



blood pressure



PROHIBIT ICH

Patient Information Manual

Doc Ref: 001-2027-LMAN3 Version: R1, Issue Date: 12 MAR 2018

Trademarks: t+ Medical® is a registered trade mark of OBS Medical Ltd.

Contents

| | |
|-----------------------------------------------|-----------|
| Introduction | 4 |
| Indications..... | 4 |
| Welcome to t+ blood pressure | 4 |
| How does t+ blood pressure work? | 5 |
| Why should I use t+ blood pressure? | 6 |
| When should I not use t+ blood pressure?..... | 6 |
| Caution..... | 6 |
| Getting Started | 7 |
| Set up instructions..... | 7 |
| Bluetooth Hub..... | 8 |
| Blood Pressure Meter | 9 |
| Blood Pressure Cuffs..... | 9 |
| Taking a blood pressure reading..... | 9 |
| Troubleshooting and Support..... | 11 |
| Description of maintenance | 11 |
| Storage instructions..... | 11 |
| Troubleshooting – Blood Pressure Meter..... | 12 |
| Troubleshooting – Bluetooth Hub | 13 |
| t+ blood pressure support | 14 |
| Oxford contact information | 14 |
| T+ contact information | 14 |

Introduction

Indications

The t+ blood pressure is intended for periodically recording blood pressure readings for the purpose of improving blood pressure management.

The t+ blood pressure provides real-time readings, graphs, and trends directly to healthcare professionals. It is intended to be used in the home to aid you to monitor your blood pressure in between hospital visits.

The t+ blood pressure is available only through healthcare professionals.

Welcome to t+ blood pressure

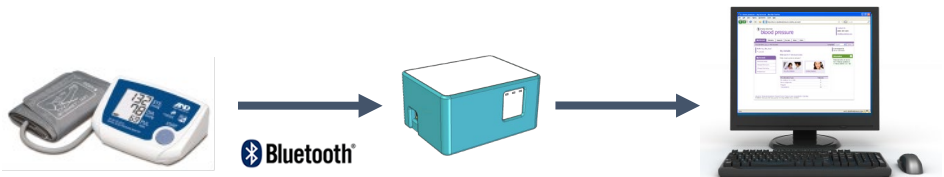
t+ blood pressure is a simple tool to help you and your health care professional keep track of your blood pressure in between hospital visits. This means they can spot any changes and track any trends as they happen.

How does t+ blood pressure work?

t+ blood pressure uses a Bluetooth Hub and a blood pressure meter (with Bluetooth) to safely and securely send information about your blood pressure directly to health care professionals.

The information about your blood pressure is automatically sent to health care professionals who can look at it on their computer.

It is really simple for you to use, all you have to do is put the blood pressure cuff on your arm and press the Start button.



You take your blood pressure at home using the Blood Pressure monitor (with Bluetooth)

The readings are automatically transmitted via Bluetooth to the Bluetooth Hub and onto the t+ System Servers

Healthcare professionals are then able to see your readings via a secure web site

Why should I use t+ blood pressure?

You will have been specifically chosen by your healthcare professional to use this equipment and advised by them how to use it.

Through the use of t+ blood pressure, both you and your healthcare professional will have a much greater insight into your health. It will help you both monitor your condition more closely.

When should I not use t+ blood pressure?

You should not use t+ blood pressure if you feel unwell before, during or after taking your blood pressure. Please inform your healthcare professional.

Caution

Please read all the instructions provided in this user guide, and ensure you are confident using the equipment. If you need any additional help using the equipment please speak to your healthcare professional.

This equipment is intended only to be used by the person it was supplied to and must only be used as instructed.

Getting Started

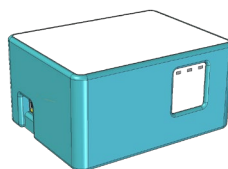
You will have been specifically chosen by your healthcare professional to use this equipment and advised by them how to use it.

Set up instructions

You will have received:



Blood pressure meter and medium sized cuff *



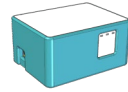
Bluetooth Hub



A t+ blood pressure
Patient user guide

*Other cuff sizes are available please discuss with your healthcare professional

Bluetooth Hub



You have been issued a Bluetooth Hub that will automatically send your blood pressure readings directly to healthcare professional to monitor your progress.

For the blood pressure monitor to transmit readings to the Bluetooth Hub, they need to be within a 10 meter range of each other, so where possible please try to use your blood pressure monitor in the same room as the Bluetooth Hub.

The Bluetooth Hub will come with a mains charger. Please plug the mains charger into a socket as soon as you get home. We would recommend leaving the Bluetooth Hub plugged in and switched on at all times.

Once plugged in, the three indication lights will illuminate for 10 seconds then go off.



Then one or more indication lights will illuminate as follows:

- **Green Light (Status)**
 - Intermittent flashing – the hub is trying to connect to the secure t+ servers
 - When permanently illuminated – the hub is now connected to secure t+ servers
- **Blue Light (Bluetooth)**
 - When illuminated – the BP Meter is transmitting readings to the Bluetooth Hub
- **Red Light (Memory)**

- When illuminated – the BP Readings have been stored awaiting transmission when connected



Blood Pressure Meter

You have been issued with a home digital blood pressure monitor as part of PROHIBIT - ICH.

It is important that **only you** use the BP monitor.

Please do not allow anyone else to use the machine or interfere with the equipment.

The purpose of this is to try and make sure that your blood pressure (BP) is well controlled.

Blood Pressure Cuffs

Your healthcare professional will advise you on which arm we would like you to measure and provide you with the appropriate size of cuff for your arm.

Taking a blood pressure reading

Your healthcare professional will instruct you on how to use the home BP monitor either in the clinic or at home where facilities exist.

Please refer to the below instructions for further information.

When to take your readings

Set 1 – as soon after waking as possible

Set 2 – mid-day or early afternoon

Set 3 – just before you go to bed

Blood pressure varies in everyone throughout the day. Having a mid-day reading better informs your healthcare professionals' management of your blood pressure.

At each sitting we would like you to measure your blood pressure **3 times**.

You should allow a couple of minutes in between each of the 3 blood pressure measurements.

If you wish to take your blood pressure more frequently, please ensure that this is in addition to the above schedule, not instead of it.

How to take your readings

For the best results:

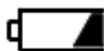
- Please rest for a few minutes prior to taking your readings.
- All measurements should be done sitting, at a table if possible.
- Please always take your blood pressure on the same arm.
- Try not to talk or move whilst the cuff is inflating.

Troubleshooting and Support

Description of maintenance

Product damage may occur if proper care is not taken whilst unpacking, installation and use.

Do not submerge any of the components in water or any other fluids. If the equipment does get wet, dry immediately.



If the batteries in the blood pressure meter run low, the battery power indicator will begin to blink.

Important: When the battery symbol on the BP Meter begins to blink; you should replace the batteries immediately.

The meter takes 2x AA batteries. More information on replacing the batteries this can be found in the BP meter user guide.

The Bluetooth Hub is mains powered and should be left on at all times to ensure the timely receipt and transmission of your daily BP readings for clinical review.

Storage instructions

Store the t+ blood pressure equipment in a dry area and remove batteries from the BP meter if it is to be stored for extended periods of time.



Troubleshooting – Blood Pressure Meter

| Problem | Possible Reason | Recommended Action |
|-----------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|
| Nothing appears in the display even when the power is turned on | Batteries are drained | Replace all batteries with new ones |
| | Battery terminals are not in the correct position | Reinstall the batteries with negative and positive terminals matching those indicated on the battery compartment. |
| The Cuff does not inflate | Battery power is low Low Battery Mark – blinks If the batteries are drained completely, the mark does not appear | Replace all batteries with new ones |
| The unit does not measure. | The cuff is not applied properly | Apply the cuff correctly |
| | You moved your arm or body during the measurement | Make sure you remain very still and quite during the measurement |
| Readings are too high or too low | The cuff position is not correct | Sit comfortably and still. Raise your hand so that the cuff is at the same level as your heart using a pillow or support. |
| | | If you have a very weak or irregular heartbeat, the device may have difficulty in determining your blood pressure |
| Other | | Remove the batteries. Place them back properly and try the measurement again. |

Troubleshooting – Bluetooth Hub



| Problem | Possible Reason | Recommended Action |
|------------------------------------------------------------------------------------|-----------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| BT Hub Status (Green) indication light is not ON or flashing | Mains power not connected | Check the mains power is connected to the BT Hub and that mains power is switched on at the plug socket. |
| BT Hub Status (Green) indication light is flashing intermittently | Poor network signal at the current BT Hub location | Relocate the BT Hub to another part of the building and retry. The Status (Green) indication light needs to be permanently ON |
| BT Hub Bluetooth (Blue) indication light does not come on when taking a BP reading | The BT Hub and BP Meter are not within 10 meters of each other | Check both the BT Hub and BP Meter are within 10 meters of each other and retry reading |
| | The BP meter needs to be reconnected with the BT Hub | <p>BP Meter - Press and hold the start button until the word uPr appears.</p> <p>Lift and re-press the start button and the words END appears.</p> <p>Now retake a BP reading. The Bluetooth (Blue) indication light should now come on.</p> |
| BT Hub Memory (Red) indication light is on. | BT Hub is not connected to secure t+ system so it is storing readings | Check the Status (Green) indication light is permanently ON |

t+ blood pressure support

For study specific questions, please contact the relevant research team as detailed via your Patient Information Letter issued along with the t+ blood pressure system.

Oxford contact information

If you have any concerns or questions regards your blood pressure investigations, please contact the Centre for Prevention of Stroke and Dementia team during office hours Monday – Friday 8:30am until 5pm

Call: 01865 234 893

T+ contact information

If you have any technical problems, please contact the customer service team who can be reached during office hours Monday - Friday 9am to 5pm excluding bank holidays.

Call: 01235 432050

Email: support@tplusmedical.com

This page has intentionally been left blank



UK Head Office
5G Park Square
Milton Park
Abingdon
OX14 4RR
UK