

# SBRI HEALTHCARE CASE STUDY

## 11 Health and Technologies Limited



### INNOVATION

Alfred Alert Sensor

*Restoring control and quality of life within stoma care*

### COMPETITION

Addressing Functional Needs in the Ostomy community

### FURTHER INFORMATION

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### CLINICAL NEED

Having an ileostomy procedure and subsequently needing to wear a stoma bag can be incredibly distressing for patients who experience uncomfortable symptoms and worry about living a full and active life.

More than 9,000 ileostomy procedures are carried out in England each year, and around 120,000 people now wear stoma bags in the UK.

A bag may be necessary to allow healing following bowel cancer treatment, to reduce inflammation of the colon in people with Crohn's disease or ulcerative colitis, or to enable complex surgery on the anus or rectum.

### SUMMARY OF INNOVATION

11 Health and Technologies has developed a discrete connected medical device alerting patients in real time when their ostomy pouch should be emptied.

The Alfred Alert Sensor uses Bluetooth wireless technology to send real-time data to smartphones, tablets and wearable devices such as watches. The data is stored in the cloud on a secure server and can be shared with physicians, clinicians, nurses and any family member who may be caring for the patient at home. Users can set individual alerts and decide when they wish to be notified.

## PATIENT PERSPECTIVE

Older people need practical support to effectively manage their stomas. Even people who have had a stoma for many years and managed it effectively may encounter problems as they grow older as a result of physical and/or cognitive impairment (and dementia in particular).

Becoming an ostomy patient is an incredibly tough state to adjust to. The number of patients having either permanent or temporary stomas is rising at 10% per annum.

The stoma bags that collect liquid digestive waste are made from hypoallergenic material to reduce the chances of skin irritation and they have filters to stop the release of unpleasant odors.

They are drained through an opening in the bottom and can be concealed under everyday clothes. Currently patients with stoma bags have no warning when their bags are filling. This results in overflows and spills, particularly at night. The incidents are distressing, embarrassing and reduce their quality of life and lead to additional health conditions including infections.

The Alfred Alert Sensor helps to improve the quality of life for patients who need to use stoma bags, by helping them to take control of their care, alerting them to when their ostomy pouch needs to be emptied.

## COMPANY OVERVIEW

The founder of 11 Health and Technologies, Michael Seres, understands from personal experience the difficulties patients with stoma bags face on a daily basis.

He was diagnosed with the incurable bowel condition Crohn's Disease aged 12 and, after more than 20 operations and intestinal failure, he became the 11th person in the UK to undergo a small bowel transplant: ***"I had a stoma bag fitted and soon realised how easily it could leak and spill and how doctors needed information on how the bag was being filled and when,"*** Seres explains.

***"During my initial research I spoke to lots of people around the world who told me there was no solution available and that they just had to get used to wearing the bag."***

Undeterred, he bought a sensor hacker, taped it to his own bag and programmed it to make a sound when the bag was full.

From this idea Seres generated some seed funding for a new business and in 2016 received his phase 1 award from SBRI Healthcare. In total SBRI Healthcare has backed the innovation with £894,500 worth of funding.

11 Health and Technologies is now actively engaged in phase two of its sensor development, with clinical trials taking place at a number of UK hospitals. The device is also available for sale in the US, where around 1,000 patients have already benefitted from this practical, simple and patient-centered solution.

## NHS IMPACT

Leakage from stoma bags is a particularly expensive and common problem for stomates, with 85% of patients reporting leakage at some point. Consequently, management of stomas results in a considerable healthcare cost burden. In 2014-15, expenditure of the supply of colostomy bags and associated accessories amounted to a total of £283 million; including dispensing fees of around 18%, the total cost annually is estimated at over £3,000 per patient.

Beyond leakage, stomas can also result in wider health problems including infection, dehydration and renal failure – which makes monitoring the nature and quantity of output vital. A US-based study revealed around one in five (17%) of patients were readmitted to hospital due to dehydration or renal failure within 30 days of an ileostomy being created. Patients over the age of 55 were at the highest risk of renal failure, with the costs of these readmissions impacting the healthcare burden.

In a pilot study, the impact upon resource utilisation, with and without the Alfred Alert Sensor was assessed in 80 experienced stoma patients (> 1 year post surgery). With the device, the number of prescription items, such as stoma bags and loperamide dispensed decreased. Patients also made fewer health care professional contacts such as telephone and face-to-face contacts, counselling and hospital admissions. This generated savings of around £500 per patient per year. As a result, the Alfred Alert has potential to lead to cost savings of up to £60 million a year, through a reduction in further health care contacts and ostomy bags.