FORA®
ForaCare Suisse AG

ForaCare Suisse AG

Blood Glucose and Multi-Functional Monitoring System FAQs

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General Blood Glucose Meter questions

General Blood Glucose Meter questions:

Q1: How is the test strips used with FORA's blood glucose monitors?

Blood Glucose Only:




Model Name	**ACS045**	**ACS047**	**ACS044**	**ACS042**
Applicable meter Name	FORA 6 Plus/ Connect/ Smart/ GTel	FORA Advance Pro/ Comfort Pro	FORA Prima/Voice/ Mini/GD50	FORA Comfort Plus/ advance/ plus mini/plus voice
Enzyme Type	GDH-FAD	GDH-FAD	GDH-FAD	GOD
Sample Size	0.5 uL	1.1 uL	0.5 uL	0.5 uL
Reaction Time	5 Seconds	5 Seconds	5 Seconds	5 Seconds
Hematocrit Range	0 ~ 70%	0 ~ 70%	20 ~ 60%	20 ~ 60%
Measuring Range	10 ~ 600 mg/dL (0.55 ~ 33.3 mmol/L)	10 ~ 600 mg/dL (0.55 ~ 33.3 mmol/L)	20 ~ 600 mg/dL (1.1 ~ 33.3 mmol/L)	20 ~ 600 mg/dL (1.1 ~ 33.3 mmol/L)
Alternative Site Testing	YES AST	No AST	YES AST	YES AST
Applicable Sample (Whole Blood)	Capillary; Venous; Arterial	Capillary; Venous	Capillary; Venous	Capillary
Intended use	General Patient; Dialysis; Gestational; Neonatal	General Patient; Dialysis; Gestational; Neonatal	General Patient; Dialysis; Gestational	General Patient
Code Type	NO Code Card	NO Code Card	NO Code Card	NO Code Card

Model Name	**ACS041**	**ACS043**
Applicable meter Name	FORA Comfort basic G20	FORA Comfort check G40
Enzyme Type	GOD	GDH-FAD
Sample Size	0.7 uL	0.7 uL
Reaction Time	7 Seconds	7 Seconds
Hematocrit Range	20 ~ 60%	35 – 60 %
Measuring Range	20 ~ 600 mg/dL (1.1 ~ 33.3 mmol/L)	20 ~ 600 mg/dL (1.1 ~ 33.3 mmol/L)
Alternative Site Testing	YES AST	YES AST
Applicable Sample (Whole Blood)	Capillary;	Capillary; Venous
Intended use	General Patient	General Patient; Dialysis; Gestational
Code Type	NO Code Card	NO Code Card

BG/HCT/HB 3 in 1 Test Strip

Model Name	**ACS051**	**ACS050**
Applicable meter Name	FORA 6 Plus/ Connect/ GTel	FORA Advance Pro
Enzyme Type	GDH-FAD	GDH-FAD
Sample Size	0.5 uL	1.1 uL
Reaction Time	5 Seconds	5 Seconds
Measuring Range	BG: 10 ~ 600 mg/dL (0.55 ~ 33.3 mmol/L) HCT: 0 ~ 70% Hb: 0~23.8 g/dL	BG: 10 ~ 600 mg/dL (0.55 ~ 33.3 mmol/L) HCT: 0 ~ 70% Hb: 0~23.8 g/dL
Alternative Site Testing	YES AST	YES AST
Applicable Sample (Whole Blood)	Capillary; Venous; Arterial	Capillary; Venous
Intended use	General Patient; Dialysis; Gestational; Neonatal	General Patient; Dialysis; Gestational; Neonatal
Code Type	NO Code Card	NO Code Card

β -Ketone (KB) Strip:

Model Name	**ACS053**	**ACS052**
Applicable meter Name	FORA 6 Plus/ Connect/ GTel	FORA Advance Pro
Enzyme Type	β- Hydroxybutyrate	β- Hydroxybutyrate
Sample Size	0.8 uL	1.0 uL
Reaction Time	10 Seconds	10 Seconds
Measuring Range	0.1 ~ 8.0 mmol/L	0.1 ~ 8.0 mmol/L
Hematocrit Range	10 ~ 70%	10 ~ 70%
Alternative Site Testing	No AST	No AST
Applicable Sample (Whole Blood)	Capillary; Venous	Capillary; Venous
Intended use	General Patient	General Patient
Code Type	Need Code Card	Need Code Card

Urine Acid (UA) Strip:

Model Name	**ACS057**
Applicable meter Name	FORA 6 Plus/ Connect/ GTel
Enzyme Type	Uric Acid Catalyst
Sample Size	1.0 uL
Reaction Time	15 Seconds
Measuring Range	3 ~ 20mg/dL (0.179~1.190mmol/L)
Hematocrit Range	20 ~ 60%
Alternative Site Testing	No AST
Applicable Sample (Whole Blood)	Capillary, Venous
Intended use	General Patient
Code Type	Need Code Card

Total Cholesterol (TCH) Strip:

Model Name	**ACS055**
Applicable meter Name	FORA 6 Plus/ Connect/ GTel
Enzyme Type	Cholesterol esterase/ Cholesterol oxidase
Sample Size	3.0 uL
Reaction Time	60 Seconds
Measuring Range	100 ~ 400 mg/dL (2.6~10.4 mmol/L)
Hematocrit Range	20 ~ 60%
Alternative Site Testing	No AST
Applicable Sample (Whole Blood)	Capillary, Venous
Intended use	General Patient
Code Type	Need Code Card

Q2: What are the precision and accuracy in FORA's test strips?

1. FOR A 6 Blood Glucose Test Strip

Accuracy

The table below displays how often FORA 6 achieves this target. The chart is based on a study carried out on 100 patients (each patient was tested six times which resulted in 600 test results) to see how well FORA 6 performed compared to Cobas Integra® 400 plus reference method results.

Table 1 Accuracy results for glucose concentration < 100 mg/dL (5.55 mmol/L)

Within ±5 mg/dL (Within ±0.28mmol/L)	Within ±10 mg/dL (Within ±0.55mmol/L)	Within ±15 mg/dL* (Within ± 0.83 mmol/L)
33.3% (52/156)	73.7% (115/156)	98.7% (154/156)

Table 2 Accuracy results for glucose concentration ≥ 100 mg/dL (5.55 mmol/L)

Within ±5 %	Within ±10 %	Within ±15 %*
69.1% (307/444)	93.9% (417/444)	99.5% (442/444)

Table 3 Accuracy results for glucose concentrations between 40 mg/dL (2.22 mmol/L) to 456 mg/dL (25.3 mmol/L)

Within ±15 mg/dL or ±15% (Within ±0.83 mmol/L or ±15%)
99.3% (596/600)

Note: * According to the accuracy criteria of EN ISO 15197: 2015, 95% of all differences in glucose values (i.e., Cobas Integra® 400 plus reference values minus glucose values of FORA 6) should be within ±15 mg/dL (0.83 mmol/L) for glucose concentration < 100 mg/dL (5.55 mmol/L), and within ±15% for glucose concentration ≥ 100 mg/dL (5.55 mmol/L). When Test Strips results are compared to the reference values, difference values below 100 mg/dL (5.55 mmol/L) are expressed in mg/dL or mmol/L, while thos above 100 mg/dL (5.55 mmol/L) are in percentage.

User performance

160 subjects were tested with blood samples taken from the fingertip and the alternative sites, the palm, the forearm and the upper arm. The tables show how well FORA 6 performed compared to Cobas C311 reference method results.

Table 1 Difference distribution for glucose concentration < 100 mg/dL (5.55 mmol/L)

Tested sites	Difference within ±5mg/dL	Difference within ±10mg/dL	Difference within ±15mg/dL
Fingertip	26/43 (60.5%)	37/43 (86.0%)	43/43 (100%)
Palm	27/42 (64.3%)	41/42 (97.6%)	42/42 (100%)
Forearm	31/42 (73.8%)	39/42 (92.9%)	42/42 (100%)
Upper arm	29/42 (69.0%)	38/42 (90.5%)	41/42 (97.6%)

Table 2 Difference distribution for glucose concentration ≥ 100 mg/dL (5.55 mmol/L)

Tested sites	Difference within ±5mg/dL	Difference within ±10mg/dL	Difference within ±15mg/dL
Fingertip	59/117 (50.4%)	102/117 (87.2%)	115/117 (98.3%)
Palm	49/118 (41.5%)	92/118 (78.0%)	118/118 (100%)
Forearm	43/118 (36.4%)	84/118 (71.2%)	115/118 (97.5%)
Upper arm	49/118 (41.5%)	87/118 (73.7%)	116/118 (98.3%)

Precision

In both intermediate precision and repeatability tests, the standard deviation (SD) is within 5 mg/dL (0.28 mmol/L) for each glucose concentration < 100 mg/dL (5.55 mmol/L) and the coefficient of variation (CV) is less than 5% for each glucose concentration ≥ 100 mg/dL (5.55 mmol/L).

2. FORA 6 Blood Glucose, Hematocrit and Hemoglobin Test Strip

(1) BG

Accuracy

The table below displays how often FORA 6 achieves this target. The chart is based on a study carried out on 100 patients (each patient was tested six times which resulted in 600 test results) to see how well FORA 6 performed compared to Cobas Integra® 400 plus reference method results.

Table 1 Accuracy results for glucose concentration < 100 mg/dL (5.55 mmol/L)

Within ±5 mg/dL (Within ±0.28mmol/L)	Within ±10 mg/dL (Within ±0.55mmol/L)	Within ±15 mg/dL* (Within ± 0.83 mmol/L)
33.3% (52/156)	73.7% (115/156)	98.7% (154/156)

Table 2 Accuracy results for glucose concentration ≥ 100 mg/dL (5.55 mmol/L)

Within ±5 %	Within ±10 %	Within ±15 %*
69.1% (307/444)	93.9% (417/444)	99.5% (442/444)

Table 3 Accuracy results for glucose concentrations between 40 mg/dL (2.22 mmol/L) to 456 mg/dL (25.3 mmol/L)

Within ±15 mg/dL or ±15% (Within ±0.83 mmol/L or ±15%)
99.3% (596/600)

Note: * According to the accuracy criteria of EN ISO 15197: 2015, 95% of all differences in glucose values (i.e., Cobas Integra® 400 plus reference values minus glucose values of FORA 6) should be within ±15 mg/dL (0.83 mmol/L) for glucose concentration < 100 mg/dL (5.55 mmol/L), and within ±15% for glucose concentration ≥ 100 mg/dL (5.55 mmol/L). When Test Strips results are compared to the reference values, difference values below 100 mg/dL (5.55 mmol/L) are expressed in mg/dL or mmol/L, while thos above 100 mg/dL (5.55 mmol/L) are in percentage.

User performance

160 subjects were tested with blood samples taken from the fingertip and the alternative sites, the palm, the forearm and the upper arm. The tables show how well FORA 6 performed compared to Cobas C311 reference method results.

Table 1 Difference distribution for glucose concentration < 100 mg/dL (5.55 mmol/L)

Tested sites	Difference within ±5mg/dL	Difference within ±10mg/dL	Difference within ±15mg/dL
Fingertip	26/43 (60.5%)	37/43 (86.0%)	43/43 (100%)
Palm	27/42 (64.3%)	41/42 (97.6%)	42/42 (100%)
Forearm	31/42 (73.8%)	39/42 (92.9%)	42/42 (100%)
Upper arm	29/42 (69.0%)	38/42 (90.5%)	41/42 (97.6%)

Table 2 Difference distribution for glucose concentration ≥ 100 mg/dL (5.55 mmol/L)

Tested sites	Difference within ±5mg/dL	Difference within ±10mg/dL	Difference within ±15mg/dL
Fingertip	59/117 (50.4%)	102/117 (87.2%)	115/117 (98.3%)
Palm	49/118 (41.5%)	92/118 (78.0%)	118/118 (100%)
Forearm	43/118 (36.4%)	84/118 (71.2%)	115/118 (97.5%)
Upper arm	49/118 (41.5%)	87/118 (73.7%)	116/118 (98.3%)

Precision

In both intermediate precision and repeatability tests, the standard deviation (SD) is within 5 mg/dL (0.28 mmol/L) for each glucose concentration < 100 mg/dL (5.55 mmol/L) and the coefficient of variation (CV) is less than 5% for each glucose concentration ≥ 100 mg/dL (5.55 mmol/L).

(2) HCT:

Accuracy: ≦ ± 5% ; Precision: SD≦3

(3) HB:

Accuracy: ≦ 1.7 g/dL ; Precision: SD≦3 g/dL

In our system, the HB is calculated by HCT. Our device is not directly got the value of HB. All the hemoglobin (HB) detect tested data are calculated from hematocrit (HCT) detect tested results (Hb = HCT x 0.34). Based on this, the Hb detect linearity performance results are the same as HCT detect linearity performance results. However, normal accuracy requirement on market (without any formal regulatory requirements) is ±1.5%.

3. FORA 6 β-Ketone Test Strip

Accuracy

The table below displays how often FORA achieves this target. The chart is based on a study carried out on 160 patients (each patient was tested three times which resulted in 480 test results) to see how well FORA performed compared to β -Hydroxybutyrate LiquiColor® reference method results.

Capillary samples (n=480)	**β-ketone concentration (mmol/L)**	**Regression analysis**
	Range: 0.10 to 6.75 Mean: 1.13	y = 0.9997x - 0.0153, R^2 = 0.9912
Venous samples (n=480)	**β-ketone concentration (mmol/L)**	**Regression analysis**
	Range: 0.10 to 6.75 Mean: 1.12	y = 0.9926x - 0.0554, R^2 = 0.9772

Precision

In repeatability test, the standard deviation (SD) is within 0.1 mmol/L for each β-Ketone concentration < 1 mmol/L and the coefficient of variation (CV) is less than 7.5% for each β-Ketone concentration ≥ 1 mmol/L.

4. FORA 6 Urine Acid Test Strip

Accuracy

Results: Difference Plot Analysis

Number of subjects (N) = 160

TABLE 1 Ratio of samples (capillary whole blood) falling within different bias ranges

Within ±5 %	Within ±10 %	Within ±15 %	Within ±20 %
64.1%	95.0%	100%	100%

Measurement range: 3.3 ~ 10 mg/dL

Linear Regression: y = 1.0098x + 0.0095, R^2 = 0.9637, (n=320)

User performance

Results: Difference Plot Analysis

Number of subjects (N) = 160

TABLE 2 Ratio of samples (capillary whole blood) falling within different bias ranges

Within ±5 %	Within ±10 %	Within ±15 %	Within ±20 %
68.1%	96.9%	100%	100%

Measurement range: 3.3 ~ 10 mg/dL

Linear Regression: y = 1.0036x + 0.0499, R^2 = 0.9633, (n=160)

Precision

TABLE 3 Precision

	Uric Acid Concentration (mg/dL)		
	LOW	**MID**	**HIGH**
Mean	5.1	10.1	15.0
SD.	o.205	0.258	0.438
CV%	4.05%	2.55%	2.92%

5. FORA 6 Total Cholesterol Test Strip

Accuracy

Results: Difference Plot Analysis

Number of subjects (N) = 320

TABLE 1 Ratio of samples (capillary whole blood) falling within different bias ranges

Within ±5 %	Within ±10 %	Within ±15 %	Within ±20 %
80.3%	99.1%	100%	100%

Measurement range: 129 ~ 399 mg/dL

Linear Regression: y = 0.9777x + 1.9945, R^2 = 0.9724, (n=640)

User performance

Results: Difference Plot Analysis

Number of subjects (N) = 160

TABLE 2 Ratio of samples (capillary whole blood) falling within different bias ranges

Within ±5 %	Within ±10 %	Within ±15 %	Within ±20 %
68.4%	98.8%	100%	100%

Measurement range: 129 ~ 399 mg/dL

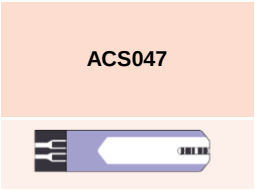
Linear Regression: y = 0.9753x + 2.0318, R^2 = 0.9693, (n=320)

Precision

TABLE 3 Precision

FORA 6 Plus	Interval 1	Interval 12
Mean	140.0	236.8
SD	9.81	16.63
CV%	7.01%	7.02%
FORA 6 Connect	Interval 1	Interval 12
Mean	137.6	241.5
SD	10.12	16.75
CV%	7.35%	6.94%

6. FORA ADVANCED pro Blood Glucose Test Strip



Accuracy

The table below displays how often FORA achieves this target. The chart is based on a study carried out on 160 patients (each patient was tested six times which had 960 test results) to see how well FORA performed compared to YSI-2300 reference method results.

Table 1 Accuracy results for glucose concentration < 100 mg/dL (5.55 mmol/L)

Within ±5 mg/dL (Within ±0.28mmol/L)	Within ±10 mg/dL (Within ±0.55mmol/L)	Within ±15 mg/dL* (Within ± 0.83 mmol/L)
59.7% (179/300)	90.7% (272/300)	99.3% (298/300)

Table 2 Accuracy results for glucose concentration≧100 mg/dL (5.55 mmol/L)

Within ±5 %	Within ±10 %	Within ±15 %*
51.2% (338/660)	85.5% (564/660)	97.1% (641/660)

Table 3 Accuracy results for glucose concentrations between 40.3 mg/dL (2.24mmol/L) to 547.0mg/dL (30.39mmol/L)

Within ±15 mg/dL or ±15% (Within ±0.83 mmol/L or ±15%)
97.8% (939/960)

Note: *According to the accuracy criteria of EN ISO 15197: 2015, 95% of all differences in glucose values (i.e., YSI-2300 reference values minus glucose values of FORA) should be within ±15 mg/dL (0.83 mmol/L) for glucose concentration < 100 mg/dL (5.55 mmol/L), and within ±15% for glucose concentration ≥ 100 mg/dL (5.55 mmol/L). When Test Strips results are compared to the reference values, difference values below 100 mg/dL (5.55 mmol/L) are expressed in mg/dL or mmol/L, while those above 100 mg/dL (5.55 mmol/L) in percentage.

User performance

160 subjects were tested with blood samples taken from the fingertip. The tables show how well FORA performed compared to YSI-2300 reference method results.

Table 1 Difference distribution for glucose concentration < 100 mg/dL (5.55 mmol/L)

Tested sites	Difference within ±5mg/dL	Difference within ±10mg/dL	Difference within ±15mg/dL
Fingertip	71.4% (35/49)	95.9% (47/49)	100.0% (49/49)

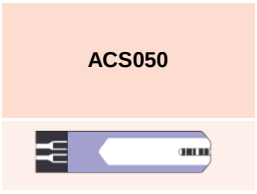
Table 2 Difference distribution for glucose concentration ≥ 100 mg/dL (5.55 mmol/L)

Tested sites	Difference within ±5mg/dL	Difference within ±10mg/dL	Difference within ±15mg/dL
Fingertip	55.0% (61/111)	88.3% (98/111)	97.3% (108/111)

Precision

In both intermediate precision and repeatability tests, the standard deviation (SD) is within 5 mg/dL (0.28 mmol/L) for each glucose concentration < 100 mg/dL (5.55 mmol/L) and the coefficient of variation (CV) is less than 5% for each glucose concentration ≥ 100 mg/dL (5.55 mmol/L).

7. FORA ADVANCED pro Blood Glucose, Hematocrit and Hemoglobin Test Strip



(1) BG

Accuracy

The table below displays how often FORA achieves this target. The chart is based on a study carried out on 160 patients (each patient was tested six times which had 960 test results) to see how well FORA performed compared to YSI-2300 reference method results.

Table 1 Accuracy results for glucose concentration < 100 mg/dL (5.55 mmol/L)

Within ±5 mg/dL (Within ±0.28mmol/L)	Within ±10 mg/dL (Within ±0.55mmol/L)	Within ±15 mg/dL* (Within ± 0.83 mmol/L)
59.7% (179/300)	90.7% (272/300)	99.3% (298/300)

Table 2 Accuracy results for glucose concentration≧100 mg/dL (5.55 mmol/L)

Within ±5 %	Within ±10 %	Within ±15 %*
51.2% (338/660)	85.5% (564/660)	97.1% (641/660)

Table 3 Accuracy results for glucose concentrations between 40.3 mg/dL (2.24mmol/L) to 547.0mg/dL (30.39mmol/L)

Within ±15 mg/dL or ±15% (Within ±0.83 mmol/L or ±15%)
97.8% (939/960)

Note: *According to the accuracy criteria of EN ISO 15197: 2015, 95% of all differences in glucose values (i.e., YSI-2300 reference values minus glucose values of FORA) should be within ±15 mg/dL (0.83 mmol/L) for glucose concentration < 100 mg/dL (5.55 mmol/L), and within ±15% for glucose concentration ≥ 100 mg/dL (5.55 mmol/L). When Test Strips results are compared to the reference values, difference values below 100 mg/dL (5.55 mmol/L) are expressed in mg/dL or mmol/L, while those above 100 mg/dL (5.55 mmol/L) in percentage.

User performance

160 subjects were tested with blood samples taken from the fingertip. The tables show how well FORA performed compared to YSI-2300 reference method results.

Table 1 Difference distribution for glucose concentration < 100 mg/dL (5.55 mmol/L)

Tested sites	Difference within ±5mg/dL	Difference within ±10mg/dL	Difference within ±15mg/dL
Fingertip	71.4% (35/49)	95.9% (47/49)	100% (49/49)

Table 2 Difference distribution for glucose concentration ≥ 100 mg/dL (5.55 mmol/L)

Tested sites	Difference within ±5mg/dL	Difference within ±10mg/dL	Difference within ±15mg/dL
Fingertip	55.0% (61/111)	88.3% (98/111)	97.3% (108/111)

Precision

In both intermediate precision and repeatability tests, the standard deviation (SD) is within 5 mg/dL (0.28 mmol/L) for each glucose concentration < 100 mg/dL (5.55 mmol/L) and the coefficient of variation (CV) is less than 5% for each glucose concentration ≥ 100 mg/dL (5.55 mmol/L).

(2) HCT:

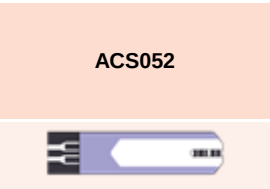
Accuracy: ≦ ± 5% ; Precision: SD≦3

(3) HB:

Accuracy: ≦ 1.7 g/dL ; Precision: SD≦3 g/dL

In our system, the HB is calculated by HCT. Our device is not directly got the value of HB. All the hemoglobin (HB) detect tested data are calculated from hematocrit (HCT) detect tested results (Hb = HCT x 0.34). Based on this, the Hb detect linearity performance results are the same as HCT detect linearity performance results. However, normal accuracy requirement on market (without any formal regulatory requirements) is ±1.5%.

8. FORA ADVANCED pro β-Ketone Test Strip Test Strip



Accuracy

Accuracy testing shows that results are comparable between trained professionals and lay users. Accuracy was assessed with 100 patients by comparing whole blood β- OHB results with plasma results obtained using reference laboratory instruments. Please see Table 1.

Table 1 - Accuracy	
Mean different plot	0.1 mmol/L
Slope	1.0693
Intercept	-0.0051
R (corr. coef.)	0.9959

Precision

Precision testing shows that results typically vary by 3.06% to 3.33%.

Please see Table 2.

Table 2 - Precision		
	Low	Mid
Mean mmol/ L	0.487	2.89
SD mmol/ L	0.051	0.088
CV%	-	3.06

9. FORA COMFORT Blood Glucose Test Strip

Accuracy

The table below displays how often FORA COMFORT achieves this target. The chart is based on a study carried out on 160 patients (each patient was tested six times which had 960 test results) to see how well FORA COMFORT performed compared to YSI-2300 reference method results.

Table 1 Accuracy results for glucose concentration < 100 mg/dL (5.55 mmol/L)

Within ±5 mg/dL (Within ±0.28mmol/L)	Within ±10 mg/dL (Within ±0.55mmol/L)	Within ±15 mg/dL* (Within ± 0.83 mmol/L)
57.3% (165/288)	90.3% (260/288)	100% (288/288)

Table 2 Accuracy results for glucose concentration≧100 mg/dL (5.55 mmol/L)

Within ±5 %	Within ±10 %	Within ±15 %*
45.7% (307/672)	77.8% (523/672)	95.4% (641/672)

Table 3 Accuracy results for glucose concentrations between 32.3mg/dL (1.79mmol/L) to 544.0mg/dL (30.22mmol/L)

Within ±15 mg/dL or ±15% (Within ±0.83 mmol/L or ±15%)
96.8% (929/960)

Note: *According to the accuracy criteria of EN ISO 15197: 2015, 95% of all differences in glucose values (i.e., YSI-2300 reference values minus glucose values of FORA COMFORT) should be within ±15 mg/dL (0.83 mmol/L) for glucose concentration < 100 mg/dL (5.55 mmol/L), and within ±15% for glucose concentration ≥ 100 mg/dL (5.55 mmol/L). When Test Strips results are compared to the reference values, difference values below 100 mg/dL (5.55 mmol/L) are expressed in mg/dL or mmol/L, while those above 100 mg/dL (5.55 mmol/L) in percentage.

User performance

160 subjects were tested with blood samples taken from the fingertip and the alternative sites, the palm, the forearm and the upper arm. The tables show how

well FORA COMFORT performed compared to YSI-2300 reference method results.

Table 1 Difference distribution for glucose concentration < 100 mg/dL (5.55 mmol/L)

Tested sites	Difference within ±5mg/dL	Difference within ±10mg/dL	Difference within ±15mg/dL
Fingertip	29/46 (63.0%)	41/46 (89.12%)	46/46 (100%)
Palm	23/57 (40.4%)	46/57 (80.7%)	57/57 (100%)
Forearm	13/57 (22.8%)	44/57 (77.2%)	57/57 (100%)
Upper arm	17/57 (29.8%)	48/57 (84.2%)	57/57 (100%)

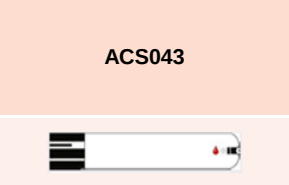
Table 2 Difference distribution for glucose concentration ≥ 100 mg/dL (5.55 mmol/L)

Tested sites	Difference within ±5mg/dL	Difference within ±10mg/dL	Difference within ±15mg/dL
Fingertip	39/114 (34.2%)	80/114 (70.2%)	110/114 (96.5%)
Palm	36/103 (35.0%)	73/103 (70.9%)	102/103 (99.0%)
Forearm	24/103 (23.3%)	70/103 (68.0%)	100/103 (97.1%)
Upper arm	22/103 (21.4%)	61/103 (59.2%)	98/103 (95.1%)

Precision

In both intermediate precision and repeatability tests, the standard deviation (SD) is within 5 mg/dL (0.28 mmol/L) for each glucose concentration < 100 mg/dL (5.55 mmol/L) and the coefficient of variation (CV) is less than 5% for each glucose concentration ≥ 100 mg/dL (5.55 mmol/L).

10. FORA COMFORT check Blood Glucose Test Strip



Accuracy

The table below displays how often FORA G40 achieves this target. The chart is based on a study carried out on 160 patients (each patient was tested six times which had 960 test results) to see how well FORA G40 performed compared to YSI-2300 reference method results.

Table 1 Accuracy results for glucose concentration < 100 mg/dL (5.55 mmol/L)

Within ±5 mg/dL (Within ±0.28mmol/L)	Within ±10 mg/dL (Within ±0.55mmol/L)	Within ±15 mg/dL* (Within ± 0.83 mmol/L)
60.6% (181/294)	90.1% (265/294)	100% (294/294)

Table 2 Accuracy results for glucose concentration≧100 mg/dL (5.55 mmol/L)

Within ±5 %	Within ±10 %	Within ±15 %*
49.7% (331/666)	81.7% (544/666)	96.4% (642/666)

Table 3 Accuracy results for glucose concentrations between 32.4mg/dL (1.80mmol/L) to 532.0mg/dL (29.56mmol/L)

Within ±15 mg/dL or ±15% (Within ±0.83 mmol/L or ±15%)
97.5% (936/960)

Note: *According to the accuracy criteria of EN ISO 15197: 2015, 95% of all differences in glucose values (i.e., YSI-2300 reference values minus glucose values of FORA G40) should be within ±15 mg/dL (0.83 mmol/L) for glucose concentration < 100 mg/dL (5.55 mmol/L), and within ±15% for glucose concentration ≥ 100 mg/dL (5.55 mmol/L). When Test Strips results are compared to the reference values, difference values below 100 mg/dL (5.55 mmol/L) are expressed in mg/dL or mmol/L, while those above 100 mg/dL (5.55 mmol/L) in percentage.

User performance

160 subjects tested on the fingertip and the alternative sites, the palm, the forearm and the upper arm. The tables show how well FORA G40 performed compared to YSI-2300 reference method results.

Table 1 Difference distribution for glucose concentration < 100 mg/dL (5.55 mmol/L)

Tested sites	Difference within ±5mg/dL	Difference within ±10mg/dL	Difference within ±15mg/dL
Fingertip	26/45 (57.8%)	38/45 (84.4%)	45/45 (100%)
Palm	27/42 (64.3%)	41/42 (97.6%)	42/42 (100%)
Forearm	31/42 (73.8%)	39/42 (92.9%)	42/42 (100%)
Upper arm	29/42 (69.0%)	38/42 (90.5%)	41/42 (97.6%)

Table 2 Difference distribution for glucose concentration ≥ 100 mg/dL (5.55 mmol/L)

Tested sites	Difference within ±5mg/dL	Difference within ±10mg/dL	Difference within ±15mg/dL
Fingertip	61/115 (53.0%)	95/115 (53.0%)	115/115 (100%)
Palm	49/118 (41.5%)	92/118 (78.0%)	118/118 (100%)
Forearm	43/118(36.4%)	84/118 (71.2%)	115/118 (97.5%)
Upper arm	49/118 (41.5%)	87/118 (73.7%)	116/118 (98.3%)

Precision

In both intermediate precision and repeatability tests, the standard deviation (SD) is within 5 mg/dL (0.28 mmol/L) for each glucose concentration < 100 mg/dL (5.55 mmol/L) and the coefficient of variation (CV) is less than 5% for each glucose concentration ≥ 100 mg/dL (5.55 mmol/L).

11. FORA COMFORT basic Blood Glucose Test Strip

ACS041

Accuracy

The table below displays how often FORA G20 achieves this target. The chart is based on a study carried out on 160 patients (each patient was tested six times which had 960 test results) to see how well FORA G20 performed compared to YSI-2300 reference method results.

Table 1 Accuracy results for glucose concentration < 100 mg/dL (5.55 mmol/L)

Within ±5 mg/dL (Within ±0.28mmol/L)	Within ±10 mg/dL (Within ±0.55mmol/L)	Within ±15 mg/dL* (Within ± 0.83 mmol/L)
49.7% (167/336)	88.1% (296/336)	97.9% (329/336)

Table 2 Accuracy results for glucose concentration≧100 mg/dL (5.55 mmol/L)

Within ±5 %	Within ±10 %	Within ±15 %*
45.8% (286/624)	80.6% (503/624)	96.0% (599/624)

Table 3 Accuracy results for glucose concentrations between 32.3mg/dL (1.79mmol/L) to 544.0mg/dL (30.22mmol/L)

Within ±15 mg/dL or ±15% (Within ±0.83 mmol/L or ±15%)
96.7% (928/960)

Note: *According to the accuracy criteria of EN ISO 15197: 2015, 95% of all differences in glucose values (i.e., YSI-2300 reference values minus glucose values of FORA G20) should be within ±15 mg/dL (0.83 mmol/L) for glucose concentration < 100 mg/dL (5.55 mmol/L), and within ±15% for glucose concentration ≥ 100 mg/dL (5.55 mmol/L). When Test Strips results are compared to the reference values, difference values below 100 mg/dL (5.55 mmol/L) are expressed in mg/dL or mmol/L, while those above 100 mg/dL (5.55 mmol/L) in percentage.

User performance

160 subjects were btested from the fingertip and the alternative sites, the palm, the forearm and the upper arm. The tables show how well FORA G20 performed compared to YSI-2300 reference method results.

Table 1 Difference distribution for glucose concentration < 100 mg/dL (5.55 mmol/L)

Tested sites	Difference within ±5mg/dL	Difference within ±10mg/dL	Difference within ±15mg/dL
Fingertip	35/45 (64.8%)	53/54 (98.1%)	54/54 (100%)
Palm	23/25 (40.4%)	46/57 (80.7%)	57/57 (100%)
Forearm	13/57 (22.8%)	44/57 (77.2%)	57/57 (100%)
Upper arm	17/57 (29.8%)	48/57 (84.2%)	57/57 (100%)

Table 2 Difference distribution for glucose concentration ≥ 100 mg/dL (5.55 mmol/L)

Tested sites	Difference within ±5mg/dL	Difference within ±10mg/dL	Difference within ±15mg/dL
Fingertip	50/106 (47.2%)	81/106 (76.4%)	104/106 (98.1%)
Palm	36/103 (35.0%)	73/103 (70.9%)	102/103 (97.1%)
Forearm	24/103 (23.3%)	70/103 (68.0%)	100/103 (97.1%)
Upper arm	22/103 (21.4%)	61/103 (59.2%)	98/103 (95.1%)

Precision

In both intermediate precision and repeatability tests, the standard deviation (SD) is within 5 mg/dL (0.28 mmol/L) for each glucose concentration < 100 mg/dL (5.55 mmol/L) and the coefficient of variation (CV) is less than 5% for each glucose concentration ≥ 100 mg/dL (5.55 mmol/L).

12. FORA Diamond Blood Glucose Test Strip

ACS044

Accuracy

The table below displays how often Diamond achieves this target. The chart is based on a study carried out on 160 patients (each patient was tested six times which had 960 test results) to see how well FORA Diamond performed compared to YSI-2300 reference method results.

Table 1 Accuracy results for glucose concentration < 100 mg/dL (5.55 mmol/L)

Within ±5 mg/dL (Within ±0.28mmol/L)	Within ±10 mg/dL (Within ±0.55mmol/L)	Within ±15 mg/dL* (Within ± 0.83 mmol/L)
44.7% (134/300)	78.7% (236/300)	100% (300/300)

Table 2 Accuracy results for glucose concentration≧100 mg/dL (5.55 mmol/L)

Within ±5 %	Within ±10 %	Within ±15 %*
45.5% (300/660)	80.2% (529/660)	95.9% (633/660)

Table 3 Accuracy results for glucose concentrations between 37.6mg/dL (2.09mmol/L) to 533.0mg/dL (29.61mmol/L)

Within ±15 mg/dL or ±15% (Within ±0.83 mmol/L or ±15%)
97.2% (933/960)

Note: *According to the accuracy criteria of EN ISO 15197: 2015, 95% of all differences in glucose values (i.e., YSI-2300 reference values minus glucose values of FORA Diamond) should be within ±15 mg/dL (0.83 mmol/L) for glucose concentration < 100 mg/dL (5.55 mmol/L), and within ±15% for glucose concentration ≥ 100 mg/dL (5.55 mmol/L). When Test Strips results are compared to the reference values, difference values below 100 mg/dL (5.55 mmol/L) are expressed in mg/dL or mmol/L, while those above 100 mg/dL (5.55 mmol/L) in percentage.

User performance

160 subjects were tested from the fingertip and the alternative sites, the palm, the forearm and the upper arm. The tables show how well FORA Diamond performed compared to YSI-2300 reference method results.

Table 1 Difference distribution for glucose concentration < 100 mg/dL (5.55 mmol/L)

Tested sites	Difference within ±5mg/dL	Difference within ±10mg/dL	Difference within ±15mg/dL
Fingertip	29/48 (64.0%)	43/48 (89.6%)	48/48 (100%)
Palm	27/42 (64.3%)	41/42 (97.6%)	42/42 (100%)
Forearm	31/42 (73.8%)	39/42 (90.5%)	42/42 (100%)
Upper arm	29/42 (69.0%)	38/42 (90.5%)	41/42 (97.6%)

Table 2 Difference distribution for glucose concentration ≥ 100 mg/dL (5.55 mmol/L)

Tested sites	Difference within ±5mg/dL	Difference within ±10mg/dL	Difference within ±15mg/dL
Fingertip	56/112 (50.0%)	87/112 (77.7%)	108/112 (96.4%)
Palm	49/118 (41.5%)	92/118 (78.0%)	118/118 (100%)
Forearm	43/118 (36.4%)	84/118 (71.2%)	115/118 (97.5%)
Upper arm	49/118 (41.5%)	87/118 (73.7%)	116/118 (98.3%)

Precision

In both intermediate precision and repeatability tests, the standard deviation (SD) is within 5 mg/dL (0.28 mmol/L) for each glucose concentration < 100 mg/dL (5.55 mmol/L) and the coefficient of variation (CV) is less than 5% for each glucose concentration ≥ 100 mg/dL (5.55 mmol/L).

Q3: What is the safety information in FORA's blood glucose monitors?

1. In FORA 6 meter, only blood glucose test strip and 3 in 1 test strip (BG/HCT/Hb) can be used for the testing of newborns.
2. In FORA ADVANCE Pro and COMFORT Pro meter, the blood glucose test strip and 3 in 1 test strip (BG/HCT/Hb) can be used for the testing of newborns.
3. The β-Ketone, total cholesterol and uric acid test strips shall **NOT** be used for the testing of newborns.
4. Use this device **ONLY** for the intended use described in the manual.
5. For single use only.
6. Do **NOT** use accessories which are not specified by the manufacturer.

7. Do **NOT** use the device if it is not working properly or damaged.
8. This device does **NOT** serve as a cure for any symptoms or diseases. The data measured is for reference only. Always consult your doctor to have the results interpreted.
9. Before using this device to test blood glucose, read all instructions thoroughly and practice the test. Carry out all the quality control checks as directed.
10. Keep the device and testing supplies away from young children. Small items such as the battery cover, batteries, test strips, lancets and vial caps are choking hazards.
11. The use of this instrument in a dry environment, especially if synthetic materials are present (synthetic clothing, carpets etc.) may cause damaging static discharges that may cause erroneous results.
12. Do **NOT** use this instrument in close proximity to sources of strong electromagnetic radiation, as these may interfere with the correct operation.
13. Proper maintenance as well as timely calibration of the device together with the control solution is essential in ensuring the longevity of your device. If you are concerned about the accuracy of the measurement, please contact the place of purchase or customer service representative for assistance.

Q4: Can hematocrit levels affect the result?

Hematocrit levels can affect results whether the sample is obtained from a forearm or a finger stick. Hematocrit levels less than 30% may cause falsely high readings and hematocrit levels greater than 55% may cause falsely low readings. If the patient does not know their hematocrit level, they should consult their health care professional. Hematocrit levels may be affected by too much kneading during puncture site preparation.

Q5: The following physical situation could lead your reading incorrect and you should consult your healthcare professional.

1. Use only fresh whole blood sample to perform a test. Using other substances will lead to incorrect results.
2. Results may be inaccurate when testing on patients with abnormally low blood pressure or those who are in shock.
3. Severe dehydration and excessive water loss may cause readings which are lower glucose measurement value than actual values. If you believe you are suffering from severe dehydration, consult a healthcare professional immediately.
4. We do not recommend using this product on severely hypotensive individuals or patients in shock. Readings which are lower than actual values may occur for individuals experiencing a hyperglycaemic-hyperosmolar state, with or without ketosis. Please consult the healthcare professional before use.
5. If your test results are lower or higher than usual, and you do not have symptoms of illness, first repeat the test. If you have symptoms or continue to get results higher or lower than usual, follow the treatment advice of your healthcare professional.
6. If you are experiencing symptoms that are inconsistent with your test results and you have followed all the instructions given in this owner's manual, contact your healthcare professional.
7. In uric acid measurement, the high concentration of acetaminophen, bilirubin, hemoglobin, methyldopa and ascorbic acid may affect the test results.
8. The user is suggested to perform a uric acid test in the morning after fasting for 12 hours.
9. In total cholesterol measurement, there are no significant interference in the presence of methyl DOPA, acetaminophen, uric acid, dopamine, gentistic acid, ascorbic acid, ibuprofen, salicylate (when at physiological or therapeutical levels). Glucose levels up to 476 mg/dL (13.89 mmol/L) also do not affect the results significantly.

10. Use ONLY heparin for anticoagulation of whole blood samples. Please do NOT use EDTA for anticoagulation.

Q6: Can we use the FORA's test strips on an airplane and what is the altitude limitation of FORA's GDH-FAD and GOD strips?

Yes, you can use it in airplane.

The most common physical influencers in accuracy of blood glucose strips are altitude (oxygen) and temperature.

You can use the FORA's BGM on an airplane because the cabin pressure (oxygen) and temperature are within our tolerance range in any altitude.

However, 3257 m (10742 ft) is the upper altitude limit for FORA's glucose/3 in 1/β-Ketone testing in mountain climbing based on oxygen issue. In total cholesterol, altitudes up to 2,438 m (8,000 ft) do not affect test results.

In FORA's blood glucose strip, we use the GDH-FAD (glucose dehydrogenase) technology in new generation test strips. Based on literature review, the glucose-dehydrogenase-based meters were more accurate at high altitude (overestimate within 5%) than glucose-oxidase-based meters (overestimate up to 6-15%).

Q7: What are the combinations between FORA's BGMs and test strips?

1. FORA 6 Series

Meter	BG Strip (ACS045)	BG/HCT/HB (3 in 1) Strip (ACS051)	β - Ketone Strip (ACS053)	Uric Acid Strip (ACS057)	Total Cholesterol Strip (ACS055)
 FORA 6 Plus (GD81)					
 FORA 6 Connect (GD82)					
 FORA 6 Smart (GD83)					
 FORA 6 GTel (GD84)					

2. FORA Diamond Series

Meter	BG Strip (ACS044)
 FORA Diamond PRIMA (DM10)	
 FORA Diamond VOICE (DM20)	
 FORA Diamond MINI (DM30a/b)	
 FORA Diamond GD50 (GD50)	

3. FORA ADVANCED Pro/ COMFORT Pro Series:

Meter	BG Strip (ACS047)	BG/HCT/HB (3 in 1) Strip (ACS050)	β - Ketone Strip (ACS052)
 FORA ADVANCED Pro (GD40 g/h)			
 FORA COMFORT Pro (GD40 a/b)			

4. FORA Comfort Series:

Meter	BG Strip (ACS042)	BG Strip (ACS041)	BG Strip (ACS043)
 FORA COMFORT advance (G31 a/b)			
 FORA COMFORT plus voice (V30a)			
 FORA COMFORT plus (G30a)			
 FORA COMFORT plus mini (G71a)			
 FORA COMFORT basic G20 (G20a)			
 FORA COMFORT check G40 (G40a)			

Q8: What kind of Substance interferes FORA's BGM glucose reading in GOD and GDH-FAD blood glucose test strips?

1. FORA 6 Series

Strip Type/Model	Blood Glucose ACS045	BG/HCT/HB ACS051	β -Ketone ACS053
Enzyme	GDH-FAD	GDH-FAD	β - Hydroxybutyrate
Applicable meter	FORA 6 Plus/ FORA 6 Connect FORA 6 Connect/ FOR A 6 Gtel		
Acetaminophen (Paracetamol)	▲ (Limiting Concentration: > 20 mg/dL)		--
Ascorbic acid	▲ (Limiting Concentration: > 5.0 mg/dL)		✖
Dopamine	▲ (Limiting Concentration: > 2.5 mg/dL)		✖
Levo - Dopa	▲ (Limiting Concentration: > 2.1 mg/dL)		--
Methyl - Dopa	▲ (Limiting Concentration: > 1.25 mg/dL)		--
Tolazamide	▲ (Limiting Concentration: > 20 mg/dL)		--
Galactose	✓		--
Hemoglobin (Hemolysis Method)	✓		--
Lipemic Samples (Triglycerides)	▲ (Limiting Concentration: > 3000 mg/dL)		--
Reduced Glutathione	▲ (Limiting Concentration: > 30 mg/dL)		--
Pralidoxime Iodide	✖		--
Salicylic Acid	✓		--
Bilirubin (Unconjugated)	✓		✖
Cholesterol	✓		✖
Creatinine	✓		--
K2EDTA	✖		--
K3EDTA	✖		--
Heparin (Li)	✓		--
Heparin (Na)	✓		--
Gentisic Acid	✓		✖
Ibuprofen	✓		--
Icodextrin	✓		--
Maltose	✓		--
Tolbutamide	✓		--
Uric acid	▲ (Limiting Concentration: > 10 mg/dL)		✖
Xylose	▲ (Limiting Concentration: > 5 mg/dL)		--
Captopril	--		✖
L-DOPA	--		✖
Paracetamol	--		✖
Triglycerides	--		✖

2. FORA ADVANCED Pro/ COMFORT Pro Series:

Strip Type/Model	Blood Glucose ACS047	BG/HCT/HB ACS050	β -Ketone ACS052
Enzyme	GDH-FAD	GDH-FAD	β - Hydroxybutyrate
Applicable meter	FORA ADVANCE Pro FORA COMFORT Pro		
Acetaminophen (Paracetamol)	▲ (Limiting Concentration: > 6.25 mg/dL)		--
Ascorbic acid	▲ (Limiting Concentration: > 5.0 mg/dL)		✖
Dopamine	▲ (Limiting Concentration: > 1.25 mg/dL)		✖
Levo - Dopa	▲ (Limiting Concentration: > 0.7 mg/dL)		--
Methyl - Dopa	▲ (Limiting Concentration: > 0.625 mg/dL)		--
Tolazamide	✓		--
Galactose	✓		--
Hemoglobin (Hemolysis Method)	✓		--
Lipemic Samples (Triglycerides)	▲ (Limiting Concentration: > 3000mg/dL)		--
Reduced Glutathione	▲ (Limiting Concentration: > 30 mg/dL)		--
Pralidoxime Iodide	✖		--
Salicylic Acid	✓		--
Bilirubin (Unconjugated)	▲ (Limiting Concentration: > 20 mg/dL)		✖
Cholesterol	✓		✖
Creatinine	✓		--
K2EDTA	✖		--
K3EDTA	✖		--
Heparin (Li)	✓		--
Heparin (Na)	✓		--
Gentisic Acid	✓		✖
Ibuprofen	✓		--
Icodextrin	✓		--
Maltose	✓		--
Tolbutamide	✓		--
Uric acid	▲ (Limiting Concentration: > 10 mg/dL)		✖
Xylose	▲ (Limiting Concentration: > 6.25 mg/dL)		--
Captopril	--		✖
L-DOPA	--		✖
Paracetamol	--		✖
Triglycerides	--		✖
Na-Fluoride/K-Oxalate	✖		--
Warfarin	✓		--

3. FORA Diamond and COMFORT Series:

Strip Type/Model	Blood Glucose ACS044	Blood Glucose ACS043	Blood Glucose ACS042
Enzyme	GDH-FAD	GDH-FAD	GOD
Applicable meter	DM10 DM20 DM30 a/b GD50	G40	G30a G31 a/b G71a V31a
Acetaminophen (Paracetamol)	▲ (> 6.25 mg/dL)	▲ (> 6.25 mg/dL)	▲ (> 6.25 mg/dL)
Ascorbic acid	▲ (> 5.0 mg/dL)	▲ (> 5.0 mg/dL)	▲ (> 5.0 mg/dL)
Dopamine	▲ (> 1.25 mg/dL)	▲ (> 1.25 mg/dL)	▲ (> 1.25 mg/dL)
Levo - Dopa	▲ (> 0.7 mg/dL)	▲ (> 0.7 mg/dL)	▲ (> 1.4 mg/dL)
Methyl - Dopa	▲ (> 1.875 mg/dL)	▲ (> 1.875 mg/dL)	▲ (> 1.25 mg/dL)
Tolazamide	▲ (> 12.5 mg/dL)	▲ (> 12.5 mg/dL)	▲ (> 12.5 mg/dL)
Galactose	▲ (> 250 mg/dL)	▲ (> 250 mg/dL)	▲ (> 250 mg/dL)
Hemoglobin (Hemolysis Method)	✓	✓	▲ (> 100 mg/dL)
Lipemic Samples (Triglycerides)	▲ (> 3000 mg/dL)	▲ (> 3000 mg/dL)	▲ (> 3000 mg/dL)
Reduced Glutathione	▲ (> 30 mg/dL)	▲ (> 30 mg/dL)	▲ (> 30 mg/dL)
Pralidoxime Iodide	✖	✖	✖
Salicylic Acid	✓	✓	✓
Bilirubin (Unconjugated)	▲ (> 20 mg/dL)	▲ (> 20 mg/dL)	✓
Cholesterol	✓	✓	✓
Creatinine	✓	✓	✓
K2EDTA	✓	✓	✓
K3EDTA	✓	✓	✓
Heparin (Li)	✓	✓	✓
Heparin (Na)	✓	✓	✓
Na-Fluoride/K-Oxalate	✖	✖	✖
Gentisic Acid	✓	✓	✓
Ibuprofen	✓	✓	✓
Icodextrin	✓	✓	✓
Maltose	✓	✓	✓
Tolbutamide	✓	✓	✓
Uric acid	▲ (> 10 mg/dL)	▲ (> 10 mg/dL)	▲ (> 10 mg/dL)
Warfarin	--	✓	--
Xylose	▲ (> 3.125 mg/dL)	▲ (> 3.125 mg/dL)	✓

* ✓: **No interference with the strips.** The therapeutic or physiologic concentration range is regularly lower than limiting concentration.

▲: **It may interference with the strips. The concentrations of therapeutic or physiologic concentration range could be possible more than limiting concentration.

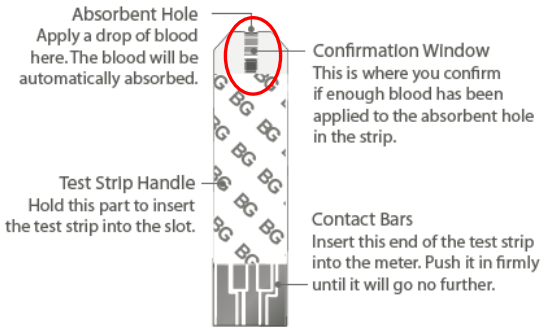
***×: **Interference with the strips.** The concentrations of therapeutic or physiologic concentration range will be usually higher than limiting concentration.

****--: No interference information with the strips.

Please refer to interfere substances information for each strips' manual.

Q9: How do you know if sufficient blood has been applied on the test strip?

The front side of test strip should face up when inserting the test strip. Test results might be wrong if the contact bar is not fully inserted into the test slot.



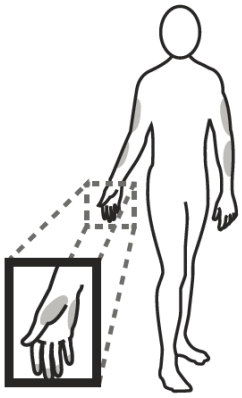
Q10: Can I use ForaCare Suisse Test Strips with other brands of Meters?

No, **DO NOT** use other accessories which are not specific to ForaCare Suisse AG.
In 2014, US FDA issued a safety warning to users of glucometers that they should carefully read the owner's manual and only use the test strips that are specific to that meter.

Q11: What happens if I use expired test strips with FORA's BGM?

Using test strips that are expired can cause your results to be inaccurate. If your test strips have expired, throw them away and begin using a new vial of strips that are not expired. The expiration date is printed on every vial (or foil) of test strips.

Q12: What is alternative site testing (AST) in FORA's test strips of BGM?



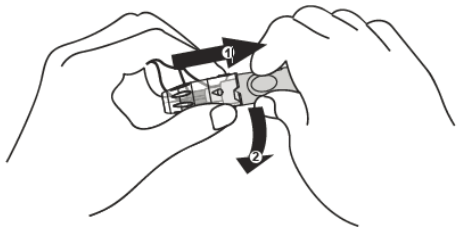
1. Alternative site testing (AST) is when individuals check their blood glucose levels using other areas of the body other than the fingertips. The FORA test strips allow AST to be performed on sites other than the fingertips. Please consult your health care professional before performing AST.

2. We strongly recommend that you perform AST **ONLY** at the following times:
   - During a pre-meal or fasting state (more than 2 hours since the last meal).
   - Two hours or more after taking insulin.
   - Two hours or more after exercise.

3. Do **NOT** use AST if:
   - You think your blood glucose is low.
   - You may not notice if you are hypoglycemic.
   - Your AST results are inconsistent with the way you feel.
   - You are testing for hyperglycemia.
   - Your routine glucose results often fluctuate.

4. To obtain a blood sample from the alternative sites, please rub the puncture site for approximately 20 seconds.

5. Replace the lancing device cap with the clear cap. Pull the cocking control out until the orange bar appears on the release button window.



6. Choose a different spot each time you test. Repeated punctures at the same spot may cause soreness and calluses.

7. Avoid lancing the areas with obvious veins to avoid excessive bleeding.

8. It is recommended to discard the first drop of blood as it might contain tissue fluid, which may affect the test result.

Q13: How many testing sites can be used with FORA's test strips of BGM?

1. Home use:

(1) Fingertips (capillary), palm, forearm, and upper arm blood are the alternative testing sites because of the AST technology in all FORA's glucose and BG/HCT/HB (3 in 1) test strips.

(2) Fingertips (capillary) blood is the only testing site in β-Ketone, urine acid and total cholesterol test strips.

2. Professional use:

(1) Arterial blood can only be used on FORA 6 blood glucose test strips and FORA 6 BG/HCT/HB (3 in 1) test strips.

(2) Venous and capillary blood can be used on FORA's all blood glucose, BG/HCT/HB (3 in 1), β-Ketone, urine acid and total cholesterol test strips.

Q14: What will happen if insufficient blood is applied on the test strip? What do I do?

If insufficient blood is applied on the test strip, there will be an error beep and an error code will be displayed on the meter screen (please refer to the owner's manual and check the error message.)

Please review the instructions and repeat the test with a new test strip.

Q15: Why would it be possible to obtain different results from the same sample of blood using the same glucometer?

The most common reasons for the discrepancies could be:

(1) Test strip problems:

A. Test strip expired

B. Test strip contaminated or damaged

C. Wrong code between test strip and meter

D. Not enough blood applied to the test strip

(2) Meter problems:

A. The meter is damaged caused by improper handling or there is a blood clot inside it.

B. Wrong code between test strip and meter

C. Unknown electronic elements defect

(3) Blood sample obtaining surface is dirty:

A. Alcohol, dirt or other substances on your skin (please wash your hand before you doing the test).

(4) Improper blood obtaining way:

A. If the fingertip is excessively squeezed, too much tissue fluid will be present in the blood samples and get the wrong measuring value (We highly

recommend wiping off the first drop of blood and using the second drop of blood).

B. If you're using a site other than your fingertip and you think the reading is wrong, test again using blood from a fingertip. Blood samples from alternate sites aren't as accurate as fingertip samples when your blood sugar level is rising or falling quickly.

(5) Extreme temperatures or humidity:

A. Keep your glucose meter and test strips at proper operating temperature and humidity based on the owner's manual in each meter and strip.

(6) The amount of red blood cells in your blood:

A. If you are dehydrated or your red blood cell count is low (anemia), your test results may be less accurate. Please refer to the owner's manual and consult doctor to check the suitable hematocrit range for testing.

Q16: What is the international standard in blood glucose's accuracy?

The glucose testing value should be followed the international standard:

EN ISO 15197:2015

- Analytical performance evaluation 95% of the measurement to fall:

  ±15mg/ dL at glucose concentrations＜100mg/ dL (＜5.55mmol/L)

  ±15% at glucose concentrations≧100mg/ dL (≧5.55mmol/L)

Q17: Reasons for abnormal readings or defect of blood glucose monitor:

Item	Outcome of defect	Root Cause	Solution
1	The variance of the results might be larger.	(1) Compare the strips between new Lot one and old Lot one. (2) The different blood obtained site for each test. (3) The time period after obtaining the blood samples is too long. (4) The blood samples are contaminated. (e.g., the pricked site is not clean.)	(1) The old Lot could be expired or malfunction by improper storage. Please do the comparison test again with new opened strips within expiry date. (2) Please obtain blood samples at the same site for comparison. (3) Do not wait too long after obtaining blood samples. (4) Please wash your hand before you doing the test
2	The results might be higher	(1) The blood samples are too much plasma due to the excessive squeezing of the fingertip. (2) The testing strip is expired or out of temperature and humidity. (3) Patient's health conditions: a. Medications. b. Time and dose of insulin were administered. c. HCT level. d. Interference factors in diet, such as vitamin C (ascorbic acid), glutathione (antioxidant), and uric acid (for GDH strips). e. Hydration level for patients.	(1) Please obtain the blood samples again. Do not excessively squeeze the pricked site. We highly recommend wiping off the first drop of blood and using the second drop of blood (avoid effusion tissue fluid). (2) Please open another vial and use new strips to do the test again. (3) Please check with your doctor to make sure your status is suitable to measure the blood glucose without any interference.
3	Error message: E-U/ Err 24	(1) Inserts a used test strip. (2) Blood sample is input before the symbol for blood blinks.	Repeat the test with a new test strip. Wait for the "blood drop" symbol to blink then re-test using a proper amount of blood.
4	Error message:E-b/ Err 36	Battery power is too low to operate the meter. The meter will not operate until the batteries are replaced.	You have to replace or charge the batteries soon.
5	Error message: E-F	Strip was removed soon after applying blood and not given enough time to be absorbed by the absorption hole	Repeat the test with a new test strip and wait for the test result.
6	The blood glucose monitor keeps beeping until it out of the battery.	The Electronic component is defect in PCBA.	Please contact with FORA customer service member to repair or replacement.

Battery

Q18: Will low battery cause inaccurate test results?

FORA meters will provide accurate test results even with low battery.

Q19: What does it mean when my meter displays a battery symbol?

You must charge or replace the battery immediately when the battery power is extremely low and "&**E-b**" symbol appears on the screen.

The detail explanations about the battery capacity are as the following stages:

1) From full to low battery warning: 100% to 30%.
2) From low battery warning to E-b display on the screen (turn off automatically): 30 % to 20%.
3) From E-b display on the screen to no reaction when turn on: 20 % to 10%.
4) From no reaction when turn on to battery death: ＜10%

Q20: How long will my battery last?

The lifespan of a battery will vary considerably with how it is used, how it is maintained and charged, temperature, and other factors such as frequency of testing.

Q21: Will replacing the battery cause memory loss?

No, replacing the battery does not affect the test results stored in the memory.

Universal Tone

Q22: What is universal tone and which devices have this function?

Universal Tone is specially designed to assist the visually impaired in measuring blood glucose. When Universal Tone is turned on, the meter guides the user through the blood glucose test and outputs the results through a series of beep tones.

The FORA devices which have universal tone:

1. FORA 6 series:

FORA 6 Plus (GD81), FORA 6 Connect (GD82), FORA 6 Smart (GD83).

2. FORA Advanced/ Comfort Pro series:

FORA Advanced pro (GD40 g/h) and Comfort Pro (GD40 a/b).

3. FORA Diamond series:

Diamond Prima (DM10), Diamond MINI (DM30 a/b) and Diamond GD50 (GD50).

4. FORA Comfort series:

FORA Comfort plus (G30a), FORA Comfort advance (G31 a/b), FORA Comfort plus mini (G71a), FORA Comport basic G20 (G20a) and FORA Comfort check G40 (G40a).

Q23: What is the meaning of universal tone in different testing results?

The blood glucose results will be broken down into individual digits and each digit represents the corresponding number of beeps. The result is announced three times in succession and each time is preceded by two quick beeps. So you will hear: 2 quick beeps – results – 2 quick beeps – results – 2 quick beeps – result.

1. For mg/dL meters, the hundreds are always announced, even when the result is below 100.

   Examples:

   (1) 80 mg/dL is announced as 1 long beep (0) – 1 single pause – 8 single beeps (8) – 1 single pause – 1 long beep (0).

(2) 182 mg/dL is announced as 1 single beep (1) – 1 single pause – 8 single beeps (8) – 1 single pause – 2 single beeps (2).

2. For mmol/L meters, the tens are always announced, even when the result is below 10. The decimal point is represented by 1 quick beep.

Examples:

(1) 6.0 mmol/L is announced as 1 long beep (0) – 1 single pause – 6 single beeps (6) – 1 single pause – 1 quick beep (.) – 1 single pause – 1 long beep (0)

Note:

Information or warnings in the form of symbols displayed together with the results are not announced acoustically.

Q24: What is the meaning of universal tone in announcement of memory result?

Only the most recent result that was saved can be announced acoustically. If you press MAIN to turn the meter on, you will first hear the Long-Beep which stands for power on and then the most recent result.

Only the average for the last 7 days is announced acoustically. If the 7-day average cannot be calculated, three horizontal bars are displayed. This is signaled acoustically with 3 long beeps representing 3 zeroes.

Ketone Warning

Q25: What is ketone warning?

When your blood glucose result is higher than 240 mg/dL (13.3 mmol/L), the meter will display the blood glucose reading as well as a Ketone warning (flashing KETONE and "⚠"). The ketone warning is to notify you that you may be at risk of elevated

Ketone levels and a Ketone test is recommended.

Changing the Setting (Universal Tone, Time, Date and Alarm)

Q26: How do I change the universal tone, time, date and alarm on my meter?

Please refer to the Owner's manual for detailed instructions. You can find them in the 「initial setup」paragraph.

Caring for Your Device

Q27: How do I clean my FORA BGM?

- To clean the exterior of the device and the areas around slots and openings, wipe it with a cloth moistened with tap water or a mild cleaning agent, then dry the device with a soft dry cloth. Do NOT rinse with water.
- **Do NOT** use organic solvents to clean the device.

Q28: When should I clean and disinfected my FORA BGM?

Clean your meter once a week, or any time blood gets on the meter. You should also clean the meter before allowing anyone else to handle it.

Meter Disposal

Q29: How do I dispose my FORA BGM?

- The used meter should be treated as contaminated and may carry a risk of infection during measurement. The batteries in this used meter should be removed and the meter should be disposed in accordance with local regulations. Please refer to the local regulations to discard the used blood glucose meter before removing batteries.
- The meter falls outside the scope of the European Directive 2002/96/ EC-Directive on waste electrical and electronic equipment (WEEE).

Coding the Meter

Q30: Which device needs coding before using? How do I code my FORA Meter?

FORA's devices do not need coding except for special strips: β-Ketone, Urine Acid and Total Cholesterol test strips.

You must calibrate/code the meter every time you begin to use a new vial of β-ketone/ Total cholesterol/ Uric acid test strips by setting the meter with the correct code. Test results may be inaccurate if the code number displayed on the monitor does not match the number printed on the strip label or strip foil pack.

Besides, FORA GD40 series (GD40a/b/g/h) can open the coding function based on customer's request. In this situation, a code card is needed to calibrate the FORA GD40 series meters to make sure the strips and meters have the same code.

Procedure:

(1) Insert the code strip into the test slot of the device. Wait for the device to display the code number.

(2) Make sure the code numbers on display, code strip, and test strip vial or foil pack are the same. The code strip should be within the expiry date; otherwise, an error message may appear.

(3) Remove the code strip, the display will show "OK". This tells you that the meter has finished coding and is ready for β-ketone/ Total cholesterol/ Uric acid testing.

Control Solution

Q31: How do I do the control solution test?

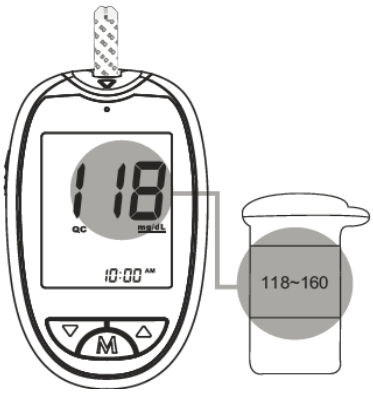
1. Insert the test strip into the test slot of the device. Wait for the device to display the blood drop.
2. **Auto QC mode in FORA 6 series and GD40g/h:** The meter will detect the difference between control solution and blood samples automatically. It will

automatically mark the result as a control solution test with “QC” display.

3. **Manual QC mode for other FORA’s meter:** Press MAIN button to mark this test as a control solution test. With “QC” displayed, the device will store your test result in the memory under “QC”. If you press MAIN button again, the “QC” will disappear and this test is no longer a control solution test.
4. Apply the control solution. Shake the control solution vial thoroughly before use. Squeeze out a drop and wipe it off, then squeeze another drop and place it on the tip of the vial cap. Hold the device to move the absorbent hole of the test strip to touch the drop. Once the confirmation window is filled completely, the device will begin counting down.
5. Read and compare the result. After counting down to 0, the test result of the control solution will appear on the display. Compare this result with the range printed on the test strip vial or individual foil pack and it should fall within this range. If the test result is out of range, read the instructions again and repeat the control solution test.

Q32: Where can I find the control solution range?

The range of the control solution test is printed on the test strip vial or individual foil pack and your test should fall within this range. If the test result is out of range, read the instructions again and repeat the control solution test.



Q33: Common Abnormal Results from Control Solution Test.

Item	Outcome of value	Root Cause	Solution
1	The results might be higher.	There is some residue on the carrier (cap or tip) of the control solution.	Clean the carrier (cap or tip of control solution) and test again. This time use the second drop of the control solution.
2	The results might be lower.	The pollutants are absorbed in the control solution.	Replace the control solution and test again.
3	The results might be higher or lower.	(1) It is not in the correct user mode (e.g., not in CTL or QC Mode during the control solution test). (2) You may be using a different control solution. (3) Control solution may have expired.	(1) Choose the correct user mode and test again. (2) Use ForaCare control solution only. (3) Discard 90 days after opening.
4	The results might be lower.	Insufficient control solution is absorbed.	Please test again and remove the strip only after hearing the "BEEP" sound from the meter.
5	The variance might be larger.	The temperature of the strips and meter is unstable.	Please test again after the strips and meter have been placed in the same environment for 30~60 minutes.

Data Management Features of the FORA BGM Meter

Q34: What is FORA's BGM Meter's platform for blood glucose management?

1. Smart phone APP (for Android and iOS):

   (1) ***iFORA BG*** (free download)

   For iOS platform, please go to:

   https://itunes.apple.com/us/app/ifora-diabetes-manager/id528184925?mt=8

For Android platform, please visit:

https://play.google.com/store/apps/details?id=com.foracare.ifora&hl=en

(2) ***iFORA MP*** (free download)

For iOS platform, please go to:

https://itunes.apple.com/us/app/ifora-mp/id834184294

For Android platform, please visit:

https://play.google.com/store/apps/details?id=com.foracare.tdlink.mp

(3) ***iFORA HM*** (free download)

For iOS platform, please go to:

https://itunes.apple.com/us/app/ifora-hm/id1169357723

For Android platform, please visit:

https://play.google.com/store/apps/details?id=com.foracare.tdlink.hm

2. Windows-based software program (free download):

FORA Healthcare System software

http://www.foracare.com/downloads/pclink/FORA_Swiss_HealthCareMgtSys_Cable_V5.01_20190415.zip

FORA Healthcare System Manual

https://foracare-suisse-ag.box.com/s/y67jlec9698gjydvpdpvxdqq0pbi1dq8

3. Website based Telehealth System :

(Should ask us for testing version and purchase the full version)

FORA TeleHealth System Manual

https://foracare-suisse-ag.box.com/s/el02o631cgzw79bdfpmy65fqv5jxpah5

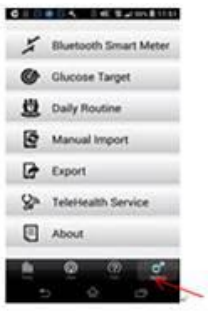
FORA TeleHealth System Marketing Material

https://foracare-suisse-ag.box.com/s/hg38kqu21fzm0jo5wcvaqo3y7n1rblbl

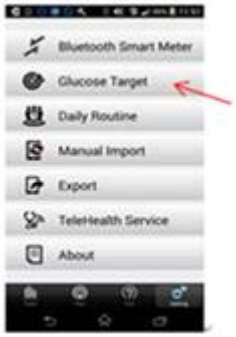
4. The way to switch the measurement in iFORA BG :

(1) Turn on iFORA BG

(2) Select『 Setting』



(3) Select『 Glucose Target』



(4) Press 『mmol/L』to switch the unit.

(5) And then, your measurement unit will be mmol/L.

Of course, you can use the same way to switch back to mg/dL.

Q35: What are the ways in which FORA BGM Meters transmit data and manage media?

BGM Product Name	Data Connection Method	Transmission Tools	The Media to Manage the Data
FORA 6 Gtel (GD84)	GPRS (3G)	Sim Card (3G)	TeleHealth System
FORA 6 Smart (GD83)	1. Cable 2. Bluetooth	1. Strip_Port_Comm Cable 2. My Dongle 2 (External Bluetooth device)	iFORA HM Healthcare Software TeleHealth System
FORA 6 Plus (GD81)			
FORA 6 Connect (GD82)	Bluetooth	Built-in Bluetooth	iFORA HM TeleHealth system
Diamond GD50 (GD50)	1. Cable 2. Bluetooth	1. RS-232 2. My Dongle (External Bluetooth device)	iFORA BG iFORA MP iFORA HM Healthcare Software TeleHealth System
COMFORT plus (G30a)			
COMFORT plus voice (V30a)			
*Diamond MINI (DM30b)	Bluetooth	Built-in Bluetooth	iFORA BG iFORA MP iFORA HM Healthcare Software TeleHealth System
ADVANCED Pro (GD40h)	Bluetooth		
COMFORT Pro (GD40b)	Bluetooth		
COMFORT advance (G31b)	Bluetooth		
Diamond PRIMA (DM10)	Cable	Micro-USB	Healthcare Software TeleHealth System
Diamond VOICE (DM20)		Micro-USB	
Diamond MINI (DM30a)		Micro-USB	
ADVANCED Pro (GD40g)	Cable	RS-232	Healthcare Software TeleHealth System
COMFORT Pro (GD40a)		RS-232	
COMFORT advance (G31a)	Cable	Mini-USB	Healthcare Software TeleHealth System
COMFORT plus mini (G71a)	N/A	N/A	N/A
COMFORT basic G20 (G20a)	N/A	N/A	N/A
COMFORT check G40 (G40a)	N/A	N/A	N/A

* The USB port on the DM30b meter can only be used for battery recharge. It does not have the function of data transmission.

Q36: What are the support operation systems in FORA Healthcare system software?

Device description	Support model number	Release Date	Support Operation System
Blood Glucose Monitors	FORA DM10 FORA DM20 FORA DM30 FORA G20 FORA G30 FORA G31 FORA G90 FORA V10 FORA V12 FORA V20 FORA V22 FORA V30 FORA GD40a FORA GD50	2016.06.04	**Windows XP** **Windows 7 64Bit** **Windows7 32Bit** **Windows 8** **Windows 10** **Support Language:** English, German, French, Italian, Dutch, Greek, Czech
2-in-1 Blood Pressure Monitors	FORA D15c FORA D15g FORA D20 FORA D30 FORA D40 FORA D40Pro FORA P20		
Blood Pressure Monitors	Diamond Cuff BP		

Q37: How is data transmission done?

Please refer to the owner's manual of each meter's 「Transferring Data」.

1. Data Transmission Via Strip_Port_Comm Cable, Micro-USB, USB or RS232 Cable

   (1) Install the software on your computer. Download Health Care System Software and instruction manual provided on the ForaCare Suisse AG Web site: http://www.foracare.ch. Follow the instructions to install the software on your computer.

   (2) Connect the device with your computer using a Micro-USB, USB or RS232 Cable (Please refer to the owner's manual as each device uses a different connection port).

   (3) Transfer data to your computer. Follow the software on-screen instructions to transmit data. The data transmitted will include results with date and time.

Remove the cable and the device will automatically turn off.

2. Data Transmission Via Bluetooth

You can use your device with an iOS (5.0.1 or higher) Android system (4.3 API Level 18 or higher) or PC (Windows 8 or higher) to download data from your BGM via Bluetooth. Follow the steps below to transmit data from your BGM. Please contact your local customer service or place of purchase for assistance.

(1) Install the APP (iFORA BG, iFORA MP, iFORA HM) to your device with an iOS or Android system.

(2) Every time the BGM is turned off, the Bluetooth will be initiated for data transmission. The Bluetooth indicator flashes in blue.

(3) Make sure your BGM is already paired with your device with an iOS, Android system or PC by following the instructions below.

(4) If your device with an iOS, Android system or PC is within the receiving range, the data transmission will start and the Bluetooth will signal in blue. Once it is finished, the BGM will automatically switch off.

Note:

- This step is recommended if it is the first time the meter is paired to a Bluetooth receiver, or another new Bluetooth receiver is paired with the meter.

(5) If your device with an iOS, Android system or PC is not within the receiving range, the BGM will automatically switch off.

Note:

- While the meter is in transmission mode, a blood glucose test

cannot be performed.

- Make sure Bluetooth is turned on on your iOS (5.0.1 or higher) or Android system device before data is transmitted and that the meter is within the receiving range.

Q38: What is the different between Bluetooth V3 and V4 on FORA's meters?

1. Bluetooth V3

   (1) Bluetooth logo: Bluetooth®

   (2) You need to do pairing in OS setting of smartphone first and then go to APP (iFORA BG) to do pairing again.

   (3) Please connect to meter by SPP (Serial Port Profile). Meter must be paired before any connection, please find the instruction in meter manual for the pairing process. The meter supports SSP (Simple Secure Pairing), as a result PIN is not required. If host does not support SSP, please use 0000 as PIN if required.

2. Bluetooth V4 (BLE)

   (1) Bluetooth logo: Bluetooth® SMART

   (2) You can directly do pairing in your APP (iFORA BG) and don't need to do additional pairing in OS setting of smartphone.

   (3) Low Energy (save electricity)

   (4) Please connect to meter by following GATT service:

   UUID Base: 1212-efde-1523-785feabcd123

   Service UUID: 0x1523

   Characteristic: 0x1524 (write/notify)

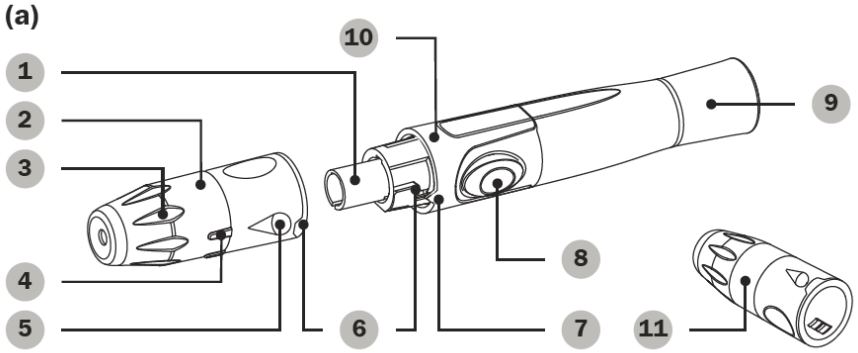
Please refer to the following link for further information:

https://foracare-suisse-ag.box.com/s/h54mphhr6r92wnzw5x9hrtbs7xx1qn9r

Lancet Device

Q39: How to prepare the lancing device?

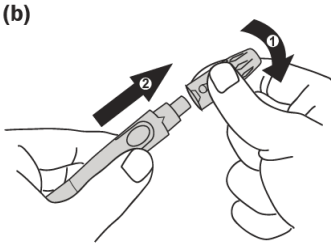
(a)



1 Lancet Holder	2 Cap	3 Adjustable Tip
4 Depth Indicator	5 Arrow	6 Lock
7 Lock Indicator	8 Release Button	9 Cocking Control
10 Ejector	11 A Clear Cap (For AST use only)	

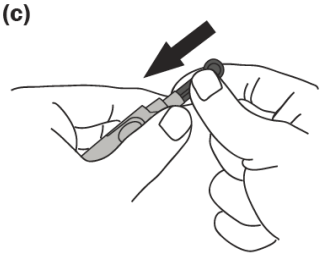
1. Twist and pull off the cap of the lancing device. (b)

(b)



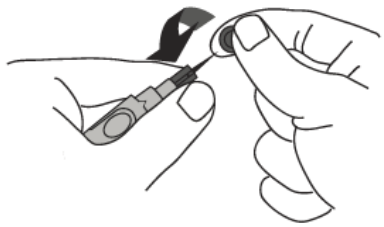
2. Insert a lancet into the lancet holder and push down firmly until it is fully secured.(c)

(c)



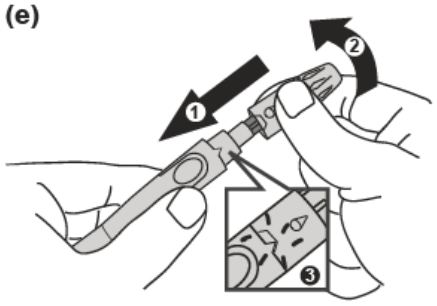
3. Twist the protective disk off the lancet. (d)

(d)



4. Replace and twist the cap to the right to close the lock as shown in the picture until you hear the click. When the lock is properly closed lock indicator is in the extreme right position. (e)

(e)



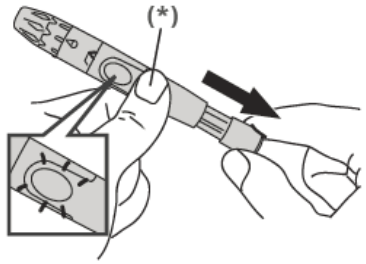
5. Holding the cap select on the depth of penetration by turning the adjustable tip in either direction so that the arrow on the cap points to the desired depth. (f)

(f)

6. Pull the cocking control back until it clicks. You will see a color change inside the release button when it is ready. (g)

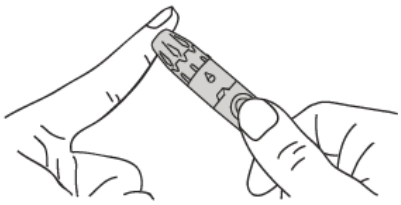
   Hold your fingers on the body NOT the cap. (*)

(g)



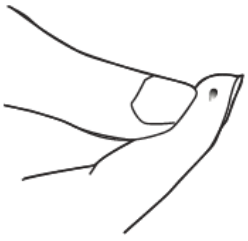
7. Lancing the finger: Press the lancing device's tip firmly against the lower side of your fingertip. Press the release button to prick your finger, then a click indicates that the puncture is complete. (h)

(h)



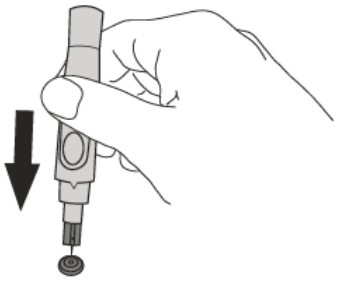
8. Remove the device from the puncture site. After penetration, remove the first drop of blood with a clean cotton swab. Gently squeeze the punctured area to obtain another drop of blood. Be careful NOT to smear the blood sample. Apply the blood to the test strip. (i)

(i)



9. Remove the lancet by twisting the cap off first. Safely dispose of the used lancet by placing the protective disk on a hard surface, and pushing the exposed tip into the disk. (j)

(j)

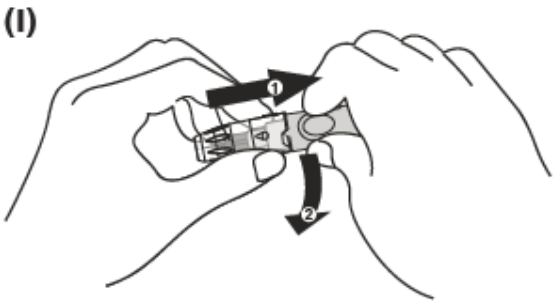


10. Slide the ejector forward to remove the used lancet. Dispose of the lancet according to your local regulations. (k)

(k)

11. For collecting blood samples from sites other than the fingertip, use the clear cap. Substitute the lancing device cap with the clear cap for alternative site testing. Pull the cocking control back until it clicks. When lancing the forearm, upper arm, hand, thigh, or calf, avoid lancing the areas with obvious veins in order to prevent excess bleeding. (l)

(l)



40: What are the warning informations in lancing devices?

1. Never share a lancet or the lancing device.
2. Always use a new, sterile lancet. Lancets are for single use only.
3. Avoid getting hand lotion, oils, dirt or debris in or on the lancets and the lancing device.
4. The used lancet may potentially be biohazardous. Discard it according to your local regulations.

Q41: How to clean the lancing devices?

1. The lancet is disposable and is intended for single use only.
2. The lancing device is reusable.
3. To clean the lancing device, use a mild soap and water to wipe clean the lancing device.
4. DO NOT rinse the device under water.
5. Disinfect the cap by placing it in 70% alcohol for 10 minutes and then allow it to air dry.
6. Do NOT place the device in a dishwasher or use detergents.