Central Blood Pressure Meter
Model cBP301

Operating Manual

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Contents

Introduction

Thank you for choosing the Central Blood Pressure Meter from Centron Diagnostics. Please take a moment to familiarise yourself with instructions for use detailed in this manual and for further information please refer to our website: www.centrondiagnostics.com .

Central systolic blood pressure is the peak of the pressure pulse at the aortic root during a cardiac cycle.

As the pulse travels through smaller arteries its shape changes so that when systolic pressure is measured conventionally, in the brachial artery of the upper arm, the systolic pressure is significantly increased. The amount of increase depends upon the stiffness of the arteries and the shape of the pressure waveform.

Recent studies have shown that different classes of antihypertensive drugs have different effects upon brachial and central blood pressure and that the reduction in central blood pressure could be over or under estimated by the use of brachial blood pressure alone[1].

It has also been shown that central systolic blood pressure is a better predictor of cardiovascular disease than brachial blood pressure[2].

The cBP301 is a compact, self contained device designed to measure both brachial blood pressure and central systolic blood pressure. Its operation requires no special training and the procedure is identical to routine oscillometric measurement. The cBP301 is portable and is battery powered.

The cBP301 measures brachial blood pressure using SunTech Medical® validated oscillometric technology.

The central systolic blood pressure is derived using waveform analysis developed by King's College London and is displayed together with the ratio of the brachial pulse height to the central pulse height.

Note: The cBP301 is not designed for use during defibrillation or electrosurgery.

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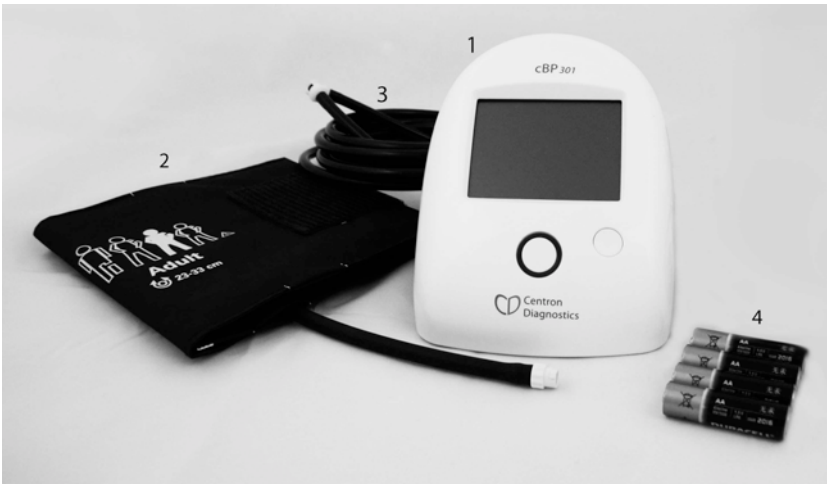
1. Morgan T, Lauri J, Bertram D, Anderson A
Effect of different antihypertensive drug classes on central aortic pressure.
Am J Hypertens 2004 Feb; 17(2): 118-23

2. Williams B, O'Rourke M
Anglo-Scandinavian Cardiac Outcomes Trial. The Conduit Artery Functional Endpoint (CAFE) study in ASCOT.
J Hum Hypertens. 2001 Aug;15 Suppl 1:S69-73

Package Contents

1 cBP301 Central Systolic Blood Pressure Meter
2 Adult and large adult cuffs
3 Hose
4 Primary Lithium AA cells



Warnings and Cautions

Caution: Possibility of injury or serious damage
Warning: conditions or practices that could result in personal injury.
Please Note: Important information for avoiding damage to the instrument or facilitating operation of the instrument.

 **CAUTION:** Read the manual before use
WARNING: The instrument is not suitable for use in the presence of explosive or flammable gases, flammable anaesthetic mixtures or in oxygen rich environments.
WARNING: The use of portable phones or other radio frequency (RF) emitting equipment near the system may cause unexpected or adverse operation
WARNING: Ensure that the hose connection to the cuff does not become kinked as this could result in continuous cuff pressure affecting the blood flow and resulting in harmful injury to the patient.
WARNING: Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the accompanying documents
WARNING: Portable and mobile RF communications equipment can affect medical electrical equipment
WARNING: Equipment should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the equipment or system should be observed to verify normal operation.
 **PLEASE NOTE:** The product you have purchased should not be disposed of as unsorted waste. Please utilise your local WEEE collection facilities for the disposal of this product.

Contraindications

WARNING: Do not place the cuff over a wound as this could cause further injury when pressurised
WARNING: Repeated use of the instrument could cause injury due to blood flow inference
WARNING: Application of the cuff to any limb where intravascular access or therapy or, or an arterio-venous (A-V) shunt is present could result in injury due to the temporary interference of blood flow during pressurisation
WARNING: The application of the cuff to the arm on the same side as a mastectomy should be avoided
WARNING: The application and pressurisation of the cuff may cause temporary loss of function of other medical monitoring equipment on the same limb
WARNING: During use the limb should be observed to ensure that there is no prolonged impairment to the circulation

Intended Use

The intended use of the product is to provide the additional measurement of central blood pressure to the routine measurement of brachial blood pressure in the upper arm in adults. The additional measurement of central blood pressure is considered to be of greater clinical significance than the peripheral measurement alone.

Environment

The cBP301 is designed for routine clinical use in an office environment. Use in temperatures outside the range 0 to 50 ^{O}C should be avoided.
The environment should be free of excessive vibrations, and sources of electrical noise.
Keep mobile phones 5 meters away during measurement.

Getting Started

Remove the protective plastic film from the screen.
Insert four AA size lithium or alkaline batteries as shown below taking care to observe the correct polarity:

WARNING: do not touch the patient when the battery cover is removed.

Connect the required cuff to the unit using the hose as shown below:

Operation

An appropriate sized cuff should be placed on the non-dominate arm where the lower edge of the cuff is located 2cm above the antecubital fossa (interior bend of the elbow). Wrap the cuff snugly around the arm for maximum oscillometric signal quality.
If possible, do not wrap the cuff over the patient's clothing.
Ensure that the **ARTERY** arrow is over the brachial artery, between the biceps and triceps on the inside of the arm.
Use the **RANGE** indicator with the **INDEX** line to check that the arms falls within the specified range for that cuff.
Use appropriate larger or smaller cuff if necessary.
The subject should be seated comfortably with their arm resting upon a table with the midpoint of the subject's upper arm at heart level for proper measurement accuracy.
When the cuff is below heart level, measurement results may be higher and when the cuff is above heart level, measurement results may be lower than comparative results obtained at heart level.
Ensure that the air hose from the monitor to the cuff is not compressed, crimped or damaged.
Please remember that using a cuff that is the wrong size may give false and misleading results.

Turn the unit on by pressing the **on/off** button on the front panel. A start up screen will be displayed showing the software version and the **START** button will be illuminated green.
Press **START** to begin the test.
The **START** button will be illuminated blue and the cuff will inflate and the brachial blood pressure measurements systolic (**SYS**) diastolic (**DIA**) and mean arterial pressure (**MAP**) will be taken and displayed.

This will be followed automatically by a re-inflation to obtain the brachial artery pressure waveform. The central systolic blood pressure (**cSYS**) together with the heart rate (**HR**) are then displayed. If motion artefact or arrhythmia results in an erroneous measurement then the **START** button will be illuminated red, a warning message will be displayed, and the results will not be displayed.
When the measurement is complete, or to abort a measurement, turn the unit off by pressing the **on/off** button.
To ensure maximum lifetime of the batteries the unit will automatically turn off 1 minute after a measurement is made. The results of the last test can be recalled after the unit has turned off by turning on, waiting until the blank results screen is displayed, and then holding down the **START** button for 3 seconds.
Do not repeat a measurement within 5 minutes.

Note: The mini USB connector on the side of the unit is for factory use only, do not use this connection

Note: The patient applied part of this instrument is the cuff; do not allow the patient to come into contact with any other parts of the cBP301 during use.

Battery Management

The cBP301is designed to use either alkaline or lithium AA size primary cells. We recommend the use of lithium primary cells for maximum life and efficiency.
Note: Lithium primary cells are not rechargeable.
To ensure maximum lifetime of the batteries the unit will automatically turn off 1 minute after a measurement is made. Remove the batteries if you do not intend to use the device for more than 3 months.

Cleaning

The casing of the unit may be cleaned using a damp cloth. Take care that no water is allowed to enter the unit.
The display may be wiped gently with a dry cloth only.
The cuff can be cleaned by spraying with a mild disinfectant solution (e.g. ENZOL or a 10% bleach solution).

Servicing

It is recommended that the cBP301 is serviced and checked for accuracy every 2 years.
Please contact service@centrondiagnostics.com if you unit requires service or repair to obtain a Returned Goods Authorisation (RGA) number. No product should be returned to Centron except in accordance with the Centron Warranty and Return Goods Policy (for full details please visit www.centrondiagnostics.com)
There are no user serviceable parts in the cBP301

Trouble Shooting Information

Should you encounter problems operating the cBP301 consult the table below:

Problem	**Possible cause**	**Solution**
Unit does not turn on	Batteries flat	Replace batteries
Error message displayed during measurement	Movement artefact detected	Ensure subject is relaxed and still and repeat test

Electromagnetic Compatibility (EMC)

<table>
<tr><th colspan="3">Guidance and manufacturer's declaration – electromagnetic emissions</th></tr>
<tr><td colspan="3">The cBP301is intended for use in the electromagnetic environment specified below. The customer or the user of the cBP301should assure that it is used in such an environment.</td></tr>
<tr><th>Emissions test</th><th>Compliance</th><th>Electromagnetic environment – guidance</th></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group1</td><td>The cBP301 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Class B</td><td rowspan="3">The cBP301 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply networks that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-3</td><td>Not applicable</td></tr>
<tr><td>Voltage fluctuations/flicker emissions</td><td>Not applicable</td></tr>
</table>

Guidance and manufacturer's declaration – electromagnetic immunity			
The cBP301 is intended for use in the electromagnetic environment specified below. The customer or user of the cBP301 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	Not applicable	
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Not applicable	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95%dip in U_T for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% (30% dip in U_T) for 25 cycles. <5% (>95% dip in U_T) for 5 s	Not applicable	
Power frequency (50/60 Hz) Magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level			

Guidance and manufacturer's declaration – electromagnetic immunity			
The cBP301 is intended for use in the electromagnetic environment specified below. The customer or user of the cBP301 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 V rms	3 V rms	Portable and mobile RF communications equipment should be used no closer to any part of the cBP301, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	3 V/m	3 V/m	**Recommended separation distance** $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacture and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range[b] Interference may occur in the vicinity of equipment marked with the following symbol:
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the cBP301 is used exceeds the applicable RF compliance level above, the cBP301 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the cBP301. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Recommended separation distances between portable and mobile RF communications equipment and the cBP301			
The cBP301 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the cBP301 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and cBP301 as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d=1.2\sqrt{P}$	80 MHz to 800 MHz $d=1.2\sqrt{P}$	800 MHz to 2,5 GHz $d=2.3\sqrt{P}$
0.01	0,12	0,12	0,23
0.1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Changes or modifications to the cBP301 that are not expressly approved by Centron Diagnostics can cause EMC issues with this or other equipment.

This instrument complies with directive EN60601-1-2 electromagnetic compatibility but can be affected by cellular phones and by electromagnetic interference exceeding levels specified in EN 50082-1:1992

Symbols

	Type BF applied part. F-TYPE APPLIED PART complying with the specified requirements of EN60601-1:2006 to provide a higher degree of protection against electric shock than that provided by TYPE B APPLIED PARTS
CE 0120	In accordance with Directive 93/42/EEC
	Disposal in compliance with WEEE
	Consult the instructions for use
	Caution: consult the accompanying documents
	Date of manufacture
	Manufacturer
SN	Serial number

Classification

Protection against electric shock:
Internally powered equipment.

Mode of operation:
Continuous

Specifications

Range:
Systolic 40 – 260mmHg
Central Systolic 40 – 250mmHg
Diastolic 20 – 200mmHg
Mean Arterial Pressure 25 – 220mmHg
Heart Rate 30 – 220 bpm

Accuracy:
Meets:
ANSI/AAMI SP10-2002
EN1060-1:1995 Non-invasive sphygmomanometer – Part 1: General requirements.
EN1060-3:1997
EN1060-4:2004
Heart Rate +/- 2% or +/- 3bpm (whichever is the greater)

Power Supply:
4 x AA size Alkaline or Lithium primary cells.

Operating current:
800mA peak

Battery life:
Alkaline cells, greater than 50 measurement cycles
Lithium cells, greater than 200 measurement cycles

Dimensions:
117mm (W) x149mm (D) x 120mm (H)

Weight:
600 g

Operating Conditions:
0^{O}C to 40^{O}C, 15% to 95% RH, non condensing

Transport and Storage Conditions:
-20^{O}C to 70^{O}C, 15% to 95% RH, non condensing

Lifetime:
5 years

NOTE: There are no user serviceable parts in the cBP301.

WARNING: No modification of this equipment is allowed

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