FORA®
ForaCare Suisse AG

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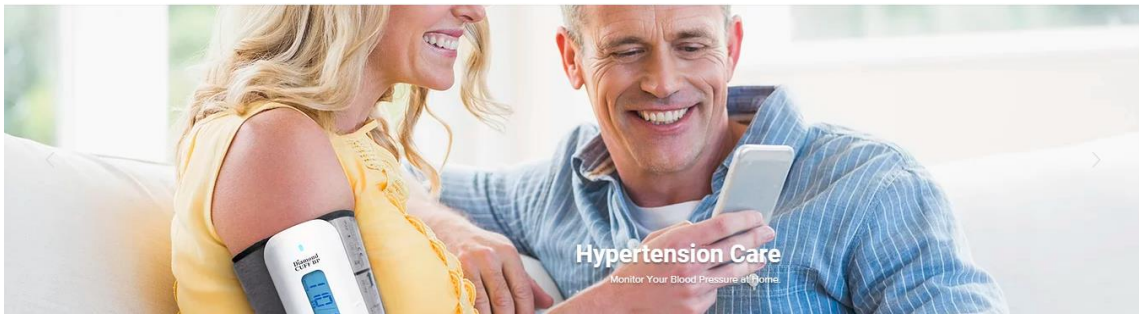
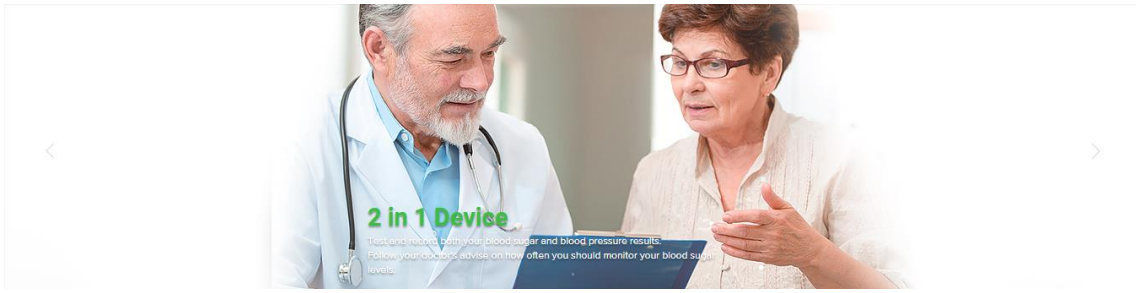
Blood Pressure Monitor and 2 in 1 Device FAQs





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Common troubleshooting

General Blood Pressure Meter Questions:

Q1: What are the general features of FORA's blood pressure monitor?

Name	DUO ultima	DUO ultima Pro	ACTIVE plus	ACTIVE WIRELESS plus
Model No.	D40 a/b/g	D40 Pro	P30 Plus	P30 Plus BT
2 in 1 Technology (BP + BG)	✓	✓		
IRB Technology	✓	✓	✓	✓
AVG Technology	✓	✓	✓	✓
Auscultatory Option		✓	✓	✓
Memory Capacity	864	864	60	200
User Name	1	1	1	1
Date/Time Indication	✓	✓	✓	✓
Large Display & Operation Button	✓	✓	✓	✓
All-in-one Button Operation				
Talking Guidance	✓			
Data Connection	USB (D40 a/b/g) BT (D40b)/ GPRS (D40g)	USB	N/A	Bluetooth
Power Source	6V AA×4/ 3.7V Li-Ion×4 (D40g) DC-6V Power Adaptor	6V AA×4 DC-6V Power Adaptor	6V AA×4 DC-6V Power Adaptor	6V AA×4 DC-6V Power Adaptor
Clinical Validated	✓	✓	✓	✓
Strip Enzyme (For Blood Glucose)	GOD	GOD		
No Coding Required (For Blood Glucose)	✓	✓		
Ketone Warning (For Blood Glucose)	✓	✓		
Other features	7, 14, 21, 28, 60, 90 Day Average	7, 14, 21, 28, 60, 90 Day Average		
Software Support	Healthcare TeleHealth	Healthcare TeleHealth	N/A	iFORA BP IFORA MP TeleHealth

Name	Diamond CUFF BP	Basic Plus
Model No.	P80	P31 Plus
2 in 1 Technology (BP + BG)		
IRB Technology	✓	✓
AVG Technology	✓	
Auscultatory Option		
Memory Capacity	200	100
User Name	1	1
Date/Time Indication	✓	✓
Large Display & Operation Button		✓
All-in-one Button Operation	✓	
Talking Guidance		
Data Connection	Bluetooth	N/A
Power Source	6V AA×4	6V A×1
Clinical Validated	✓	✓
Strip Enzyme (For Blood Glucose)		
No Coding Required (For Blood Glucose)		
Ketone Warning (For Blood Glucose)		
Other features	iFORA BP APP	
Software Support	iFORA BP iFORA MP Healthcare TeleHealth	

Q2: How accurate is FORA's Blood Pressure Monitor?

In order to ensure its accuracy, the FORA's blood pressure monitor has passed the ESH 2010 validation (European Society of Hypertension 2010), which ensures its accuracy. The ESH international protocol compares results of the FORA's device with those of a mercury manometer. The test should be followed specific testing requirement and are processed and analysed in order to guarantee the medical reliability of the blood pressure monitor. The FORA blood pressure monitor is accurate in static pressure within ± 3 mmHg (or ±2 % of reading) and ± 4% in pulse rate readings.

Q3: What are the recommended values for blood pressure?

Based on 2013 ESH-ESC Practice Guidelines for Management of Arterial Hypertension, the Office BP is usually higher than ambulatory and home BP and the difference increases as office BP increases.

Generally speaking, hypertension defines high blood pressure readings:

1. Office blood pressure:

   (1) Systolic Blood Pressure ≥ 140

   (2) Diastolic Blood Pressure ≥ 90

2. Self-measurement at home:

   (1) Systolic Blood Pressure ≥ 135

   (2) Diastolic Blood Pressure ≥ 85

The term 'white-coat' or 'isolated office' hypertension refers to a condition in which BP is elevated in the office at repeated visits and normal out of the office either on ambulatory blood pressure monitoring or on home blood pressure monitoring.

Conversely, BP may be normal in the office and abnormally high out of the medical environment, which is termed 'masked' or 'isolated ambulatory' hypertension.

Please classify your blood pressure levels according to the following table.

1. Definitions and classification of office blood pressure levels (mmHg)

Category	SBP		DBP
Optimal	<120	and	<80
Normal	120–129	and/or	80–84
High normal	130–139	and/or	85–89
Grade 1 hypertension	140–159	and/or	90–99
Grade 2 hypertension	160–179	and/or	100–109
Grade 3 hypertension	≥180	and/or	≥110
Isolated systolic hypertension	≥140	and	<90

The blood pressure (BP) category is defined by the highest BP level, whether systolic blood pressure (SBP) or diastolic blood pressure (DBP). Isolated systolic hypertension should be graded 1, 2 or 3 according to SBP values in the ranges indicated.

2. Definitions of hypertension by office and out-of-office (Home) blood pressure levels

Category	SBP (mmHg)		DBP (mmHg)
Office BP	≥140	and/or	≥90
Ambulatory BP			
Daytime (or awake)	≥135	and/or	≥85
Night-time (or asleep)	≥120	and/or	≥70
24-h	≥130	and/or	≥80
Home BP	≥135	and/or	≥85

BP, blood pressure; DBP, diastolic blood pressure; SBP, systolic blood pressure.

Source: The European Society of Hypertension and European Society of Cardiology Task Force Members. 2013 ESH-ESC Practice Guidelines for the Management of Arterial Hypertension. Journal of Hypertension 2013, 31:1925–1938.

Q4: When I take measurements and never get the same reading, is the device inaccurate?

No.

(1) Blood pressure always fluctuates during the day, therefore:

- 2 measurements taken one after the other will be different.

- Average taken over multiple readings is more relevant than a single measurement. Therefore several measurements are necessary.

(2) Some external elements can influence your blood pressure level: caffeine, tea, alcohol, tobacco, Stress, Emotional status and Physical activities.

(3) Incorrect using way or cuff size of blood pressure monitor.

(4) Timing of taking measurements. Try to take readings at the same general times each day (for example, once in the morning and once at night) for comparison purposes.

Q5: Are there differences between taking a blood pressure reading on the right arm vs. left arm?

Blood pressure measurement values vary from the left arm to the right arm. The average is generally within 10 mmHg (millimeters of mercury) for most individuals. We suggest you to use FORA's blood pressure monitors on the left arm as they are validated through clinical studies using the left arm. You should talk to your doctor before using the right arm to take a measurement.

Q6: Which pressure is more important about hypertension -- the Systolic or Diastolic blood pressure?

Both of them are important about hypertension.

When systolic pressure is higher, the heart is squeezing and pushing the blood round the body and it gives the best idea of your risk of having a stroke or heart attack. Having a raised systolic blood pressure but normal or low diastolic blood pressure is called Isolated Systolic Hypertension (ISH) and carries an increased risk of developing heart attacks or strokes and should be treated.

Diastolic blood pressure is also the risk indicator about stroke or heart attack. Some studies suggest that, in people aged younger than 40 years, diastolic blood pressure is a better way of assessing risk. It could be that diastolic blood pressure becomes

more important when it is very high. There is some evidence to suggest that, for example, a blood pressure of 180/120mmHg gives a greater risk of stroke or heart attack than 180/100mmHg.

Q7: What are the things I need to check for before measuring my blood pressure so as to avoid varied readings?

(1) Avoid caffeine, tea, alcohol and tobacco for at least 30 minutes before the measurement.

(2) Wait 30 minutes after exercising or bathing before the measurement.

(3) Sit or lie down for at least 10 minutes before the measurement.

(4) Take a 5-10-minute break between measurements. This break can be longer (the rest time should be more than 30 mins after doing exercises) if necessary, depending on your physical condition.

(5) Blood pressure varies between each arm. Always measure your blood pressure on the same arm.

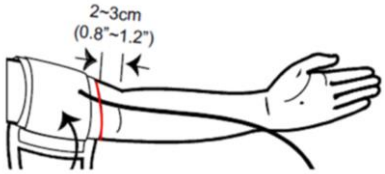
(6) The accurate size and way to fit the cuff.

(7) The accurate measuring position.

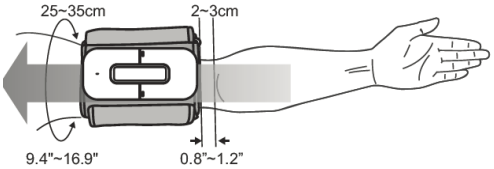
Q8: What is the accurate way to fit the cuff?

A. Stretch your left (right) arm in front of you with your palm facing up. Slide and place the cuff onto your arm with the air tube and artery mark region (in red) toward the lower arm.

B. Wrap and tighten the cuff above your elbow. The red line on the edge of the cuff should be approximately 0.8 to 1.2 inches (2 to 3 cm) above your elbow. Align the tube over the main arteries on the inside.



P30 plus, P30 Plus BT, P31 Plus, D40a/b/g and D40 Pro



Diamond CUFF BP (P80)

C. Leave a little free space between the arm and the cuff. You should be able to fit 2 fingers between them.

D. Press the hook material firmly against the pile material. The top and bottom edges of the cuff should be tightened evenly around your upper arm.

Q9: What is the accurate position to measure my blood pressure?

(1) Sit down for at least 10 minutes before the measurement.

(2) Place your elbow on a flat surface. Relax your hand with the palm facing up.

(3) Makes sure the cuff is positioned around the same height as the location of your heart (15 cm lower than the heart may result in a higher reading around 10 mmHg).

P30 plus, P30 Plus BT, P31 Plus, D40a/b/g and D40 Pro

Diamond CUFF BP (P80)

(4) Press the Start button. The device will turn on and the cuff will begin to inflate automatically. Remain still and do not talk or move during the measurement.

Q10: What is Auscultatory Mode? Which FORA's Device can use it? Where we can get the direction about using Auscultatory Mode?

(1) This is the manual method involves applying a stethoscope to the arm and listening to the pulse while the air is slowly let out from the cuff (the Korotkoff method). Only well trained persons may use this mode to measure blood pressure manually.

(2) The FORA's BPMs can use it that are:

DUO ultimate Pro (D40 Pro), Active plus (P30 Plus) and ACTIVE WIRELESS plus (P30 Plus BT).

(3) Please refer to the owner's manual for each BPM. There is clear direction for Auscultatory Mode in Measuring Blood Pressure section. The systolic pressure is the maximum pressure in an artery at the moment when the heart is beating and pumping blood through the body. The diastolic pressure is the lowest pressure in an artery in the moments between beats when the heart is resting.

Q11: What does Oscillometric mode mean?

The Oscillometric method of measuring blood pressure with an automated cuff yields valid estimates of mean pressure. Oscillometric technology measures the vibration of your blood traveling through your arteries and converts the movement into digital readings. All FORA's digital BPMs are default oscillometric mode.

Spare Parts - Cuff:

Q12: Does the size of the cuff matter? How do I determine the cuff size that I need?

(1) In order to get the correct measuring values, the appropriate size cuff for your arm is very important. If you use the wrong size, you will get inaccurate reading values and even error messages from your blood pressure monitor.

(2) You can use a cloth tape to measure the circumference of your upper arm between your elbow and shoulder.

Q13: What are the cuff sizes?

There is a wide range of cuffs which come with our blood pressure monitors. The cuff size 24 ~ 43 cm (9.4~16.9 inches) fits almost all adults. Please contact us if you require a smaller size: 19~25 cm (7.5 ~ 9.8 inches) or medium: 25~35 (9.8 ~ 13.8 inches).

Q14: What is the most common situation when cuff is out of life expectancy?

Cuff is the consumables. If the cuff is out of the life expectancy or overuse, it will be air leakage in rubber part between bladder and tube. The pressure monitor will display Error-1 message on the screen. Please replace new cuff to solve this problem.

Q15: What is the average life expectancy of a monitor cuff?

The general average life expectancy is around 3,000 using times. It could be involved by your storage condition too.

Cleaning and Storage:

Q16: How do I clean my blood pressure monitor?

(1) To clean the device exterior, 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 flush with water.

(2) Do NOT use organic solvents to clean the device.

(3) Do NOT wash or iron the pressure cuff.

Q17: How do I store my blood pressure monitor?

(1) We highly recommended removing the batteries from the blood pressure monitor if you are not going to use the device for an extended period. Batteries may leak chemicals and damage your monitor.

(2) Always store or transport the device in its original storage case.

(3) Avoid dropping and heavy impact.

(4) Avoid direct sunlight and high humidity. The suitable storage and operation conditions are as the following:

BPM	Storage Conditions	Operation Conditions
P30 plus P30 Plus BT P31 Plus	Temperature:-20℃ to 60℃ (-4° F to 140° F) Humidity: below 95% RH	Temperature:10℃ to 40℃ (50° F to 104° F) Humidity: below 85% RH
Diamond CUFF BP	Temperature: -25℃ ~ 70℃ (-13° F to 158° F) Humidity: 10% ~ 95%	Temperature: 5℃ ~ 40℃ (41° F to 104° F) Humidity: 15% ~ 93%
D40a/b/g	Temperature:-20℃ to 60℃ (-4° F to 140° F) Humidity:5 - 95% RH	Temperature:10℃ to 40℃ (50° F to 104° F) Humidity: below 85% RH
D40 Pro	Temperature:-20°C to 60°C (-4°F to 140°F) Humidity: 5 - 95% RH	Temperature:10°C to 40°C (50°F to 104°F) Humidity: below 85% RH

Common troubleshooting:

Q18: Is it normal that my blood pressure is variable?

Yes, it is quite normal for people's blood pressure to change throughout the day and night, stress levels, food or drink intake, recent activities, the measuring technique or in different conditions where you may measure your blood pressure.

Q19: What is the international standard of blood pressure?

All FORA's BPM follow the accuracy criteria for the International Protocol of the European Society for Hypertension (ESH), the British Hypertension Society (BHS) and the Association for the Advancement of Medical Instrumentation (AAMI) Standard. The specification of ESH international protocol 2010 is as following table:

ESH International Protocol 2010			
Sequential Measurements			
IP Grading Part 1 - Minimum Requirements			
N	≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg
Two of	73	87	96
All of	65	81	93

Recruitment Ranges			
SBP		DBP	
mmHg	Subjects	mmHg	Subjects
90*..129	10 - 12	40*..79	10 - 12
130..160	10 - 12	80..100	10 - 12
161..180*	10 - 12	101..130*	10 - 12
*	Altogether, up to 4 recruitment pressures are permitted to be outside these limits.		

Test Measurement Distribution			
SBP		DBP	
mmHg	Measurements	mmHg	Measurements
≤ 100	≥ 1	≤ 50	≥ 1
< 130	22 - 44*	< 80	22 - 44*
130..160	22 - 44*	80..100	22 - 44*
> 160	22 - 44*	> 100	22 - 44*
≥ 170	≥ 1	≥ 120	≥ 1
*	The difference between the maximum and minimum of these 3 counts for SBP and, separately, for DBP, must be less than or equal to 19.		

http://www.dableducational.org/accuracy_criteria.html

ESH: European Society of Hypertension (for EU)

BSH: British Society of Hypertension (for UK)

AAMI: Association for Advancement of Medical Instrumentation (for USA)

For a BPM to be considered as accurate, it must be subjected to formal validation protocols by independent investigators. The 3 bodies stated above are the 3 most widely accepted and recognised.

Q20: My blood pressure results appear to be abnormal – what should I do?

If you feel your blood pressure level is abnormal, please directly consult your doctor. You will get a proper diagnosis from him or her.

Q21: What are the common measuring error reasons?

Symptom	Cause	Solution
Error 1 message	Inflation or pressure error: 1. Cuff leakage. 2. Motor line malfunctions or ruptures.	1. Replace the cuff. 2. Contact the local service member to repair the device.
Error b message	Battery is too low.	Replace the batteries.
Error E message	The IC inside the device could be damaged by unknown reason.	Contact the local service member to repair the device.
Nothing is displayed after pressing the start button.	1. Batteries exhausted or incorrectly installed. 2. Device malfunction (PCB board burned).	1. Replace or correctly install the batteries. 2. Contact the local service member to repair the device.
The **pressure** result is **higher/lower** than the user's average measurement.	1. The cuff may not fit properly or the measuring position is wrong. 2. There is insufficient rest before taking the measurement. 3. Device malfunction (the air tube broken inside the BPM). 4. Arm unsupported while	1. Please follow the manual to adjust your cuff and measuring position. 2. Please rest at least 5-10 mins (30 mins after doing exercises). 3. Contact the local service member to repair the device. 4. Follow the instruction to sit and put your measurement arm on

	sitting or standing	the supported table.
The **heart rate** is **higher/ lower** than the user's average rate.	1. Movement during the measurement. 2. The measurement is taken just after doing exercises. 3. Device malfunction.	1. Do not move and repeat the measurement. 2. Rest at least 30 minutes before repeating the measurement. 3. Contact the local service member to repair the device.

Please refer to the owner's manual to check the detailed error codes and error symptoms for different types of blood pressure monitors.