before/After Meal Target Ranges

When the **Meal Marker** feature is On, you have 2 Target Ranges on your meter: a **Before Meal Target Range** (the same as Fasting) and an **After Meal Target Range**.

You can change these ranges in **Settings** in your meter and in the Contour Diabetes app.

1. From the **Home** screen, select the **Settings** ⚙ symbol and press **OK** to enter **Settings**.
2. When you are on the **Settings** screen, press the ▼ button repeatedly until the **Target** symbol is blinking, then press **OK**.

Before Meal/After Meal Low Target

The Before Meal / After Meal Low Target number is blinking.

NOTE: There is only 1 Low number for both the **Before Meal** and **After Meal** Target Ranges.

3. To change the blinking **Low** end for both Target Ranges, press the ▲ or ▼ button.
4. Press **OK**.

Before Meal High Target

5. To change the blinking **High** end of the **Before Meal Target Range**, press the ▲ or ▼ button.
6. Press **OK**.

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NOTE: The **Before Meal Target Range** is also the Target Range for a blood glucose reading marked as **Fasting**.

After Meal High Target

7. To change the blinking **High** end of the **After Meal Target Range**, press the ▲ or ▼ button.
8. Press **OK**.

Set smartLIGHT target range indicator

Your meter comes with the **smartLIGHT** target range indicator turned On. When this feature is On, the test strip port light displays a colour that corresponds to your test result.

Yellow means **Above Target** ◆
Green means **In Target** ✓
Red means **Below Target** ◆

1. From the **Home** screen, select the **Settings** ⚙ symbol and press **OK** to enter **Settings**.
2. When you are on the **Settings** screen, press the ▼ button repeatedly until the **smartLIGHT** ✦ symbol is blinking, then press **OK**.

smartLIGHT Symbol ✦

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3. To turn the **smartLIGHT** feature On or Off, press the ▲ or ▼ button to display the option you want.
4. Press **OK**.

Set Bluetooth Wireless Functionality

After pairing your meter with a mobile device, you can turn the **Bluetooth** setting On or Off. For pairing instructions, see Section 4 *Settings: Pairing Mode*.

1. From the **Home** screen, select the **Settings** ⚙ symbol and press **OK** to enter **Settings**.
2. When you are on the **Settings** screen, press the ▼ button repeatedly until the **Bluetooth** ᛒ symbol is blinking, then press **OK**.

Bluetooth Symbol ᛒ

3. To turn **Bluetooth** wireless functionality On or Off, press the ▲ or ▼ button.
4. Press **OK**.

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Contour Diabetes app

The Contour Diabetes app for Your Contour Next meter

Your Contour Next meter is designed to work with the Contour Diabetes app and your compatible smartphone or tablet.

You can do the following with your Contour Diabetes app:

- Add Notes after testing that help to explain your results.
- Set testing reminders.
- Access easy to read graphs of test results over a day or over a period of time.
- Share reports.
- Change meter settings, as necessary.

The Contour Diabetes app:

- Automatically stores your results.
- Saves your Notes in **My Readings**.
- Displays your trends and test results as they compare with your targets.
- Offers quick and valuable tips to help you manage your diabetes.
- Syncs your most recent Target Range from the app or meter, across the system.
- Syncs the app date and time to your meter.

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Download the Contour Diabetes app

1. On your compatible smartphone or tablet, go to the App Store℠ or the Google Play™ store.
2. Search for the Contour Diabetes app.
3. Install the Contour Diabetes app.

CAUTION: The Contour Next meter has not been tested for use with any software other than compatible Ascensia Diabetes Care software. The manufacturer is not responsible for any erroneous results from the use of other software.

Pairing Mode

CAUTION: There is a remote possibility that a computer specialist could listen in on your wireless communications when you pair the blood glucose meter and would then be able to read your blood glucose readings from your meter. If you believe this is a risk, pair your blood glucose meter far away from other people. After you pair your device, you do not need to take this precaution.

To pair your meter with the Contour Diabetes app, and follow the instructions for *Pair a Meter*.

To put your meter in pairing mode:

1. If your meter is off, press and HOLD **OK** until the meter turns on. The meter displays the **Home** screen.

2. Press and HOLD the ▲ button for about 3 seconds, until you see the blinking **Bluetooth** symbol (as shown in the next step). A blue light blinks when you are in pairing mode.

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3. When the meter displays the serial number, follow the instructions on the app to match the meter serial number.

Meter serial number

Example: Your meter in pairing mode.

Pass code

When a connection is made, the meter displays the 6-digit pass code.

4. Enter the pass code on the smart device.

When you have successfully paired your meter with the Contour Diabetes app, the meter displays a blue light and the **Bluetooth** symbol.

The meter returns to the **Home** screen.

NOTE: You can update your Target Ranges from the meter or from the app. The most recently changed Target Ranges will update in the meter and the app when they are synced.

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5 HELP

Meter Care

Caring for your meter:

- Store the meter in the carrying case provided, wherever possible.
- Wash and dry hands well before handling to keep the meter and test strips free of water, oils, and other contaminants.
- Handle the meter carefully to avoid damaging the electronics or causing other malfunctions.
- Avoid exposing your meter and test strips to excessive humidity, heat, cold, dust, or dirt.

Cleaning and Disinfection

CAUTION: Do not allow cleaning or disinfectant solution to run into the meter through open areas, such as around the buttons or the meter's test strip or data ports, such as the USB port.

NOTE: Using cleaning and disinfecting solutions other than those recommended by the manufacturer could result in damage to system components.

The cleaning and disinfecting directions provided should not cause any damage or degradation to the external case, buttons, or display.

Your Contour Next meter has been tested for 260 cycles of cleaning and disinfection (equivalent to one cycle per week for 5 years). This device has been demonstrated to withstand 5 years of cleaning and disinfection without damage.

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You should call Customer Service for assistance if your device malfunctions for any reason or if you notice any changes in the external meter case or display.

Self-Testing

It is recommended to clean and then disinfect your meter once a week.

NOTE: Do not insert anything into the test strip port or attempt to clean inside the test strip port.

1. The exterior of the meter may be cleaned using a moist (not wet) lint-free tissue with soapy water.
2. For disinfection, clean and then disinfect the meter for 1 minute using a solution made of 1 part bleach mixed with 9 parts water. Alternatively, commercially available wipes containing 0.55% sodium hypochlorite (bleach) may be used following the instructions provided with the wipes.
3. Dry the meter with lint-free tissue after cleaning and disinfection.

Health Care Professionals

Health care professionals or persons using this system on multiple patients should follow the infection control procedure and the recommendations for prevention of blood-borne transmissible diseases approved by their facility. The Contour Next meter case components have been shown to be compatible (by soaking for 168 hours) with the following disinfectant solutions: 70% isopropyl alcohol, 6.0% sodium hypochlorite (full bleach), 0.6% sodium hypochlorite (diluted bleach), and didecyldimethylammonium chloride (DDAC).

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Technical Assistance

If you notice any of the following signs of deterioration after cleaning or disinfecting of your meter system, stop using the system and contact Customer Service at **www.diabetes.ascensia.com** for assistance:

- Cloudy or damaged display.
- On/off button malfunction.
- or quality control results outside of the specified range.

Transfer Results to a Personal Computer

CAUTION: Do not attempt to perform a blood glucose test when the Contour Next meter is connected to a computer.

You can transfer test results from the Contour Next meter to a computer where they can be summarized in a report with graphs and tables. To make use of this feature, you need diabetes management software and a 1-metre (or 3-foot) long USB-A to Micro USB-B cable. This type of cable is available in electronics retail stores.

USB Port

Ensure your meter's USB port door is completely closed when not in use.

CAUTION: Use only approved equipment (for example, USB cable) from the manufacturer or certified body such as UL, CSA, TUV, or CE.

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Batteries

When the batteries are low, the meter operates normally, displaying the **Low Batteries** symbol until you replace the batteries.

When you are no longer able to perform a test, the meter displays the **Dead Batteries** screen. Replace the batteries immediately.

Replace the Batteries

1. Turn off your meter.
2. Turn the meter over and slide the battery cover in the direction of the arrow.

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3. Remove both of the old batteries and replace them with two 3-volt CR2032 or DL2032 coin cell batteries.

NOTE: Always check the date and time after you replace the batteries.

4. Make sure the "+" sign is facing up on the new batteries.
5. Press each battery into a compartment.
6. Slide the battery cover back into place.
7. Discard old batteries according to your local environmental regulations.

⚠ WARNING

Keep batteries away from children. Many types of batteries are poisonous. If swallowed, immediately contact your poison control centre.

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Control Solution

⚠ WARNING

Shake the control solution well before testing.

CAUTION: Use only Contour Next control solution (Normal, Low, and High) with your Contour Next blood glucose monitoring system. Using anything other than Contour Next control solution can cause inaccurate results.

You should perform a control test when:

- Using your meter for the first time.
- You open a new package of test strips.
- You think your meter may not be working properly.
- You have repeated, unexpected blood glucose results.

⚠ WARNING

- **Do not calibrate your continuous glucose monitoring device from the control result.**
- **Do not calculate an insulin dose based on a control result.**

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Some supplies are not available in every region.

CAUTION: Do not use expired materials. Using expired material can cause inaccurate results. Always check the expiration dates on your test materials.

Refer to your control solution insert.

Normal, Low, or High control solutions are available and sold separately if not included in the meter kit. You should test your Contour Next meter with control solution only when the temperature is 15°C–35°C. Store control solutions between 9°C and 30°C.

Contact Customer Service to obtain control solution. See *Contact Information*.

Control Solution Testing

NOTE: Tightly close the bottle lid immediately after you remove the test strip.

1. Remove a Contour Next test strip from the bottle or foil packet.

2. Insert the grey square end of the test strip into the test strip port until the meter beeps.

The meter turns on, displaying a test strip with a flashing blood drop.

CAUTION: Do not use control solution that is more than 6 months past the date you first opened the bottle.

NOTE: If this is the first time you are opening the control solution, write the date on the bottle.

3. Shake the control solution bottle well, about 15 times before every use.

Unmixed control solution may cause inaccurate results.

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4. Remove the bottle cap and use a tissue to wipe away any solution around the bottle tip before dispensing a drop.
5. Squeeze a small drop of solution onto a clean, nonabsorbent surface.

CAUTION: Do not apply control solution to your fingertip or to the test strip directly from the bottle.

6. Immediately touch the tip of the test strip to the drop of control solution.
7. **Hold the tip in the drop until the meter beeps.**

The meter counts down for 5 seconds before the meter displays the control test result. The meter automatically marks the result as a control test. Control test results are not included in your meter **Logbook**, in blood glucose averages, or in targets in the Contour Diabetes app.

8. Compare your control test result with the range printed on the test strip bottle, foil packet, or bottom of the test strip box.
9. Remove the test strip and dispose as medical waste or as advised by your health care professional.

If your control test result is out of range, do not use your Contour Next meter for blood glucose testing until you resolve the issue. Contact Customer Service. See *Contact Information*.

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6 TECHNICAL INFORMATION

Error Detection Displays

The meter screen displays error codes (**E** plus a number) for test result errors, strip errors, or system errors. When an error occurs, the meter beeps 2 times and displays an error code. Press **OK** to turn off the meter.

If you experience continued errors, contact Customer Service. See *Contact Information*.

Error Code	What It Means	What to Do
Strip Errors		
E 1	Too Little Blood	Remove the strip. Repeat the test with a new strip.
E 2	Used Test Strip	Remove the strip. Repeat the test with a new strip.
E 3	Strip Upside Down	Remove the strip and insert it correctly.
E 4	Wrong Strip Inserted	Remove the strip. Repeat the test with a Contour Next test strip.
E 6	Moisture Damaged Strip	Remove the strip. Repeat the test with a new strip.
E 8	Strip or Test Errors	Repeat the test with a new strip. If the error persists, contact Customer Service.

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Error Code	What It Means	What to Do
Testing Errors		
E20	Testing Error	Repeat the test with a new strip. If the error persists, contact Customer Service.
E24	Too Cold to Test Control Solution	Move the meter, strip, and control solution to a warmer area. Test in 20 minutes.
E25	Too Hot to Test Control Solution	Move the meter, strip, and control solution to a cooler area. Test in 20 minutes.
E27	Too Cold to Test	Move the meter and strip to a warmer area. Test in 20 minutes.
E28	Too Hot to Test	Move the meter and strip to a cooler area. Test in 20 minutes.
System Errors		
E30–E99	Meter software or hardware malfunctioned	Turn the meter off. Turn the meter back on. If the error persists, contact Customer Service.

Speak to a Customer Service representative before returning your meter for any reason. Contact Customer Service. See *Contact Information*.

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Customer Service Checklist

When speaking with the Customer Service representative:

1. Have your Contour Next blood glucose meter, Contour Next test strips, and Contour Next control solution available when you call.
2. Locate the model number (**A**) and serial number (**B**) on the back of the meter.
3. Locate the test strips' expiration date on the bottle or foil packet.
4. Check the battery status.

Parts Information

To replace missing parts or reorder supplies, contact Customer Service. See *Contact Information*.

- Two 3-volt CR2032 or DL2032 coin cell batteries.
- Contour Next user guide.
- Contour Next quick reference guide.
- Contour Next test strips.
- Contour Next normal control solution.
- Contour Next low control solution.
- Contour Next high control solution.
- Lancing device, as in your kit, if provided.
- Lancets, as in your kit, if provided.

Some supplies are sold separately and are not available through Customer Service.

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Technical Information: Accuracy

The Contour Next blood glucose monitoring system was tested with capillary blood samples from 100 subjects. Two replicates were tested with each of 3 lots of Contour Next test strips for a total of 600 readings. Results were compared to the YSI glucose analyzer, which is traceable to the CDC hexokinase method. The following accuracy results were obtained.

Table 1: System accuracy results for glucose concentration < 5.55 mmol/L

Difference range in values between YSI laboratory reference method and Contour Next meter	Within ± 0.28 mmol/L	Within ± 0.56 mmol/L	Within ± 0.83 mmol/L
Number (and percent) of samples within specified range	190 of 192 (83.3%)	190 of 192 (99.0%)	192 of 192 (100%)

Table 2: System accuracy results for glucose concentration ≥ 5.55 mmol/L

Difference range in values between YSI laboratory reference method and Contour Next meter	Within ± 5%	Within ± 10%	Within ± 15%
Number (and percent) of samples within specified range	282 of 408 (64.2%)	397 of 408 (97.3%)	408 of 408 (100%)

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Table 3: System accuracy results for glucose concentrations from 1.9 mmol/L to 29.1 mmol/L

Within ± 0.83 mmol/L or ± 15%
600 of 600 (100%)

Acceptance criterion in ISO 15197:2013 is that 95% of the measured glucose values shall fall within either a 0.83 mmol/L of the average measured values of the reference measurement procedure at glucose concentrations < 5.55 mmol/L or within a 15% at glucose concentrations ≥ 5.55 mmol/L.

User Accuracy

A study evaluating glucose values from fingertip capillary blood samples obtained by 324 lay persons showed the following results.

100% within ± 0.83 mmol/L of the medical laboratory values at glucose concentrations < 5.55 mmol/L and 98.60% within ± 15% of the medical laboratory glucose concentrations ≥ 5.55 mmol/L.

Technical Information: Precision

A measurement repeatability study was conducted with the Contour Next blood glucose monitoring system using 5 venous whole blood specimens with glucose levels from 2.2 mmol/L to 19.3 mmol/L. With each blood specimen, each of 3 lots of Contour Next test strips was tested 10 times on each of 10 instruments for a total of 500 readings. The following precision results were obtained.

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Table 1: System repeatability results for Contour Next meter using Contour Next test strips

Mean, mmol/L	Pooled Standard Deviation, mmol/L	95% CI of SD, mmol/L	Coefficient of Variation, %
2.25	0.06	0.056–0.068	2.8
4.36	0.07	0.067–0.079	1.7
7.63	0.11	0.102–0.121	1.5
11.80	0.18	0.170–0.202	1.6
18.94	0.24	0.223–0.264	1.3

Intermediate measurement precision (which includes variability across multiple days) was evaluated using control solutions at 3 glucose levels. With each control solution, each of 3 lots of Contour Next test strips was tested once on each of 10 instruments on 10 separate days for a total of 300 readings. The following precision results were obtained.

Table 2: System intermediate precision results for Contour Next meter using Contour Next test strips

Control Level	Mean, mmol/L	Pooled Standard Deviation, mmol/L	95% CI of SD, mmol/L	Coefficient of Variation, %
Low	2.34	0.03	0.032–0.038	1.5
Normal	6.99	0.10	0.096–0.113	1.5
High	20.53	0.38	0.352–0.417	1.9

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Specifications

Test Sample: Arterial, capillary and venous whole blood
Test Result: Referenced to plasma/serum glucose
Sample Volume: 0.6 µL
Measuring Range: 0.6 mmol/L–33.3 mmol/L of glucose in blood
Countdown Time: 5 seconds
Memory: Stores most recent 800 test results
Battery Type: Two 3-volt CR2032 or DL2032 coin cell batteries, 225 mAh capacity
Battery Life: Approximately 1000 tests (1 yr. average use, 3 tests per day)
Meter Storage Temperature Range: -20°C–60°C
Meter Operating Temperature Range: 8°C–44°C
Control Testing Temperature Range: 8°C–44°C
Meter Operating Humidity Range: 10% RH–93% RH
Test Strip Storage Conditions: 0°C–30°C, 10%–80% Relative Humidity (RH)
Dimensions: 76.5 mm (L) x 56 mm (W) x 18 mm (H)
Weight: 53 grams
Meter Life: 5 years with normal use in accordance with instructions

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Sound Output: 45 dB(A)–85 dB(A) at a distance of 10 cm
Radio Frequency Technology: Bluetooth Low Energy
Radio Frequency Band: 2.4 GHz–2.483 GHz
Maximum Radio Transmitter Power: 1 mW
Modulation: Gaussian Frequency Shift Keying (GFSK)
Electromagnetic Compatibility (EMC): This Contour Next meter complies with the electromagnetic requirements specified in ISO 15197:2013. Electromagnetic emissions are low and unlikely to interfere with other nearby electronic equipment, nor are emissions from nearby electronic equipment likely to interfere with the Contour Next meter. The Contour Next meter meets the requirements of IEC 61000-4-2 for immunity to electrostatic discharge. Avoid use of electronic devices in very dry environments, especially if synthetic materials are present. The Contour Next meter meets the requirements of IEC 61000-1 for radio frequency interference. To avoid radio frequency interference, do not use the Contour Next meter near electrical or electronic equipment that are sources of electromagnetic radiation, as these may interfere with the proper operation of the meter.

Hereby, Ascensia Diabetes Care declares that the radio equipment type Blood Glucose Meter is in compliance with Directive 2014/53/EU.

The full text of the EU declaration of conformity is available at the following Internet address:
www.diabetes.ascensia.com/declarationofconformity

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Product Labeling Symbols

The following symbols are used throughout the product labeling for the Contour Next blood glucose monitoring system (meter packaging and labeling, and test strip and control solution packaging and labeling).

Symbol	What It Means
	Use by date (last day of the month)
	Caution: Read all warnings and precautions in Instructions for use
	Do not reuse
STERILE R	Sterilized using Irradiation
LOT	Batch Code
	Control Discard Date
0°C 30°C	Temperature limitations
	Consult Instructions for use
IVD	In Vitro Diagnostic Medical Device
	Manufacturer
REF	Catalogue number
CONTROL L	Control Range Low
CONTROL N	Control Range Normal
CONTROL H	Control Range High
	Shake 15 times

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Symbol	What It Means
	Number of test strips included
	Recycle Packaging
	Batteries must be disposed of in accordance with laws in your country. Contact your competent local authority for information on the relevant laws regarding disposal and recycling in your area. The meter should be treated as contaminated and disposed of according to local safety rules. It should not be disposed of with waste electronic equipment. Contact your health care professional or local waste disposal authority for medical waste disposal guidelines.

Principles of the Procedure: The Contour Next blood glucose test is based on measurement of electrical current caused by the reaction of the glucose with the reagents on the electrode of the test strip. The blood sample is drawn into the tip of the test strip through capillary action. Glucose in the sample reacts with FAD glucose dehydrogenase (FAD-GDH) and the mediator. Electrons are generated, producing a current that is proportional to the glucose in the sample. After the reaction time, the glucose concentration in the sample is displayed. No calculation by the user is required.

Comparison Options: The Contour Next system is designed for use with capillary and venous whole blood. Comparison with a laboratory method must be done simultaneously with aliquots of the same sample.

NOTE: Glucose concentrations drop rapidly due to glycolysis (approximately 5%–7% per hour).[7]

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References

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Warranty

Manufacturer's Warranty: Ascensia Diabetes Care warrants to the original purchaser that this instrument will be free from defects in materials and workmanship for 5 years from the date of original purchase (except as noted below). During the stated 5-year period, Ascensia Diabetes Care shall, at no charge, replace a unit found to be defective with an equivalent or current version of the meter's model.

Limitations of Warranty: This warranty is subject to the following exceptions and limitations:

1. A 90-day warranty only will be extended for consumable parts and/or accessories.
2. This warranty is limited to replacement due to defects in parts or workmanship. Ascensia Diabetes Care shall not be required to replace any units that malfunction or are damaged due to abuse, accidents, alteration, misuse, neglect, maintenance by someone other than Ascensia Diabetes Care, or failure to operate the instrument in accordance with instructions. Further, Ascensia Diabetes Care assumes no liability for malfunction of or damage to Ascensia Diabetes Care instruments caused by the use of test strips or control solution other than the appropriate products recommended by Ascensia Diabetes Care (i.e., Contour Next test strips and Contour Next control solutions).
3. Ascensia Diabetes Care reserves the right to make changes in the design of this instrument without obligation to incorporate such changes into previously manufactured instruments.

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4. Ascensia Diabetes Care has no knowledge of the performance of the Contour Next blood glucose meter when used with any test strips other than Contour Next test strips, and therefore does not warrant the performance of the Contour Next meter when used with any test strips other than Contour Next test strips or when the Contour Next test strip is altered or modified in any manner.
5. Ascensia Diabetes Care makes no warranty regarding the performance of the Contour Next meter or test results when used with any control solution other than Contour Next control solution.
6. Ascensia Diabetes Care makes no warranty regarding the performance of the Contour Next meter or test results when used with any software other than the Contour Diabetes app (where supported) from Ascensia Diabetes Care.

ASCENSIA DIABETES CARE MAKES NO OTHER EXPRESS WARRANTY FOR THIS PRODUCT. THE OPTION OF REPLACEMENT, DESCRIBED ABOVE, IS THE ONLY OBLIGATION OF ASCENSIA DIABETES CARE UNDER THIS WARRANTY.

IN NO EVENT SHALL ASCENSIA DIABETES CARE BE LIABLE FOR INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES, EVEN IF ASCENSIA DIABETES CARE HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

For warranty service: Purchaser must contact Ascensia Diabetes Care Customer Service for assistance and/or instructions for obtaining service of this instrument. See *Contact Information*.

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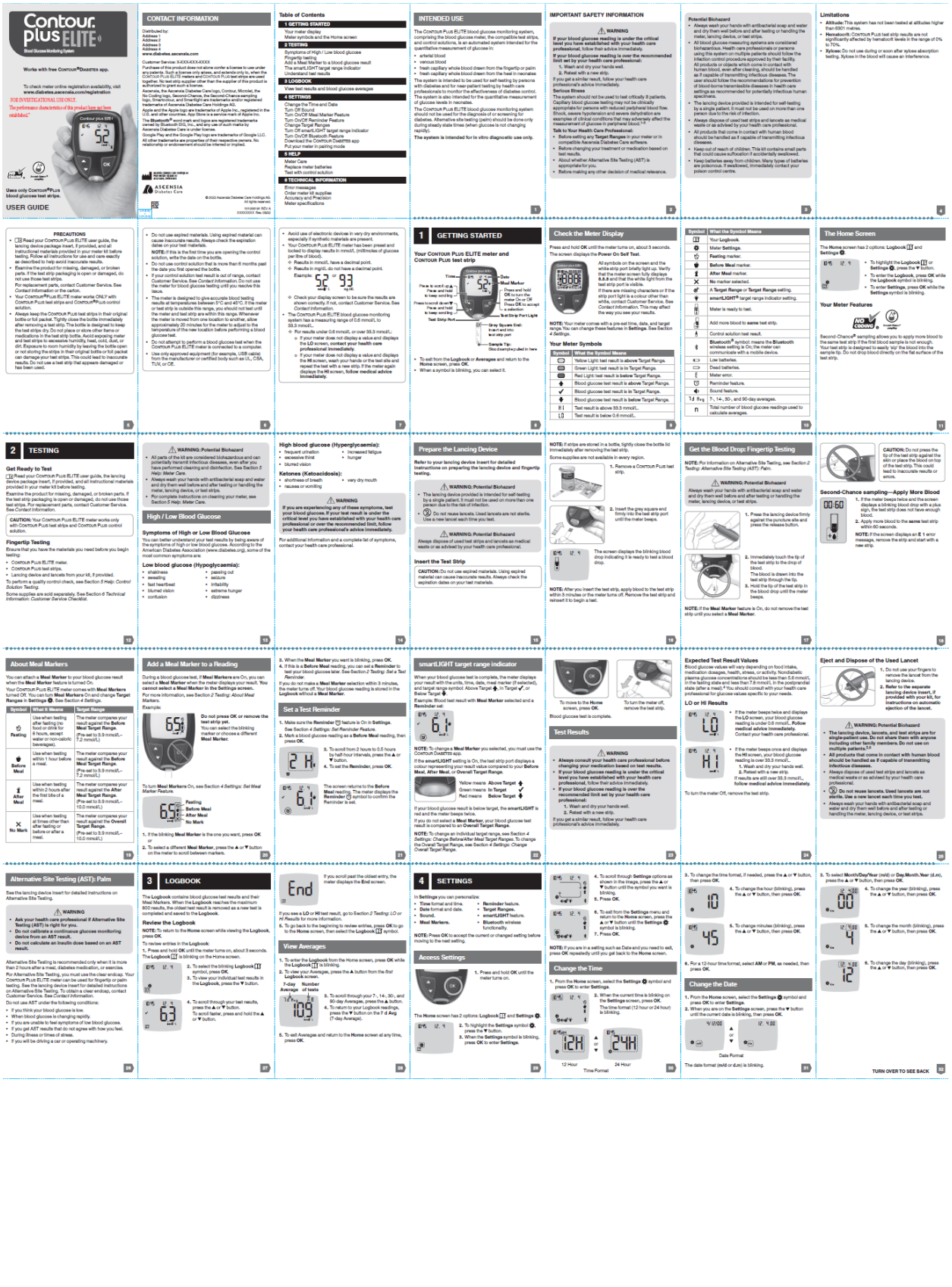
Attachment 2 - CONTOUR PLUS ELITE User Guide



Set the Sound

1. From the **Home** screen, select the **Settings** ⚙ symbol and press **OK** to enter **Settings**.
2. When you are on the **Settings** screen, press the ▼ button repeatedly until the **Sound** 🔊 symbol is blinking, then press **OK**.

Sound Symbol 🔊

3. To turn the **Sound** On or Off, press the ▲ or ▼ button.
4. Press **OK**.

Your meter comes with the **Sound** turned On. Certain error messages override any **Sound** setting.

When **Sound** is On:

- One long beep indicates a confirmation.
- Two beeps indicate an error or something that needs your attention.

NOTE: Some sounds remain On even when you turn the **Sound** feature Off. To turn sounds Off for a below-target blood glucose reading, turn the **smartLIGHT** feature to Off.

Set Meal Marker Feature

1. From the **Home** screen, select the **Settings** ⚙ symbol and press **OK** to enter **Settings**.
2. When you are on the **Settings** screen, press the ▼ button repeatedly until the **Meal Marker** symbol is blinking, then press **OK**.

Meal Marker Symbols

Your meter comes with the **Meal Marker** feature turned Off.

3. To turn **Meal Markers** On or Off, press the ▲ or ▼ button.
4. Press **OK**.

NOTE: When the **Meal Marker** feature is On, you can select a **Meal Marker** during a blood glucose test.

Set Reminder Feature

When **Meal Markers** are On, you can set a **Reminder** to test your blood glucose after you mark a reading as **Before Meal**. If **Meal Markers** are Off, see Section *4 Settings: Set Meal Marker Feature*.

1. From the **Home** screen, select the **Settings** ⚙ symbol and press **OK** to enter **Settings**.
2. When you are on the **Settings** screen, press the ▼ button repeatedly until the **Reminder** symbol is blinking, then press **OK**.

Your meter comes with the **Reminder** feature turned Off.

3. To turn the **Reminder** feature On or Off, press the ▲ or ▼ button.

Reminder Symbol

4. Press **OK**.

Change Overall Target Range

⚠ **WARNING**

Discuss your Target Range settings with your health care professional.

Your meter provides a pre-set **Overall Target Range**. You can change the **Overall Target Range** in **Settings**.

1. From the **Home** screen, select the **Settings** ⚙ symbol and press **OK** to enter **Settings**.
2. When you are on the **Settings** screen, press the ▼ button repeatedly until the **Target** symbol is blinking, then press **OK**.

3. To change the blinking **Low** end of the **Overall Target Range**, press the ▲ or ▼ button.
4. Press **OK**.

5. To change the blinking **High** end of the **Overall Target Range**, press the ▲ or ▼ button.
6. Press **OK**.

Change Before/After Meal Target Ranges

When the **Meal Marker** feature is On, you have 2 Target Ranges on your meter: a **Before Meal Target Range** (the same as Fasting) and an **After Meal Target Range**.

You can change these ranges in **Settings** in your meter and in the CONTOUR DIABETES app.

1. From the **Home** screen, select the **Settings** ⚙ symbol and press **OK** to enter **Settings**.
2. When you are on the **Settings** screen, press the ▼ button repeatedly until the **Target** symbol is blinking, then press **OK**.

Before Meal/After Meal Low Target

The **Before Meal** / **After Meal** **Low Target** number is blinking.

NOTE: There is only 1 **Low** number for both the **Before Meal** and **After Meal** Target Ranges.

3. To change the blinking **Low** end for both Target Ranges, press the ▲ or ▼ button.
4. Press **OK**.

Before Meal High Target

5. To change the blinking **High** end of the **Before Meal Target Range**, press the ▲ or ▼ button.
6. Press **OK**.

NOTE: The **Before Meal Target Range** is also the Target Range for a blood glucose reading marked as **Fasting**.

After Meal High Target

7. To change the blinking **High** end of the **After Meal Target Range**, press the ▲ or ▼ button.
8. Press **OK**.

Set smartLIGHT target range indicator

Your meter comes with the **smartLIGHT** target range indicator turned On. When this feature is On, the test strip port light displays a colour that corresponds to your test result.

Yellow means **Above Target** ↑
Green means **In Target** ✓
Red means **Below Target** ↓

1. From the **Home** screen, select the **Settings** ⚙ symbol and press **OK** to enter **Settings**.
2. When you are on the **Settings** screen, press the ▼ button repeatedly until the **smartLIGHT** symbol is blinking, then press **OK**.

smartLIGHT Symbol

3. To turn the **smartLIGHT** feature On or Off, press the ▲ or ▼ button to display the option you want.
4. Press **OK**.

Set Bluetooth Wireless Functionality

After pairing your meter with a mobile device, you can turn the **Bluetooth** setting On or Off. For pairing instructions, see Section *4 Settings: Pairing Mode*.

1. From the **Home** screen, select the **Settings** ⚙ symbol and press **OK** to enter **Settings**.
2. When you are on the **Settings** screen, press the ▼ button repeatedly until the **Bluetooth** ᛒ symbol is blinking, then press **OK**.

Bluetooth Symbol ᛒ

3. To turn **Bluetooth** wireless functionality On or Off, press the ▲ or ▼ button.
4. Press **OK**.

CONTOUR DIABETES app

The CONTOUR DIABETES app for Your CONTOUR PLUS ELITE meter

Your CONTOUR PLUS ELITE meter is designed to work with the CONTOUR DIABETES app and your compatible smartphone or tablet.

You can do the following with your CONTOUR DIABETES app:

- Add Notes after testing that help to explain your results.
- Set testing reminders.
- Access easy-to-read graphs of test results over a day or over a period of time.
- Share reports.
- Change meter settings, as necessary.

The CONTOUR DIABETES app:

- Automatically stores your results.
- Saves your Notes in **My Readings**.
- Displays your trends and test results as they compare with your targets.
- Offers quick and valuable tips to help you manage your diabetes.
- Syncs your most recent Target Range from the app or meter, across the system.
- Syncs the app date and time to your meter.

Download the CONTOUR DIABETES app

1. On your compatible smartphone or tablet, go to the App Store℠ or the Google Play™ store.
2. Search for the CONTOUR DIABETES app.
3. Install the CONTOUR DIABETES app.

CAUTION: The CONTOUR PLUS ELITE meter has not been tested for use with any software other than compatible Ascensia Diabetes Care software. The manufacturer is not responsible for any erroneous results from the use of other software.

Pairing Mode

CAUTION: There is a remote possibility that a computer specialist could listen in on your wireless communications when you pair the blood glucose meter and would then be able to read your blood glucose readings from your meter. If you believe this is a risk, pair your blood glucose meter far away from other people. After you pair your device, you do not need to take this precaution.

To pair your meter with the CONTOUR DIABETES app, download the app and follow the instructions to *Pair a Meter*.

To put your meter in pairing mode:

1. If your meter is off, press and HOLD **OK** until the meter turns on. The meter displays the **Home** screen.

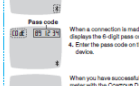
2. Press and HOLD the ▲ button for about 3 seconds, until you see the blinking **Bluetooth** symbol (as shown in the next step). A blue light blinks when you are in pairing mode.

3. When the meter displays the serial number, follow the instructions on the app to match the meter serial number.

Meter serial number

Example: Your meter in pairing mode.

Pass code



When a connection is made, the meter displays the 6-digit pass code.

4. Enter the pass code on the smart device.

When you have successfully paired your meter with the CONTOUR DIABETES app, the meter displays a blue light and the **Bluetooth** symbol.

The meter returns to the **Home** screen.

Bluetooth

NOTE: You can update your Target Ranges from the meter or from the app. The most recently changed Target Ranges will update in the meter and the app when they are synced.

5 HELP

Meter Care

Caring for your meter:

- Store the meter in the carrying case provided, whenever possible.
- Wash and dry hands well before handling to keep the meter and test strips free of water, oils, and other contaminants.
- Handle the meter carefully to avoid damaging the electronics or causing other malfunctions.
- Avoid exposing your meter and test strips to excessive humidity, heat, cold, dust, or dirt.

Cleaning and Disinfection

CAUTION: Do not allow cleaning or disinfectant solution to run into the meter through open areas, such as around the buttons or the meter's test strip or data ports, such as the USB port.

NOTE: Using cleaning and disinfecting solutions other than those recommended by the manufacturer could result in damage to system components.

The cleaning and disinfecting directions provided should not cause any damage or degradation to the external case, buttons, or display.

Your CONTOUR PLUS ELITE meter has been tested for 260 cycles of cleaning and disinfection (equivalent to one cycle per week for 5 years). This device has been demonstrated to withstand 5 years of cleaning and disinfection without damage.

You should call Customer Service for assistance if your device malfunctions for any reason or if you notice any changes in the external meter case or display.

Self-Testing

It is recommended to clean and then disinfect your meter once a week.

NOTE: Do not insert anything into the test strip port or attempt to clean inside the test strip port.

1. The exterior of the meter may be cleaned using a moist (not wet) lint-free tissue with soapy water.
2. For disinfection, clean and then disinfect the meter for 1 minute using a solution made of 1 part bleach mixed with 9 parts water. Alternatively, commercially available wipes containing 0.55% sodium hypochlorite (bleach) may be used following the instructions provided with the wipes.
3. Dry the meter with lint-free tissue after cleaning and disinfection.

Health Care Professionals

Health care professionals or persons using this system on multiple patients should follow the infection control procedure and the recommendations for prevention of blood-borne transmissible diseases approved by their facility. The CONTOUR PLUS ELITE meter case components have been shown to be compatible (by soaking for 168 hours) with the following disinfectant solutions: 70% isopropyl alcohol, 6.0% sodium hypochlorite (full bleach), 0.6% sodium hypochlorite (diluted bleach), and didecyldimethylammonium chloride (DDAC).

Technical Assistance

If you notice any of the following signs of deterioration after cleaning or disinfecting of your meter system, stop using the system and contact Customer Service at **www.diabetes.ascensia.com** for assistance:

- Cloudy or damaged display.
- on/off button malfunction.
- or quality control results outside of the specified range.

Transfer Results to a Personal Computer

CAUTION: Do not attempt to perform a blood glucose test when the CONTOUR PLUS ELITE meter is connected to a computer.

You can transfer test results from the CONTOUR PLUS ELITE meter to a computer where they can be summarized in a report with graphs and tables. To make use of this feature, you need diabetes management software and a 1-metre (or 3-foot) long USB-A to Micro USB-B cable. This type of cable is available in electronics retail stores.

Ensure your meter's USB port door is completely closed when not in use.

USB Port

CAUTION: Use only approved equipment (for example, USB cable) from the manufacturer or certified body such as UL, CSA, TUV, or CE.

Batteries

When the batteries are low, the meter operates normally, displaying the **Low Batteries** symbol until you replace the batteries.

When you are no longer able to perform a test, the meter displays the **Dead Batteries** screen. Replace the batteries immediately.

Replace the Batteries

1. Turn off your meter.
2. Turn the meter over and slide the battery cover in the direction of the arrow.

3. Remove both of the old batteries and replace them with two 3-volt CR2032 or DL2032 coin cell batteries.

NOTE: Always check the date and time after you replace the batteries.

4. Make sure the "+" sign is facing up on the new batteries.
5. Press each battery into a compartment.
6. Slide the battery cover back into place.
7. Discard old batteries according to your local environmental regulations.

⚠ **WARNING**

Keep batteries away from children. Many types of batteries are poisonous. If swallowed, immediately contact your poison control centre.

Control Solution

⚠ **WARNING**

Shake the control solution well before testing.

CAUTION: Use only CONTOUR PLUS control solution (Normal, Low, and High) with your CONTOUR PLUS ELITE blood glucose monitoring system. Using anything other than CONTOUR PLUS control solution can cause inaccurate results.

You should perform a control test when:

- Using your meter for the first time.
- You open a new package of test strips.
- You think your meter may not be working properly.
- You have repeated, unexpected blood glucose results.

⚠ **WARNING**

- **Do not calibrate your continuous glucose monitoring device from the control result.**
- **Do not calculate an insulin dose based on a control result.**

Some supplies are not available in every region.

CAUTION: Do not use expired materials. Using expired material can cause inaccurate results. Always check the expiration dates on your test materials.

Refer to your control solution insert.

Normal, Low, or High control solutions are available and sold separately if not included in the meter kit. You should test your CONTOUR PLUS ELITE meter with control solution only when the temperature is 15°C–35°C. Store control solutions between 9°C and 30°C.

Contact Customer Service to obtain control solution. See *Contact Information*.

Control Solution Testing

NOTE: Tightly close the bottle lid immediately after you remove the test strip.

1. Remove a CONTOUR PLUS test strip from the bottle or foil packet.

2. Insert the grey square end of the test strip into the test strip port until the meter beeps.

The meter turns on, displaying a test strip with a flashing blood drop.

CAUTION: Do not use control solution that is more than 6 months past the date you first opened the bottle.

NOTE: If this is the first time you are opening the control solution, write the date on the bottle.

3. Shake the control solution bottle well, about 15 times before every use.

Unmixed control solution may cause inaccurate results.

4. Remove the bottle cap and use a tissue to wipe away any solution around the bottle tip before dispensing a drop.
5. Squeeze a small drop of solution onto a clean, nonabsorbent surface.

CAUTION: Do not apply control solution to your fingertip or to the test strip directly from the bottle.

6. Immediately touch the tip of the test strip to the drop of control solution.
7. **Hold the tip in the drop until the meter beeps.**

The meter counts down for 5 seconds before the meter displays the control test result. The meter automatically marks the result as a control test. Control test results are not included in your meter **Logbook**, in blood glucose averages, or in targets in the CONTOUR DIABETES app.

8. Compare your control test result with the range printed on the test strip bottle, foil packet, or bottom of the test strip box.
9. Remove the test strip and dispose as medical waste or as advised by your health care professional.

If your control test result is out of range, do not use your CONTOUR PLUS ELITE meter for blood glucose testing until you resolve the issue. Contact Customer Service. See *Contact Information*.

6 TECHNICAL INFORMATION

Error Detection Displays

The meter screen displays error codes (E plus a number) for test result errors, strip errors, or system errors. When an error occurs, the meter beeps 2 times and displays an error code. Press **OK** to turn off the meter.

If you experience continued errors, contact Customer Service. See *Contact Information*.

Error Code	What It Means	What to Do
Strip Errors		
E1	Too Little Blood	Remove the strip. Repeat the test with a new strip.
E2	Used Test Strip	Remove the strip. Repeat the test with a new strip.
E3	Strip Upside Down	Remove the strip and insert it correctly.
E4	Wrong Strip Inserted	Remove the strip. Repeat the test with a CONTOUR PLUS test strip.
E6	Moisture Damaged Strip	Remove the strip. Repeat the test with a new strip.
E8	Strip or Test Errors	Repeat the test with a new strip. If the error persists, contact Customer Service.

Error Code	What It Means	What to Do
Testing Errors		
E20	Testing Error	Repeat the test with a new strip. If the error persists, contact Customer Service.
E24	Too Cold to Test Control Solution	Move the meter, strip, and control solution to a warmer area. Test in 20 minutes.
E25	Too Hot to Test Control Solution	Move the meter, strip, and control solution to a cooler area. Test in 20 minutes.
E27	Too Cold to Test	Move the meter and strip to a warmer area. Test in 20 minutes.
E28	Too Hot to Test	Move the meter and strip to a cooler area. Test in 20 minutes.
System Errors		
E30–E99	Meter software or hardware malfunctioned	Turn the meter off. Turn the meter back on. If the error persists, contact Customer Service.

Speak to a Customer Service representative before returning your meter for any reason. Contact Customer Service. See *Contact Information*.

Customer Service Checklist

When speaking with the Customer Service representative:

1. Have your CONTOUR PLUS ELITE blood glucose meter, CONTOUR PLUS test strips, and CONTOUR PLUS control solution available when you call.
2. Locate the model number (**A**) and serial number (**B**) on the back of the meter.
3. Locate the test strips' expiration date on the bottle or foil packet.
4. Check the battery status.

Parts Information

To replace missing parts or reorder supplies, contact Customer Service. See *Contact Information*.

- Two 3-volt CR2032 or DL2032 coin cell batteries.
- CONTOUR PLUS ELITE user guide.
- CONTOUR PLUS ELITE quick reference guide.
- CONTOUR PLUS test strips.
- CONTOUR PLUS normal control solution.
- CONTOUR PLUS low control solution.
- CONTOUR PLUS high control solution.
- Lancing device, as in your kit, if provided.
- Lancets, as in your kit, if provided.

Some supplies are sold separately and are not available through Customer Service.

Technical Information: Accuracy

The CONTOUR PLUS ELITE blood glucose monitoring system was tested with capillary blood samples from 100 subjects. Two replicates were tested with each of 3 lots of CONTOUR PLUS test strips for a total of 600 readings. Results were compared to the YSI glucose analyzer, which is traceable to the CDC hexokinase method. The following accuracy results were obtained.

Table 1: System accuracy results for glucose concentration < 5.55 mmol/L.

Difference range in values between YSI laboratory reference method and CONTOUR PLUS ELITE meter	Within ± 0.28 mmol/L	Within ± 0.56 mmol/L	Within ± 0.83 mmol/L
Number (and percent) of samples within specified range	154 of 174 (88.5%)	174 of 174 (100%)	174 of 174 (100%)

Table 2: System accuracy results for glucose concentration ≥ 5.55 mmol/L

Difference range in values between YSI laboratory reference method and CONTOUR PLUS ELITE meter	Within ± 5%	Within ± 10%	Within ± 15%
Number (and percent) of samples within specified range	350 of 426 (82.2%)	425 of 426 (99.8%)	426 of 426 (100%)

Table 3: System accuracy results for glucose concentrations from 1.2 mmol/L to 28.8 mmol/L

Within ± 0.83 mmol/L or ± 15%
600 of 600 (100%)

Acceptance criterion in ISO 15197:2013 is that 95% of the measured glucose values shall fall within either ± 0.83 mmol/L of the average measured values of the reference measurement procedure at glucose concentrations < 5.55 mmol/L or within ± 15% at glucose concentrations ≥ 5.55 mmol/L.

User Accuracy

A study evaluating glucose values from fingertip capillary blood samples obtained by 128 lay persons showed the following results:

100% within ± 0.83 mmol/L of the medical laboratory values at glucose concentrations < 5.55 mmol/L and 99.1% within ± 15% of the medical laboratory glucose concentrations ≥ 5.55 mmol/L.

Technical Information: Precision

A measurement repeatability study was conducted with the CONTOUR PLUS ELITE blood glucose monitoring system using 5 venous whole blood specimens with glucose levels from 2.2 mmol/L to 19.3 mmol/L. With each blood specimen, each of 3 lots of CONTOUR PLUS test strips was tested 10 times on each of 10 instruments for a total of 300 readings. The following precision results were obtained.

Table 1: System repeatability results for CONTOUR PLUS ELITE meter using CONTOUR PLUS test strips

Mean, mmol/L	Pooled Standard Deviation, mmol/L	95% CI of SD, mmol/L	Coefficient of Variation, %
2.28	0.06	0.058–0.069	2.8
4.40	0.06	0.054–0.064	1.3
7.77	0.10	0.095–0.113	1.3
12.00	0.14	0.130–0.154	1.2
19.29	0.24	0.224–0.265	1.3

Intermediate measurement precision (which includes variability across multiple days) was evaluated using control solutions and 3 glucose levels. With each control solution, each of 3 lots of CONTOUR PLUS test strips was tested once on each of 10 instruments on 10 separate days for a total of 300 readings. The following precision results were obtained.

Table 2: System intermediate precision results for CONTOUR PLUS ELITE meter using CONTOUR PLUS test strips

Control Level	Mean, mmol/L	Pooled Standard Deviation, mmol/L	95% CI of SD, mmol/L	Coefficient of Variation, %
Low	2.38	0.03	0.029–0.035	1.3
Normal	7.09	0.08	0.073–0.086	1.1
High	20.77	0.26	0.239–0.283	1.2

Specifications

Test Sample: Arterial, capillary and venous whole blood
Test Result: Referenced to plasma/serum glucose
Sample Volume: 0.6 µL
Measuring Range: 0.6 mmol/L–33.3 mmol/L of glucose in blood
Countdown Time: 5 seconds
Memory: Stores most recent 800 test results
Battery Type: Two 3-volt CR2032 or DL2032 coin cell batteries, 225 mAh capacity
Battery Life: Approximately 1000 tests (1 yr. average use, 3 tests per day)

Meter Storage Temperature Range: -4°C to 158°F

Meter Operating Temperature Range: 50°F to 113°F

Control Testing Temperature Range: 59°F

Meter Operating Humidity Range: 10%–90%, Rh
Test Strip Storage Conditions: 0°C–30°C, 10%–80% Relative Humidity (Rh)
Dimensions: 78.8 mm (L) x 56 mm (W) x 18 mm (H)
Weight: 53 grams
Meter Life: 5 years with normal use in accordance with instructions

Sound Output: 45 dB(A)–85 dB(A) at a distance of 10 cm
Radio Frequency Technology: Bluetooth Low Energy
Radio Frequency Band: 2.4 GHz–2.483 GHz
Maximum Radio Transmitter Power: 1 mW
Modulation Technique: Frequency Shift Keying (GFSK)
Electromagnetic Compatibility (EMC): The CONTOUR PLUS ELITE meter complies with the electromagnetic requirements specified in ISO 15197:2013. Electromagnetic emissions are low and unlikely to interfere with other nearby electronic equipment, nor are emissions from nearby electronic equipment likely to interfere with the CONTOUR PLUS ELITE meter. The CONTOUR PLUS ELITE meter meets the requirements of IEC 61000-4-2 for immunity to electrostatic discharge. Avoid use of electronic devices in very dry environments, especially if synthetic materials are present. The CONTOUR PLUS ELITE meter meets the requirements of IEC 61326-1 for radio frequency interference. To avoid radio frequency interference, do not use the CONTOUR PLUS ELITE meter near electrical or electronic equipment that are sources of electromagnetic radiation, as these may interfere with the proper operation of the meter.

Hereby, Ascensia Diabetes Care declares that the radio equipment type Blood Glucose Meter is in compliance with Directive 2014/53/EU.

The full text of the EU declaration of conformity is available at the following Internet address:
www.diabetes.ascensia.com/declarationofconformity

Product Labeling Symbols

The following symbols are used throughout the product labeling for the CONTOUR PLUS ELITE blood glucose monitoring system (meter packaging and labeling, and test strip and control solution packaging and labeling).

Symbol	What It Means
	Use by date (last day of the month)
	Caution; Read all warnings and precautions in Instructions for use
	Do not reuse
STRILE 1	Sterilized using irradiation
LOT	Batch Code
	Control Discard Date
	Temperature limitations
	Consult Instructions for use
IVD	In Vitro Diagnostic Medical Device
	Manufacturer
REF	Catalogue number
NORMAL	Control Range Low
NORMAL	Control Range Normal
NORMAL	Control Range High
	Shake 15 times

Symbol	What It Means
	Number of test strips included
	Recycle Packaging
	Batteries must be disposed of in accordance with laws in your country. Contact your competent local authority for information on the relevant laws regarding disposal and recycling in your area. The meter should be treated as contaminated and disposed of according to local safety rules. It should not be disposed of with waste electronic equipment. Contact your health care professional or local waste disposal authority for medical waste disposal guidelines.

Principles of the Procedure: The CONTOUR PLUS ELITE blood glucose test is based on measurement of electrical current caused by the reaction of the glucose with the reagents on the electrode of the test strip. The blood sample is drawn into the tip of the test strip through capillary action. Glucose in the sample reacts with FAD glucose dehydrogenase (FAD-GDH) and the mediator. Electrons are generated, producing a current that is proportional to the glucose in the sample. After the reaction time, the glucose concentration in the sample is displayed. No calculation by the user is required.

Comparison Options: The CONTOUR PLUS ELITE system is designed for use with capillary and venous whole blood. Comparison with a laboratory method must be done simultaneously with aliquots of the same sample.

NOTE: Glucose concentrations drop rapidly due to glycolysis (approximately 5%–7% per hour).

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6. Centers for Disease Control and Prevention. Infection Prevention during Blood Glucose Monitoring and Insulin Administration. US Department of Health and Human Services; update June 8, 2017. http://www.cdc.gov/injectionsafety/blood-glucose-monitoring.html
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Warranty

Manufacturer's Warranty: Ascensia Diabetes Care warrants to the original purchaser that this instrument will be free from defects in materials and workmanship for 5 years from the date of original purchase (except as noted below). During the 5-year period, Ascensia Diabetes Care shall, at no charge, replace a unit found to be defective with an equivalent or current version of the owner's model.

Limitations of Warranty: This warranty is subject to the following exceptions and limitations:

1. A 90-day warranty only will be extended for consumable parts and/or accessories.
2. This warranty is limited to replacement due to defects in parts or workmanship. Ascensia Diabetes Care shall not be required to replace any units that malfunction or are damaged due to abuse, accidents, alteration, misuse, neglect, maintenance by someone other than Ascensia Diabetes Care, or failure to operate the instrument in accordance with Instructions. Further, Ascensia Diabetes Care assumes no liability for malfunction or damage to Ascensia Diabetes Care Instruments caused by the use of test strips or control solution other than the appropriate products recommended by Ascensia Diabetes Care (i.e., CONTOUR PLUS test strips and CONTOUR PLUS control solutions).
3. Ascensia Diabetes Care reserves the right to make changes in the design of this Instrument without obligation to incorporate such changes into previously manufactured Instruments.

4. Ascensia Diabetes Care has no knowledge of the performance of the CONTOUR PLUS ELITE blood glucose meter when used with any test strips other than CONTOUR PLUS test strips, and therefore does not warrant the performance of the CONTOUR PLUS ELITE meter when used with any test strips other than CONTOUR PLUS test strips or when the CONTOUR PLUS test strip is altered or modified in any manner.
5. Ascensia Diabetes Care makes no warranty regarding the performance of the CONTOUR PLUS ELITE meter or test results when used with any control solution other than CONTOUR PLUS control solution.
6. Ascensia Diabetes Care makes no warranty regarding the performance of the CONTOUR PLUS ELITE meter or test results when used with any software other than the CONTOUR DIABETES app (where supported) from Ascensia Diabetes Care.

ASCENSIA DIABETES CARE MAKES NO OTHER EXPRESS WARRANTY FOR THIS PRODUCT. THE OPTION OF REPLACEMENT, DESCRIBED ABOVE, IS THE ONLY OBLIGATION OF ASCENSIA DIABETES CARE UNDER THIS WARRANTY.

IN NO EVENT SHALL ASCENSIA DIABETES CARE BE LIABLE FOR INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES, EVEN IF ASCENSIA DIABETES CARE HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

For warranty service: Purchaser must contact Ascensia Diabetes Care Customer Service for assistance and/or instructions for obtaining service of this Instrument. See *Contact Information*.