

# **Summary of Safety and Performance for Blood Glucose Monitoring System (Model: 1017+, 1018+)**

## Foreword

This Summary of Safety and Performance (SSP) is intended to provide public access to an updated summary of the main aspects of the safety and performance of the Blood Glucose Monitoring System (Model: 1017+, 1018+) .

The SSP is not intended to replace the Instructions For Use as the main document to ensure the safe use of the device, nor is it intended to provide diagnostic or therapeutic suggestions.

The SSP is not intended to give general advice on the diagnosis and/or treatment of a medical condition. Please contact your healthcare professional in case you have questions about your medical condition or about the use of the device in your situation.

## 1. Device Identification and General Information

### 1.1. Manufacturer

MicroTech Medical(Hangzhou) Co., Ltd.

No. 108 Liuze St., Cangqian, Yuhang District, Hangzhou, 311121 Zhejiang

P.R.China.

SRN: CN-MF-000001157

### 1.2. Device Trade Name

GoChek2 Blood Glucose Monitoring System (Model 1017+)

GoChek2 Connect Blood Glucose Monitoring System (Model 1018+)

### 1.3. Basic UDI-DI and EMDN Code

Product/Components	Model	Basic UDI-DI	EMDN Code
Blood Glucose Meters	1017+ 1018+	69585903W0201060102VX	W0201060102
Blood Glucose Test Strips	1026	69585903W0101060101V6	W0101060101
Glucose Control Solution	A-1	69585903W010106GCSXM	W0101060108
1018+ Blood Glucose Monitoring System	1018+	69585903W0201061017+SMX	/
1017+ Blood Glucose Monitoring System	1017+	69585903W0201061018+SN4	/

**1.4. Risk Class**

Class C (IVDR Annex VIII, Rule 4a and Rule 4b combined with Rule 3)

**1.5. Year when the device was first CE-marked under Regulation EU 2017/746**

Not listed yet.

**1.6. Authorised representative**

Lotus NL B.V.

Koningin Julianaplein 10, 1e Verd, 2595 AA, The Hague, Netherlands

Tel : +31644168999(Dutch)

Email:peter@lotusnl.com

Authorised Representative SRN: NL-AR-000000121

**1.7. Notified Body**

BSI Group The Netherlands B.

Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands

Notified Body Identification Number: 2797

**2. Intended Use****2.1. Intended Purpose**

The Blood Glucose Monitoring System is intended to quantitative detect glucose in whole blood samples, as an aid in monitoring the effectiveness of controlling glucose for diabetic patients. When used for self-testing (over-the-counter testing), the system can accept fresh human capillary whole blood obtained from the fingertip, forearm, and/or palm by non-professional users. Healthcare professionals can also use venous, arterial, and neonatal blood specimen with the Blood Glucose Monitoring System in a hospital environment. Test results serve only as helpful information, not for diagnosis. The Blood Glucose Monitoring System is non-automatic.

**2.2. Intended Patient Population**

Diabetes patients who need to measure the glucose concentration and take the test results as reference only.

### 2.3. Contra-Indications and Limitations

- The 1017+/1018+ meters, test strips, and other components of the 1017+/1018+ Blood Glucose Monitoring System have been designed, tested, and proven to work together effectively to provide accurate blood glucose measurements. Do not use components from other brands.
- The system is tested to accurately read the measurement of glucose in whole blood within the range of 0.6-33.3mmol/L(10 to 600 mg/dL).
- The packed cell volume (hematocrit) should be between 10% and 70%. Outside of range may cause false results. Talk to your healthcare professional to find out your hematocrit level,
- At normal therapeutic level and up to high-test concentration level of Acetaminophen , Bilirubin, Cholesterol , Creatinine, EDTA , Galactose , Genstisicacid, Glutathione, Haemoglobin, Heparin, Ibuprofen, L-DOPA,Maltose, Methyl-DOPA, Pralidoxime Iodide , Salicylicacid , Tolbutamide, Triglycerides , Uric acid, will not significantly affect blood glucose results.
- Fatty substances (triglycerides up to 3,000 mg/dL or cholesterol up to 500 mg/dL have no major effect on blood glucose test results.
- Severely ill persons should not run the glucose test with the 1026 Blood Glucose Monitoring System.
- Blood samples from patients in shock, or with severe dehydration or from patients in a hyperosmolar state (with or without ketosis) have not been tested and are not recommended for testing with 1017+/1018+ Blood Glucose Monitoring System.
- Dispose of blood samples and materials carefully. Treat all blood samples as if they are infectious materials. Follow proper precautions when disposing of materials.

## 3. Device Description

### 3.1. General Device Description

The Blood Glucose Monitoring System group, manufactured by MicroTech Medical (Hangzhou) Co., Ltd., includes two models: 1017+ and 1018+. Each system consists of meters (models 1017+ and 1018+), test strips (1026), and control solutions (A-1).

The lancing device and lancets were purchased from a third party certified with EC certificates.

This system does not have the function of ketone testing, just a reminder.

### 3.2. Work Principle

The Blood Glucose Monitoring System is a quantitative assay for the detection of glucose in whole blood sample. Amperometric technology is used for the detection of glucose from testing the strip (with whole blood sample) on the meter.

The reagent consisting of glucose dehydrogenase and a mediator is deposited onto the reaction cell section of the test strip with printed electrodes. When a drop of whole blood sample is applied to the reaction cell on the test strip, glucose in the blood sample reacts in the presence of glucose dehydrogenase and the mediator, yielding electrons. Thus, a current signal is produced from the reaction and detected by the meter. The detected current signal is then calculated by the meter, and the glucose concentration reading is displayed on the meter.

### 3.3. Components

The Blood Glucose Monitoring System are including test strips, meters, and control solutions that belong to the In-vitro Diagnosis device. The Lancing device and sterile lancets are purchased from the third-party companies with MDR certification.

#### 3.3.1. Test Strip

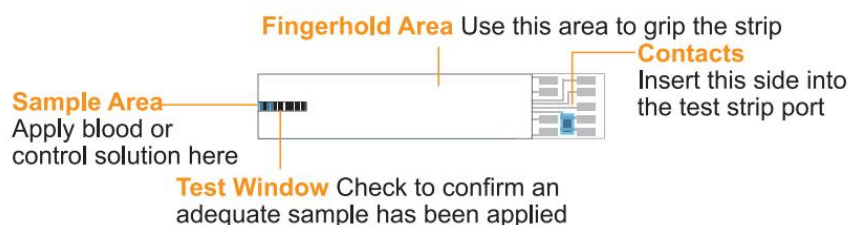


Figure 1 Blood glucose Test Strip (Illustration)

The test strip has a reagent system including glucose dehydrogenase and mediator that reacts with the glucose in the whole blood sample to produce electrical current signal. This current is measured by the meter, and after calculation by the meter, the blood glucose concentration reading, calibrated to plasma reference, is displayed on the meter display.

### 3.3.2. Glucose Control Solution

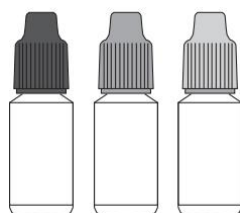


Figure 2 Glucose control solution (Illustration)

The quality control of Blood Glucose Monitoring System is performed by testing the test strip on meter with glucose control solution to confirm that the test strip and meter are working together properly. The glucose control solution contains a known concentration of glucose with preservatives in an aqueous based mixture. The control solution test result should fall within the predetermined control solution range for the given strip lot to confirm the accuracy of the GDH-FAD Blood Glucose Monitoring System group.

### 3.3.3. Meter

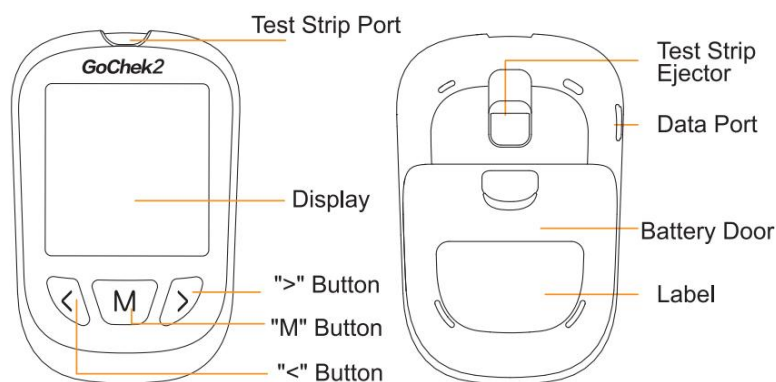


Figure 3 Blood Glucose Meter (Illustration)

The Blood Glucose Meter is mainly designed to read the Test Strips and to display the blood glucose concentration. The appearance of the meter is shown above. The meter for the Blood Glucose Monitoring System is manufactured by MicroTech Medical Co., Ltd.

### 3.4. Device to Be Used Together

#### 3.4.1. Lancing Device

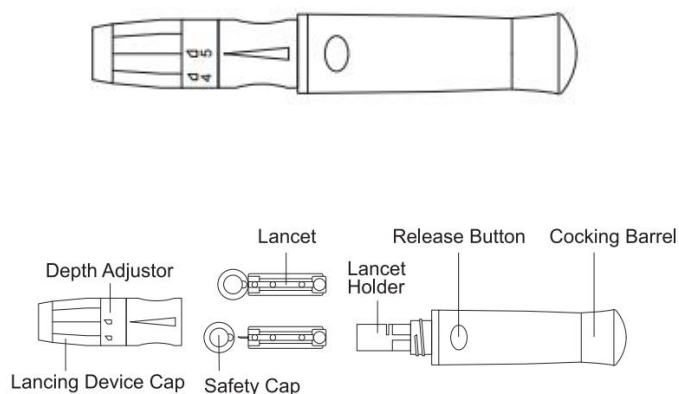


Figure 4 Lancing Device (Illustration)

The Blood Glucose Monitoring System is using for testing blood glucose levels using fresh capillary blood samples obtained from the fingertip, palm and forearm; thus, a lancing device is included in the starter kit. The lancing device included in the starter kit is manufactured by a third party vendor with sufficient CE certificates.

#### 3.4.2. Sterile Lancets

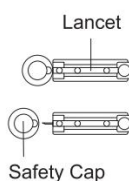


Figure 5 Sterile Lancet (Illustration)

The Blood Glucose Monitoring System is for blood glucose testing using the fingertip, palm and forearm sourced capillary blood samples; thus, lancets are included in the starter kit. The lancets included in the starter kit are manufactured by a third party vendor with sufficient CE certificates.

## 4. Applied Regulation/Directives/Standards

No	Applicable Regulation/Directives/Standards	
1	Regulation 2017/746/EC	In Vitro Diagnostic Medical Devices Regulation
2	EN ISO 13485:2016/A11:2021 (ISO 13485:2016)	Medical device-Quality management system-requirements for regulatory
3	EN ISO 14971:2019 (ISO 14971:2019)	Medical devices-Application of risk management to medical devices
4	ISO/TR 24971:2020	Medical devices — Guidance on the application of ISO 14971
5	Directive 2011/65/EU	Restriction of the use of certain hazardous substances (RoHS)
6	Directive 2015/863/EU	List of Restricted Substances
7	Regulation (EU) No 1907/2006	REACH
8	DIRECTIVE 2014/53/EU	Radio Equipment and Repealing Directive (RED)
9	ISO 18113-1:2022	In Vitro Diagnostic Medical Devices -Information Supplied by the Manufacturer (labelling) - Part 1: Terms, Definitions and General Requirements
10	ISO 18113-2:2022	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use
11	ISO 18113-3:2022	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 3: In vitro diagnostic instrument for professional use
12	ISO 18113-4:2022	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 4: In vitro diagnostic reagents for self-testing
13	ISO 18113-5:2022	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 5: In vitro diagnostic instruments for self-testing
14	EN ISO 15197:2015 (ISO 15197:2013)	In vitro diagnostic test systems Requirements for blood-glucose monitoring systems for self testing in managing diabetes mellitus
15	EN ISO 23640:2015 (ISO 23640:2011)	In vitro diagnostic medical devices-Evaluation of stability of in vitro diagnostic reagents
16	EN 13612:2002	Performance evaluation of in vitro diagnostic medical devices
17	EN62366-1:2015+A1:2020	Medical devices - Application of usability engineering to



No	Applicable Regulation/Directives/Standards	
	(IEC 62366-1:2015+A1:2020)	medical devices
18	EN 13532:2002	General requirements for in vitro diagnostic medical devices for self-testing
19	ISO 15223-1:2021 (ISO 15223-1:2021)	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements
20	EN ISO 20417:2021 (ISO 20417:2021)	Information supplied by the manufacturer of medical devices
21	EN 61010-1:2010+A1:2019 (IEC 61010-1:2010+A1:2016)	Safety requirements for electrical equipment for measurement, control, and laboratory use Part 1: General requirements
22	EN 61010-2-101:2017 (IEC 61010-2-101:2018)	Standard   Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic(IVD) medical equipment
23	EN IEC 61326-1:2021 (IEC 61326-1:2020)	Electrical equipment for measurement, control and laboratory use – EMC requirements Part 1: General requirements
24	EN IEC61326-2-6:2021 (IEC 61326-2-6:2020)	Electrical equipment for measurement, control and laboratory use
25	EN 62304:2006+A1:2015 (IEC 62304:2006+A1:2015)	Medical device software – Software life-cycle processes
26	ASTM D4169-23	Standard Practice for Performance Testing of Shipping Containers and Systems
27	EN ISO 9227:2022 (ISO 9227: 2022)	Corrosion tests in artificial atmospheres — Salt spray tests
28	EN 13641:2002/AC:2002	Elimination or reduction of risk of infection related to in vitro diagnostic reagents

## 5. Risks and Warnings

Contact your healthcare professional if you are concerned about the use of the device or about the results. This document is not intended to replace a consultation with your healthcare professional, if needed.

### 5.1. Potential Risks Control and Management

According to the requirements of MicroTech's internal procedure CQP0801, the international standards ISO 14971 and ISO/TR 24971, we carried out the product risk management work and made a systematic and comprehensive analysis of various risks of the product.

### 5.2. Remaining Risks and Undesirable Effects

In accordance with the internal procedure CQP0801, the international standards ISO 14971 and ISO/TR 24971, the risk of this product has been reduced to an acceptable standard through corrective/preventive measures.

### 5.3. Warnings and Precautions

The related warnings and precautions are mentioned in the IFU after risks analysis.

### 5.4. Summary of Field Safety Corrective Actions

The manufacturer has prepared internal procedure CQP2022 to specify the Field Safety Corrective Actions. However, to date, no Field Safety Corrective Actions (FSCA) have been undertaken for these products, as there have been no reports of death or serious health deterioration associated with the blood glucose monitoring system.

## 6. Summary of Performance Evaluation and PMPF

### 6.1. Scientific validity of the device

Type	No.	Literature	Published by	Published date
Consensus expert opinions from relevant professional associations	1	Standards of Medical Care in Diabetes – 2021	American Diabetes Association	January, 2023
	2	EN ISO 15197 2015 Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus	ISO (the International Organization for Standardization)	June, 2015
Literature	3	Glucose monitoring - state of the art and future possibilities	Pubmed	June, 1996
	4	Commercial and Scientific Solutions for Blood Glucose Monitoring—A Review	Pubmed	January, 2021
	5	Quality of Glucose Measurement with Blood	Pubmed	2010

		Glucose Meters		
	6	Effects of Drugs on Glucose Measurements With BGM meter	Pubmed	2000
	7	Evaluation of Linearity and Interference Effect on SMBG and POCT devices	Pubmed	2019
	8	Evaluation of the Impact of Hematocrit and Other Interference on the Accuracy of Hospital	Pubmed	2008

For consensus expert opinions from relevant professional associations and literature from public database, glucose testing is one of the most common and important monitoring method for diabetes mellitus. When used properly, a glucose monitoring system allows the user to monitor and take action to control the concentration of glucose present in the blood. The test method of electrochemistry method is one of the state of art blood glucose testing method. There is no obvious race/ethnic difference for glucose testing result.

## 6.2. Performance Data

The Blood Glucose Monitoring System complies with the requirements of EN ISO 15197:2015( In vitro diagnostic test systems-Requirements for blood-glucose monitoring systems for self- testing in managing diabetes mellitus )

System measurement range: 10 - 600 mg/dL (0.6-33.3 mmol/L)

Sample size:0.5 uL

Test time: 5 Seconds

### Repeatability

Ten replicate assays were each run on ten Blood Glucose Meters. Heparinized venous blood samples at five concentration levels were used in the testing. The results provided the following estimates for reproducibility, precision.

<b>Mean Value</b>	(mg/dL)	33.6	99.4	120.1	156.8	328.1
	(mmol/L)	1.87	5.52	6.67	8.71	18.23
<b>95% Confidence Interval Lower for Standard deviation</b>	(mg/dL)	0.93	2.90	3.69	4.34	9.53
	(mmol/L)	0.05	0.16	0.20	0.24	0.53
<b>95% Confidence Interval Upper for Standard deviation</b>	(mg/dL)	1.09	3.40	4.33	5.09	11.19
	(mmol/L)	0.06	0.19	0.24	0.28	0.62
<b>Coefficient of variance(%)</b>		3.0%	3.1%	3.3%	3.0%	3.1%

### System Accuracy

The capillary blood glucose measurements from at east 100 participants were taken bva trained technician using the Blood Glucose Meter(y). Capillary blood samples were obtained from fingertip, Palm,Forearm for the Gochek2 Blood Glucose Meter testing. Fingertip samples from the same subjects were also analyzed with YSI Model 2300 STAT PLUS Glucose Analyzer(x). The results were compared in the table below.

Fingertip Sample Site Tested by Technician			
Strip Lots:03160810A-1,03160810B-1,03160810C-1			
System Accuracy Results for Glucose Concentration≥100mg/dL			
Within ±5%	Within ±10%	Within ±15%	Within ±20%
276 / 462 ( 59.7%)	432 / 462 ( 93.5%)	460 / 462 ( 99.6% )	462 / 462 ( 100.0%)
System Accuracy Results for Glucose Concentration <100mg/dL			
Within ±5mg/dL	Within ±10mg/dL	Within ±15mg/dL	
121 / 150 ( 80.7% )	149 / 150 ( 99.3% )	150 / 150 ( 100.0% )	
System Accuracy Results for both Glucose Concentration≥100mg/dL and <100mg/dL			
Within ±15% or ±15mg/dL			
610 / 612 ( 99.7% )			

Palm Sample Site Tested by Technician			
Strip Lots:03160810A-1,03160810B-1,03160810C-1			
System Accuracy Results for Glucose Concentration≥100mg/dL			
Within ±5%	Within ±10%	Within ±15%	Within ±20%
242 / 462 ( 52.4%)	406 / 462 ( 87.9%)	458 / 462 ( 99.1% )	462 / 462 ( 100.0%)
System Accuracy Results for Glucose Concentration <100mg/dL			
Within ±5mg/dL	Within ±10mg/dL	Within ±15mg/dL	
115 / 150 ( 76.7% )	147 / 150 ( 98.0% )	150 / 150 ( 100.0% )	
System Accuracy Results for both Glucose Concentration≥100mg/dL and <100mg/dL			
Within ±15% or ±15mg/dL			
608 / 612 ( 99.3% )			

Forearm Sample Site Tested by Technician			
Strip Lots: 03160810A-1,03160810B-1,03160810C-1			
System Accuracy Results for Glucose Concentration≥100mg/dL			
Within ±5%	Within ±10%	Within ±15%	Within ±20%
253 / 462 ( 54.8%)	420 / 462 ( 90.9%)	460 / 462 ( 99.6% )	462 / 462 ( 100.0%)
System Accuracy Results for Glucose Concentration <100mg/dL			
Within ±5mg/dL	Within ±10mg/dL	Within ±15mg/dL	
114 / 150 ( 76.0% )	148 / 150 ( 98.7% )	150 / 150 ( 100.0% )	
System Accuracy Results for both Glucose Concentration≥100mg/dL and <100mg/dL			
Within ±15% or ±15mg/dL			
610 / 612 ( 99.7% )			

### Intermediate Precision

Ten replicate assays drawn from three strip lots were run on ten Blood Glucose Meters. These tests were run each day for a total of ten days. Control solutions at three concentration levels were used in the testing. The results provided the following intermediate precision estimates.

<b>Mean Value</b>	(mg/dL)	40	120	350
	(mmol/L)	2.22	6.67	19.44
<b>95% Confidence Interval Lower for Standard deviation</b>	(mg/dL)	0.76	2.10	6.28
	(mmol/L)	0.04	0.12	0.35
<b>95% Confidence Interval Upper for Standard deviation</b>	(mg/dL)	0.89	2.47	7.37
	(mmol/L)	0.05	0.14	0.41
<b>Coefficient of variance(%)</b>		2.0%	1.9%	1.9%

### User Performance

The fingertip capillary blood glucose measurements from at least 100 participants were taken by Layperson using the Blood Glucose Meter.

Fingertip Sample Site Tested by Layperson			
Strip Lots: 03160810A-1,03160810B-1,03160810C-1			
System Accuracy Results for Glucose Concentration≥100mg/dL			
Within ±5%	Within ±10%	Within ±15%	Within ±20%
261 / 462 ( 56.5%)	414 / 462 ( 89.6%)	457 / 462 ( 98.9% )	462 / 462 ( 100.0%)
System Accuracy Results for Glucose Concentration <100mg/dL			
Within ±5mg/dL	Within ±10mg/dL	Within ±15mg/dL	
123 / 150 ( 82.0% )	150 / 150 ( 100.0% )	150 / 150 ( 100.0% )	
System Accuracy Results for both Glucose Concentration≥100mg/dL and <100mg/dL			
Within ±15% or ±15mg/dL			
607 / 612 ( 99.2% )			

### Venous Study

The venous blood glucose measurements from 350 participants were taken by a trained technician using one lot glucose test strip and Blood Glucose Meter(y). The venous blood glucose range is 38.9 to 460.0mg/dL. The HCT(Hematocrit)range is 27.8% to 62.2%.The venous blood sample from the same subjects were also analyzed with YSI Model 2300 STAT PLUS Glucose Analyzer (x).The results were compared in the table below.

<b>Venous Sample Site Tested by Technician</b>			
<b>Strip Lot: 03160810A-1</b>			
System Accuracy Results for Glucose Concentration $\geq 100$ mg/dL			
Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	Within $\pm 20\%$
124 / 270 ( 45.9%)	233 / 270 ( 86.3%)	270 / 270 ( 100% )	270 / 270 ( 100.0%)
System Accuracy Results for Glucose Concentration $< 100$ mg/dL			
Within $\pm 5$ mg/dL	Within $\pm 10$ mg/dL	Within $\pm 15$ mg/dL	Within $\pm 20$ mg/dL
59 / 80 ( 73.8% )	78 / 80 ( 97.5% )	80 / 80 ( 100.0% )	80 / 80 ( 100.0% )
System Accuracy Results for both Glucose Concentration $\geq 100$ mg/dL and $< 100$ mg/dL			
Within $\pm 15\%$ or $\pm 15$ mg/dL			
350 / 350 ( 100% )			



### Neonatal Study

The neonatal blood glucose measurements from 106 participants were taken by a trained technician using one lot glucose test strip and the Blood Glucose Meter(y).The neonatal blood glucose range is 36.3 to 252.9mg/dL. The HCT(Hematocrit)range is 26.0% to 66.7%.The neonatal blood sample from the same subjects were also analyzed with YSI Model 2300 STAT PLUS Glucose Analyzer (x).The results were compared in the table below.

Neonatal Sample GoChek2 Result (vs. Plasma YSI with Neonatal Sample)			
Strip Lot: 03190627A-1			
System Accuracy Results for Glucose Concentration≥100mg/dL			
Within ±5%	Within ±10%	Within ±15%	Within ±20%
41 / 70 ( 58.6%)	62 / 70 ( 88.6%)	69 / 70 ( 99% )	70 / 70 ( 100%)
System Accuracy Results for Glucose Concentration <100mg/dL			
Within ±5mg/dL	Within ±10mg/dL	Within ±15mg/dL	
90 / 142 ( 63.4% )	133 / 142 ( 93.7% )	142 / 142 ( 100% )	
System Accuracy Results for both Glucose Concentration≥100mg/dL and <100mg/dL			
Within ±15% or ±15mg/dL			
211 / 212 ( 100% )			

### Arterial Study

The arterial blood glucose measurements from 100 participants were taken by a trained technician using the one lot GoChek2 glucose test strip and GoChek2 Blood Glucose Meter(y). The arterial blood glucose range is 23.2 to 521.6mg/dL. The HCT(Hematocrit) range is 21.0% to 64.0%. The arterial blood sample from the same subjects were also analyzed with YSI Model2300 STAT PLUS Glucose Analyzer(x). The results were compared in the table below.

Arterial Sample GoChek2 Result (vs. Plasma YSI with Arterial Sample)			
Strip Lot: 03190627A-1			
System Accuracy Results for Glucose Concentration≥100mg/dL			
Within ±5%	Within ±10%	Within ±15%	Within ±20%
67 / 150 ( 44.7%)	128 / 150 ( 85.3%)	149 / 150 ( 99% )	150 / 150 ( 100.0%)
System Accuracy Results for Glucose Concentration <100mg/dL			
Within ±5mg/dL	Within ±10mg/dL	Within ±15mg/dL	
37 / 54 ( 68.5% )	50 / 54 ( 92.6% )	54 / 54 ( 100.0% )	
System Accuracy Results for both Glucose Concentration≥100mg/dL and <100ma/dl			
Within ±15% or ±15mg/dL			
203 / 204 ( 100% )			

### **6.3. Summary of Performance and safety**

The precision, accuracy, Interference, temperature, humidity, hematocrit, drop, stability and other properties of the whole system were verified and evaluated, and the results showed that all the performance indicators of the system met the requirements of EN ISO 15197:2015. At the same time, safety regulations and EMC third-party testing also meet the regulatory requirements.

### **6.4. Post-market performance follow-up**

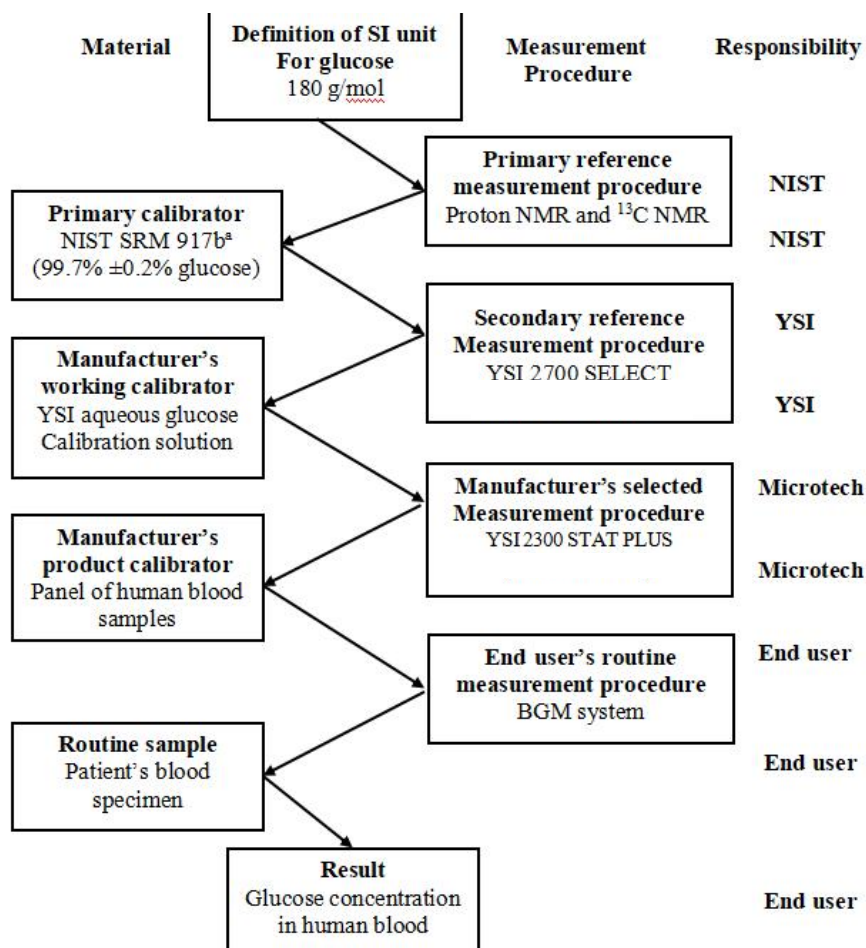
According to the requirements of IVDR, a post-market performance follow-up plan is set to evaluate whether the product performance meets the requirements of EN ISO 15197:2015 after the devices are listed under IVDR.

As a legacy device under the IVDD 98/79/EC, The device has conducted related post-market performance follow-up activities and has issued a PMPF report. During the cycle of monitoring Blood Glucose System (GDH) (2023.01.01-2023.12.31)

- a. MicroTech has collected information such as customer complaints, non-serious incidents, returned quality product, product recalls, customer questionnaires, device maintenance, experts and scientific and technical literature, and information published by social and public media after the Blood Glucose System (GDH) are placed on the market. The summary of the information is as follows: 1) There are 2 confirmed complaints about blood glucose strips (GDH) and 42 confirmed complaints about blood glucose meters, and no problems affecting safety occur and the quality, performance and safety of the product are stable; 2) There are 15 adverse events happening in China that are caused by self-discharge of the battery for too long storage of the product, improper operation of customers and poor hydrophilicity of the hydrophilic cover by chance and so on, which have nothing to do with product quality; 3) 1 case is returned due to quality reasons of blood glucose strips (GDH) and 6 cases are returned due to the quality reasons of the blood glucose meter. External packaging damage problem has been improved by starting CAPA; 4) There is no recall of this product and similar products; 5) Customers express satisfaction overall after MicroTech selects key domestic and international distributors to conduct questionnaire survey; 6) There is no device maintenance record during the cycle; 7) After literature collection and analysis, the technical level of our blood glucose system is maintained at a high level; 8) There is no information about the surveillance of similar products after placed on the market.
- b. The Blood Glucose System (GDH) have not resulted in death, serious injury or the possibility of death or serious injury during use. The current risk has been assessed to be acceptable through cause investigation and incident occurrence, combined with product risk control measures.

## 7. Metrological Traceability

A system traceability chain for the Blood Glucose Monitoring System is illustrated below:



<sup>a</sup> NIST SRM917b refers to the Certificate of Analysis issued by the National Institute of Standards and Technology (NIST) for the standard reference material (SRM) 917b, D-glucose (dextrose), used for calibration in this example.

Note: This illustration was modified from a full traceability chain taken from ISO 17511:-, 4.3.3 h.

### 7.1. The unit of measurement

The international units “mg/dL” or “mmol/L” is used according to customer requirements.

### 7.2. Calibration

YSI 2300 is selected as the reference instrument. Test results for this product can be traced to NIST SRM917b and ultimately to the definition of the international Unit of glucose (180g/mol).



## 8. Suggested profile and training for users

The IFU and Quick Operation Card will be provided to users for profile and training.

## 9. Public Revision History

Version No.	Date issued	Change description	Revision validated by the Notified Body
V1.0	January 2023	Document created	<input type="checkbox"/> YES Validation language: <input checked="" type="checkbox"/> No
V2.0	April 2024	Correct the NB number and update the performance data Update the intended purpose according to the TD and IFUs.	<input type="checkbox"/> YES Validation language: <input checked="" type="checkbox"/> No
V3.0	July 2024	Update the Basic-UDIs, performance data, Scientific validity and Post-market data	<input checked="" type="checkbox"/> YES Validation language: English <input type="checkbox"/> No
V4.0	August 2024	Update the Trade Name	<input checked="" type="checkbox"/> YES Validation language: English <input type="checkbox"/> No

