MANUFACTURER STATEMENT

Electromagnetic Compatibility and Pacemakers

1   INTRODUCTION

Chiptech designs and manufactures a range of telecare base units and wearable alerting devices to support people to be independent and safe. Our electronic devices use low power Radio Frequency (RF) transmissions and some utilise cellular frequency. Wearable products from Chiptech do not have any magnets. Chiptech base units and wearables are independently tested by accredited test labs for compliance to a range of standards, including Electromagnetic Compatibility (EMC) and the Radio Equipment Directive (RED).

Please refer to the applicable Technical Specification document for a list of standards that each product complies with, along with the frequencies utilised, and their automated testing intervals.

2   ELECTROMAGNETIC INTERFERENCE

Electromagnetic Compatibility (EMC) is the interaction of electrical and electronic equipment with its electromagnetic environment, and with other equipment. All electronic devices have the potential to emit electromagnetic fields.

Pacemakers, defibrillators, ECG monitors and other electronic medical device implants are made to withstand electromagnetic interference (EMI) in accordance with the government or regional regulations. As these standards vary across different markets and device types it is important that an end user is referred to their medical specialist to discuss any specific concerns about electromagnetic interference. The specialist can provide further information and guidance provided by the implanted device manufacturer.

3   GENERAL RECOMMENDATIONS FOR CHIPTECH PRODUCTS

Please note, the EMC recommendations we provide are generalised. Medical device manufactures' products are made to differing specifications and standards and these will change over time and in different markets. Along with this, industry and advisory groups may have different recommendations depending on the market being supplied. If in doubt the user with the implanted electronic device should consult their medical specialist.

3.1   Base Units

Chiptech base units utilise cellular technology, therefore it is recommended that a base unit be installed **a minimum distance of 25cms away from the pacemaker** or implanted electronic medical device.

3.2   Pearl

Pearl personal help buttons, including Pearl Advanced, utilise a low power (60µW) radio frequency signal (RF) to connect with a Chiptech base unit. These RF transmissions are very brief, typically 0.2 seconds, and only occur at automated test times (typically every 7 hours), and when they are activated by a button press.

Pearl personal help buttons are designed and manufactured to reduce electromagnetic interference with other electronic devices. Pearl can be worn by a user with a pacemaker or other implanted electronic device. However, if the end user has any concerns, please request they consult their medical specialist for further advice.

3.3   Standard Interface Device (SID)

SID products utilise the same low power radio frequency (RF) signal as Pearl products to connect to a base unit, and SID can be used near a pacemaker or other implanted electronic device, if required. The exception is SID Door and SID Gate products, which are supplied with magnets. Products with magnets should be kept at a **minimum distance of 15cms from the implanted electronic device** at all times.

3.4   GO mobile Personal Emergency Response System (mPERS):

GO utilises both RF and cellular frequencies (the same as a cellular phone). If the end user has a pacemaker, they cannot wear GO around the neck, as a pendant. GO can be attached with the supplied split ring to a belt clip or keys. GO must be kept at a **minimum distance of 15cm from the pacemaker** at all times.

GO utilises a Qi compliant wireless inductive charging system, when connected to power the charger must be kept a **minimum distance of 25cm away from the pacemaker**. This includes when GO is charging.

4   FURTHER INFORMATION

Up to date Compliance Reports, Declarations of Conformity, Technical Specifications and User Guides including various warnings, can be download from the Chiptech Web Portal.