ACTION OF A MICRA TRANSCATHETER PACING SYSTEM DURING THE CREMATION PROCESS

REPORT

February, 2018

Table of Contents

1.0 Introduction

Pacemakers are known to pose a risk of explosion during cremation. This is because they contain batteries and sometimes compressed gases. Most pacemakers have a lithium/iodine-polyvinylpyridine (PVP) battery. Some other pacemakers batteries include zinc/mercuric oxide, nickel cadmium and even plutonium 238. This is why they are generally removed prior to cremation.

Please refer to https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1279940/ Pacemaker explosions in crematoria: problems and possible solutions, Christopher P Gale, BSc MRCP and Graham P Mulley, DM FRCP.

Facultatieve Technologies Ltd has been asked on numerous occasions by its international clientele and numerous trade associations around the world, relating to the effect of the Medtronics – Micro Transcatheter Pacemaker insertion into the cremator. Facultatieve Technologies took on the role to test the equipment on its own cremation equipment to ascertain three main areas of concern:-

1. Charging and whether the operator was at increased risk when charging a cadaver with this type of implant
2. The effect on the structural integrity of the equipment both internally and externally
3. The environmental impact on the atmosphere from such a device

Facultatieve Technologies trials followed detailed protocols to establish these main areas of concern. The three Medtronics – Micro Transcatheter Pacemakers were donated to Facultatieve Technologies under strict confidentiality rules by Medtronics to be able to conduct operational trials of cremations containing such a device. Facultatieve Technologies used a recently installed FTIII blocked cremator in Crematorium, on the Dignity Funerals PLC sites, to carry out these trials under the specific protocols already mentioned.

1.2 Equipment to be tested.

The device to be tested is the Micra Transcatheter Pacing System, manufactured by Medtronic.

The Transcatheter Pacing System MC1VR01 contains a battery with the specification as below.

Battery characteristics	
Manufacturer	Medtronic Energy and Component Center
Model	M957651A001
Chemistry	Lithium-hybrid CFx silver vanadium oxide
Initial voltage	3.2 V
Mean usable capacity	120 mAh
Estimated time from RRT to EOS	6 months (180 days)

1.3 Purpose

The tests were carried out to determine if a new smaller device poses the same risks as those previously described types. The new device is a Micra Transcatheter Pacing System

The tests intended to ascertain three areas of concern relating to the impact of a Micra Transcatheter Pacing System (referred to as the 'device' hereafter) during a normal cremation cycle. To simulate this, the device will be enclosed in a media, this media will be formed to prevent the instantaneous combustion of the device. This not only replicated the normal combustion of the device but provides a safe time delay, to prevent the operator being exposed to any risk. The intended media is a small cardboard box with wet tissue inside, the device will be located inside. This media will be tested and if found to be unnecessary then the items will be charged directly without a loading media.

2.0 Test Summary

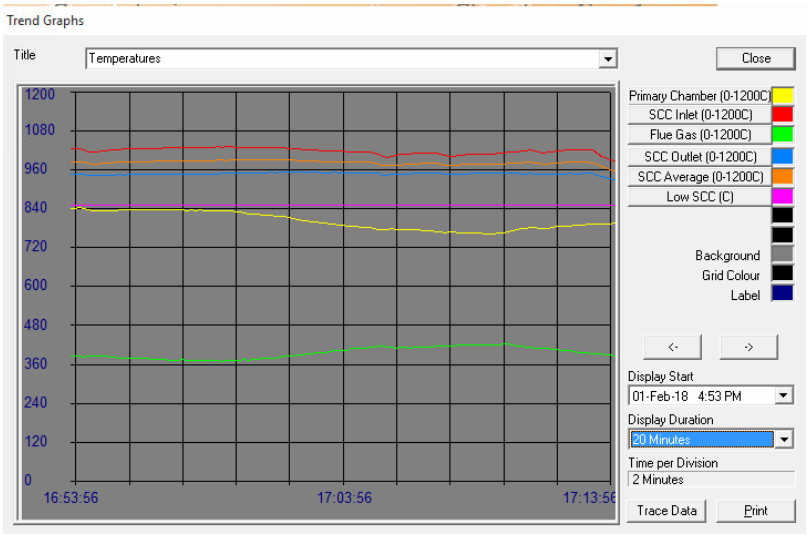
Project Name: *Assessment of Micra Transcatheter Pacing System activity during the cremation process*
Testing Location: *Earlham Crematorium*
Facultative Testing Staff: *Scott Simpson, Jeff Pickard*
Emissions Testing Staff: *Davies and Co*
Test Date: *1st February 2018*
Additional Attendees: *Tony Davidson (Dignity)*
Version Number: *1.0*
Additional Comments: *Video footage of each test was recorded. Trend graphs recorded for each event*

2.1 TEST 1

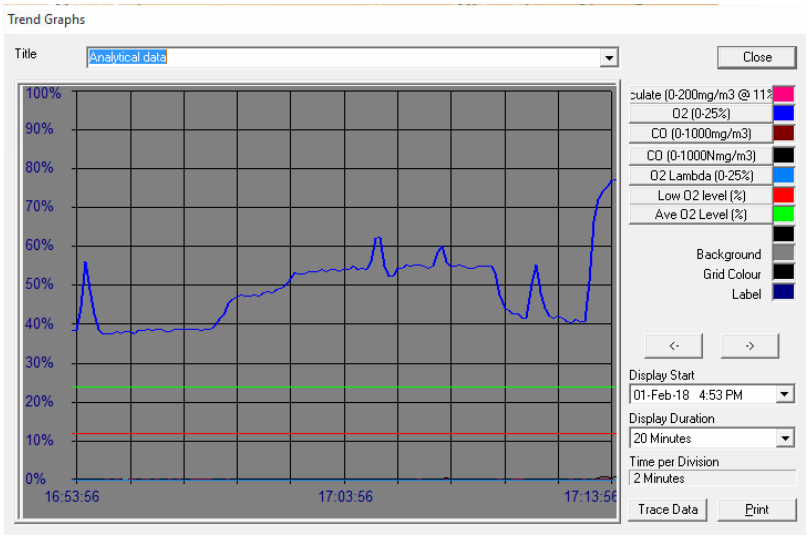
The cremator was already at operating temperatures having previously performed three cremations earlier in the day.

The first test charge was made at 16:54:05 the PCC temperature was 833C.

The chamber temperature graphs are shown below. Because of the small nature of the device, no discernable data can be obtained from these trend graphs



The chamber Analytical graphs are also shown. Because of the small nature of the device, no discernable data can be obtained from these trend graphs. For that reason they are not shown for each test.



The device inside its charging medium was charged manually using the specialist rake provided for the test. The emissions testing company prepared prior to the test and started sampling immediately after charge. As a safety precaution no one was in the vicinity of the charge or ash door during the trial until it is confirmed that the device has combusted (this was observed remotely by the video footage). The device exploded at approximately 7:30:00 minutes from closure of the charge door. On completion of the test the cycle was stopped at 17:04:57, ready for the next test. This was approximately 10 minutes after the charge.

Test Owner: *Facultatieve Technologies Limited, Moor Road, Leeds, LS10 2DD (Part of the Facultatieve Group of Companies)*
Test Device *Test 1 Device No. MCR6056545 MC1VR01*
Test Date: *01/02/18*
Additional Test Equipment Used: *Video footage of each test was recorded – Ref – Micra Transcatheter Cremation test 1.mp4. Trend graphs recorded for each event.*

2.2 TEST 2

Following the previous test it was decided that due to the length of time for the device to combust, that it was safe to charge the device without the storage medium. The 2nd test device was charged at 17:05:14 using the specialist rake provided for the test. The primary chamber was at approximately 783C (normal charging temperature). The emissions testing company prepared prior to the test and started sampling immediately after charge. The device exploded at approximately 14 seconds from closure of the charge door. On completion of the test the cycle was stopped at 17:07:25, ready for the next test. This was approximately 2 minutes after the charge.

Test Owner: *Facultatieve Technologies Limited, Moor Road, Leeds, LS10 2DD (Part of the Facultatieve Group of Companies)*
Test Device *Test 2 Device No. MCR6058105 MC1VR01*
Test Date: *01/02/18*
Additional Test Equipment Used: *Video footage of each test was recorded – Ref – Micra Transcatheter Cremation test 2.mp4. Trend graphs recorded for each event.*

2.3 TEST 3

Again the device was charged without the storage medium. The 3rd test device was charged at 17:10:54 using the specialist rake provided for the test. The primary chamber was at approximately 772C (normal charging temperature). The emissions testing company prepared prior to the test and started sampling immediately after charge. The device exploded at approximately 15 seconds from closure of the charge door. On completion of the test the cycle was stopped at 17:11:03, ready for the next test. This was approximately 2 minutes after the charge.

Test Owner: *Facultatieve Technologies Limited, Moor Road, Leeds, LS10 2DD (Part of the Facultatieve Group of Companies)*
Test Device *Test 3 Device No. MCR6056705 MC1VR01*
Test Date: *01/02/18*
Additional Test Equipment Used: *Video footage of each test was recorded – Ref – Micra Transcatheter Cremation test 3.mp4. Trend graphs recorded for each event.*

3.0 Conclusions

Each of the tests showed a similar result.

The device combusts after exposure to the direct heat within the cremator.

These eruptions or ignition of the device was regarded as low in intensity with the explosion best described as a small “pop”.

These eruptions when loaded unprotected and with direct exposure to the heat of the cremator, took between 15 and 17 seconds, significantly delayed even in an unprotected condition as not to cause additional risk during charging.

When protected from the direct heat of the cremator, as would be normal, the eruption took significantly longer. In our trials this was more than 7 minutes.

The second aspect considered during the trials was the possible damage to the structure or components of the cremator. It was evident that the energy release from the device was so low that it is not considered a risk to the internal linings of the cremator.

Facultatieve Technologies therefore concluded that there is no additional risk whilst charging or cremating such a device in its equipment.

An environmental study was then performed to assess if there was any impact on the environment from the cremation of such a device.

The results of those emission tests proved that there was no measurable emission release during the trials and therefore the environmental impact to atmosphere was also negligible.

4.0 Summation

In summary, without any consideration of statutory requirements, permitting or trade association guidelines requiring the removal of pacemakers, which may differ country to country, Facultatieve Technologies have concluded that if a Medtronics Transcatheter pacing system was charged deliberately or in error, there would be no impact to personnel, equipment or the environment and as such considers no additional protocols would be required for the cremation process in our equipment.

The author wishes to thank the following participants for their assistance in conducting these trials:

Medtronics	for providing three samples for testing
Dignity Funerals PLV	for allowing the trials to be conducted at their crematorium
Davies & Co (Engineering) Ltd	for carrying out the emission testing during the trials