

OSTOM-i™ POUCH FILL SENSOR

Getting started

Download the Ostom-i app from the [Google Play store](#) or [Apple App store](#). Once downloaded, open it & follow these simple instructions.

Step 1 Activate the sensor by removing the plastic tag from the bottom of the case to activate the battery. Use a small blunt object such as the end of a paperclip to press the button on the sensor. A green light will then indicate that it is working.

Step 2 Turn on Bluetooth mode on your mobile device as instructed by the app. The screen will move to the devices menu.

Step 3 Press the scan button to scan for your mobile device. This may take a couple of attempts. Under the section marked 'Visible devices', 'Ostom-i' should appear.

Step 4 Press the 'Ostom-i' button. The screen will change to show a thermometer.

Step 5 Press the alarm tab to set the point at which the alarm on your mobile device sounds – anywhere between 1% and 100% full. You can edit the alarms at any time via the 'New Alarm' button.

Step 6 Connect the Ostom-i Alert to your bag. It is now ready for use.

Details of other functions can be found at www.11health.com

This device is to be used as a guide only and should not be used for the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease.

CE

Patent pending

Issuance date: 8/12/14 Ostom-i v1

Available for use by all patients, infant, child, adolescent and adult

Precaution: Nurses or other healthcare personnel should visually inspect an ostomy pouch every 12 hours

SINGLE PATIENT USE ONLY. WHEN RE ATTACHING TO POUCH WIPE CASING AND SENSOR STRIP CLEAN USING A DAMP CLOTH.

DO NOT USE IN WATER.

Be aware electromagnetic interference can occur between this bluetooth device and nearby electronic equipment. Bluetooth works as long as both the device and mobile device are within a 15 meter range. Do not try and pair any other Bluetooth devices to the mobile app.

Potential electromagnetic interference can be mitigated by increasing the separation distance between the Ostom-i™ Alert sensor and surrounding electronic equipment.

Frequently Asked Questions

Website FAQs

Q. How long will the battery last?

A. The device is designed to last up to 3 months. As you know it is constantly sending a Bluetooth signal to your mobile device checking whether the bag/pouch is filling to your alarm settings. This process is unlike any other use of Bluetooth technology. If you imagine a Bluetooth ear piece used in your car then this has a life of about 2 hours before needing to be recharged. The actual life will be determined based on how many alarms you set each day. We anticipate an average user setting three different alarms per day and that will give you maximum battery life. However you are free to set as many alarms as you wish and it will only slightly start to reduce the battery life.

Q. Do I need to change the settings at night?

A. When lying down the bag will appear not to be as full when compared to standing up. This obviously is not true so we suggest reducing your alarms settings by 50%. For example if you set your alarm to go off at 30% full then reset the alarm to 15% when going to sleep.

Q. Will the device stay connected to my mobile at all times?

A. The device should stay “paired” ie connected to your mobile providing you keep the mobile relatively close to the device at all times. Should it become unpaired then simply go to the devices tab on your mobile app and scan and re-pair your device.

Q. What distance do you call “relatively close”?

A. The recommended distance as given by the Bluetooth manufacturers is 15 meters.

Q. When I go in to hospital can I connect my device to the hospital app used by the nurses and to my own mobile?

A. You can only connect to one device at a time. If your device is connected to the hospital app then make sure you have unpaired it from your own mobile app.

Q. How many devices will I need to purchase per year?

A. Should you wish to use the device every day then we would expect you to purchase 4 devices per annum.

Q. Can this device be prescribed through insurers in the USA?

A. The device is approved as a class 1 medical device by the FDA. This means that your doctor or hospital is allowed to prescribe it. However you will need to check with your own insurance policy and they do vary from one to another.

Q. What medical regulatory approval does the device have?

A. The device is regulated in Europe through the Medical and Healthcare Regulatory Agency (MHRA) as a class 1 device. It is also regulated in the USA via the FDA as a class 1 medical device.

Q. My device is broken what should I do?

A. In the first instance you should contact our 24hr customer service line as detailed on the website.