Application for granting a new RoHS exemption:

Lead in solders used in mobile medical equipment

1. Name and address of applicant

COCIR : European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry
Brussels
Contact: Mr. Riccardo Corridori

2. Summary of request

Medical equipment must have high reliability as unexpected failures can be fatal. Many types of medical device can be constructed using lead-free solders but these mobile medical devices and especially given that some of them are life-critical equipment that is transported in ambulances, helicopters or around hospitals may suffer from high G impacts, severe vibration and experience frequent large temperature changes. Tin/lead (SnPb) solder has been found to be reliable under these conditions but research has shown that there is no lead-free substitute alloy that has the same or better reliability under all of these environmental conditions. Therefore a temporary exemption to allow the continued use of lead solders is needed until further research has been carried out to identify alloys that are reliable for the normal life of mobile medical devices.

3. Description of materials and equipment for which the exemption is required

Most of the safety critical medical equipment used in hospitals is not designed to be carried or routinely transported although many items are moved from one location to another within a hospital and so levels of vibration are not high and there is little risk of being dropped. There are however a number safety-critical products that are regularly carried by patients and medical staff both within hospitals and elsewhere which will experience at least one of the following:

- high levels of vibration,
- large temperature fluctuations
- High risk of being dropped:

The biggest risk is where all three occur.

Types of mobile medical device (MMD) and their Medical Device Directive classifications at risk from these factors include the following examples. Medical device directive classifications of products are determined by manufacturers based on Annex IX of Directive 93/42/EEC. If Class IIB products do not function due to a fault, there is a severe and immediate risk to the patient (i.e. irrevocable harm within minutes). Unexpected faults with Class IIA equipment can also have serious consequences although in general, these may not be as severe as Class IIB. One exception could be patient carried or worn devices used outside of the usual clinical environment where there is medical professional present for periodic bedside checks such as with home monitoring. Some conditions can go on for

hours before there is irreversible damage but others, such as a heart attack can be fatal if untreated quickly. If the patient is alone, the equipment failure could prove fatal if the condition goes undetected long enough:

Medical Device Directive Class IIB

3.1. Automated Cardio Pulmonary Resuscitation (CPR) EU CLASS IIB

These are battery powered mobile devices that are carried in ambulances and medical helicopters, and they are used in combination with defibrillators. As such they are exposed to the same tough use environment as are defibrillators outside of the hospital. Medical guidelines call for the application of CPR before attempting to restart the heart if there is any question as to how long it has been since the victim's heart stopped beating[1]. Providing 1.5 to 2 minutes of CPR is a physically demanding effort. In the event that the heart does not resume a normal rhythm after defibrillation, the CPR must be restarted for several more minutes before another shock can be administered. It is these situations where CPR is required for extended periods of time that demand the need for automation. These devices can satisfy the medical guidelines that require that any adult chest be compressed by 5cm at a rate of >100 compressions per minute[1]. A human being can only sustain this level of effort for several minute before someone else needs to take over the work. Outside of the hospital with a team of only two individuals to draw upon, the need for reliable automated CPR is an absolute must. Why is this crucial? Without the continuous flow of oxygenated blood, the heart cannot be restarted, and both the heart muscle and the brain experience permanent damage[1]. Timing is critical as the likelihood of revival and a return to a normal life is reduced by 10% for every minute that therapy is delayed. Therefore, there is no time to troubleshoot or retrieve a spare device.

3.2. Ventilators – EU CLASS IIB

These mobile medical devices provide ventilation of the lungs of patients. These devices provide total ventilatory support and augment patient breathing in treatment of respiratory insufficiency. Failure of these devices can result in patient respiratory failure followed by death. Ventilators can be classified by where they are used. Some are only used within hospitals and others are used additionally in homes, outdoors, and in transit. These environments have unique shock and vibration requirements for ventilators. Hospital ventilators are specified to withstand 100g shocks due to impacts with doorway and elevator thresholds; walls, doorways, elevator doors, and other equipment; and during loading on and off of delivery vehicles and are subjected to vibration during transport in delivery vehicles between medical facilities. Home, outdoor, and transit ventilators can be exposed to 300g shocks due to drops as high as 50 cm and higher; vibration during use and transport in ambulances and helicopters; and temperature extremes.

[1] *American Heart Association "Highlights of the 2010 American Heart Association Guidelines for CPR and ECC, Editor M. F. Hazinski and "Resuscitation after cardiac arrest" by M. L. Weisfeldt and L. B. Becker, Journal of the American Medical Association, Vol 288 (23) December 2002, p3035..*

3.3. Infant Apnea Monitors – EU CLASS IIB

Monitor: Central apnea, Bradycardia, Tachycardia, and Oxygen saturation. These are life support devices that are used to continuously, normally less than three years of age. The monitors provide audible and visual alarms to alert caregivers, typically parents, when the infant experiences a cessation of breathing (central apnea), bradycardic event (low heart rate), tachycardiac event (high heart rate), or a decrease in oxygen saturation. These alarms are necessary for caregivers to respond to these events and provide proper care. Infant Apnea Monitors are used primarily in the non-clinical environments, home, outdoor, and transit for use by non-healthcare professionals and are subject to high levels of vibration, frequent drops, and temperature extremes as described above.

3.4. CO_2 Sensors – EU CLASS IIB

These are used to monitor breathing of patients having endotracheal (ET) tubes. ET tubes are used to keep patients airways open. It is necessary to ensure that the tube is in the correct position when patients are transported, for example in an ambulance and CO_2 sensors are used to monitor breathing[2] and to ensure that the tube has been placed in the trachea (windpipe – connects to lungs) and not in the esophagus (passes food to stomach). The American Heart Association[3] has found that observation of patients for clinical signs due to misplaced tubes is unreliable and that if misplaced, other signs that indicate serious harm may be occurring may take several minutes to be observed. Portable CO_2 monitors are delicate instruments and susceptible to damage if dropped or subject to intense vibration, such as can occur in ambulances and emergency helicopters as well as hospital trolleys.

Medical Device Directive Class IIA

Patient worn devices (PWD), portable ultrasound and portable monitors are less safety critical than portable defibrillators and so are classified as class IIA by directive 93/42/EEC "non-life sustaining and diagnostic tool devices". In some circumstances another device will be available if one fails and failure will not always be life threatening unlike portable defibrillators. However there will be circumstances where defects or complete failure would be life threatening. For example if a patient with a PWD suffers heart failure while out of sight, no alarm would be sent. If the monitor being used for a patient in an ambulance fails, any changes to the patient's condition would be missed. At best, equipment failure will delay diagnosis or treatment ands this can have serious implications.

3.5. Devices carried by patients – EU Class IIA

Also referred to as Patient-Worn Devices (PWD) are RF devices carried by patients who may have very recently completed surgery, are anesthetized or otherwise require monitoring or have been recently discharged from the hospital and need home monitoring. In the past, these devices were large and not portable so patients could not move about. Modern portable devices however allow recuperating patients to move around the hospital/home and be continuously monitored. They need to be continuously monitored while they are walking or being moved and in locations where wired connections are not possible. The vital signs data such as heart condition, blood pressure and temperature are wirelessly

[2] *http://journals.lww.com/em-news/Fulltext/2005/04000/Monitoring_CO2_Improves_ID_of_Misplaced_ET_Tube.21.aspx and http://erexpert.com/RevisedArticles07/Confirmation%20of%20Endotracheal%20Tube%20Placement.pdf*

[3] *Guidelines 2000 for Cardiovascular Resuscitation and Emergency Cardiovascular Care, Circulation 102 (suppl I) 8, August 22, 2000*

transmitted in a short range radio frequency from the PWD to the nearby network router which will then download the data to the nurse stations via an Ethernet network. PWD units are also used for fall detection so if a patient wearing the device falls on the ground, the unit is expected to make a call to a Personal Response Centre. If a PWD is dropped onto the floor by a patient, which is likely in view of their condition, the PWD could be damaged and fail to transmit a warning alarm. PWD must also be unaffected if they are worn by a patient taking a shower or if dropped into water (bath, toilet, etc.).

3.6. Ultrasound – EU Class IIA

Ultrasound equipment was in the past relatively large and not mobile but smaller MMD equipment has been developed that can be carried in ambulances and by general practitioners. Small hospitals and doctors practices may have only one ultrasound monitor and increasingly these will be portable types. These are susceptible to damage from vibration during transportation and if dropped in the same way as portable defibrillators. If they fail to function, as there will be no alternative equipment nearby, patients would be at risk in an emergency. Small ultrasound equipment mounted on trolleys is also used with CT for visualising soft tissue and then with radiotherapy to find the correct location for treatment. This ultrasound therefore is moved around the hospital and so can suffer impacts with walls, doors and lifts. Any malfunction can cause a delay to treatment for cancer which will extent treatment times and may prevent successful eradication of tumours.

3.7. Patient monitors – EU Class IIA

Equipment for monitoring body functions of patients are widely used in hospitals, ambulances, emergency helicopters and elsewhere. These monitor a variety of functions such as pulse, blood pressure, temperature, etc. Most are designed to be used in a variety of locations and many are fitted with batteries to allow transportation. Some are mounted on a stand by a patients bed and so do not need to be readily portable but others are hand carried or attached to other portable equipment such as a patient transportation trolleys or stretchers. More examples of how these products are used include:

- monitors mounted on tiltable / swivel arms, where users tend to pull on the device rather than on the handle provided
- patient monitors permanently mounted on wheeled anaesthesia machines or ventilator carts, and these carts being wheeled to the ventilator maintenance department (may happen twice a week for critical care ventilators!)
- patient monitors mounted permanently to patient stretchers in emergency departments or patient receiving areas, where they travel everywhere the stretcher goes
- small patient monitors that are used inside a baby incubator in neonatal intensive care units, where the caregiver constantly has to make sure the device is out of reach of the patient
- flexible/ replacement/ spare monitors that are wheeled or hand-carried to the location inside a hospital where they are immediately needed
- patient monitors mounted permanently to patient stretchers in CT or NMR set-ups or radiology C-bows, where they constantly travel with the stretcher or C-bow.

Patient monitoring equipment is safety critical because if it were to malfunction, any life-critical changes to a patient could be missed.

MMD products can experience severe vibration, large temperature changes, high humidity and shock from being dropped. All of these can cause solder joints to fail.

3.8. Severe vibration

Especially for equipment carried in ambulances, emergency helicopters and vehicles of doctors on call but will also occur with equipment mounted on trolleys that are moved around hospitals and between hospital buildings.

Large temperature fluctuations – mobile equipment is transported outside of buildings between locations, for example in ambulances and in helicopters and so will experience large temperature changes. Some parts of Europe can exceed 40°C in summer (>60°C is possible inside parked vehicles) and this equipment can be transported to other locations where at night or in mountains, the ambient temperature can be well below zero. An extreme situation would be transporting from southern Europe in summer by helicopter to an Alpine location.

High humidity – this increases the risk of tin whiskers which grow on tin electroplated tin coatings, corrosion and the formation of dendrites on PCBs, especially if solders with silver are used. High humidity is a particular problem especially when cold equipment such as is stored in a vehicle overnight and then moved to a warm humid environment causing condensation.

Shock from being dropped or striking objects – possible for any type of equipment designed to be carried such as portable ultrasound, patient worn devices or when attached to equipment that is carried such as stretchers. Manufacturers test their equipment using drops from 1 meter onto concrete because this is a fairly common occurrence. Shock also occurs with trolley mounted equipment if this strikes a wall or door frame.

High levels of vibration, large temperature fluctuations and being dropped are all known to cause solder bonds to fail. Tin/lead (SnPb) solders and lead-free solders are known to behave differently and research that will be described below has shown that under some circumstances, lead-free solders are less reliable than SnPb. The ERA report for the European Commission on whether inclusion of categories 8 and 9 in the scope of RoHS concluded that temporary exemptions for lead in solders may be required[4]. This report was published in 2006 and since then research with lead-free solders for these applications has been carried out and results have shown that lead-free solders may be less reliable. Inferior reliability poses a risk to patient's health if life-critical medical devices were to stop functioning unexpectedly.

4. Justification for exemption

This exemption is required because there is evidence from extensive research that the reliability of these types of equipment produced with lead-free solders could be inferior to those made with SnPb solder. When equipment is transported it may be subjected to vibration, fluctuating temperatures, high humidity or shock from being dropped. The effect of these on equipment reliability is well understood for SnPb solders as a result of many

[4] *http://ec.europa.eu/environment/waste/weee/pdf/era_study_final_report.pdf*

decades in use but there is much less field data for lead-free products. An issue for medical devices is that before a new product or one with a modified design can be sold in the EU, it must be approved by a Notified Body under the Medical Devices Directive. In order to gain approval, the manufacturer must prove that the equipment is reliable. The only way to do this is by extensive reliability trials which involve accelerated testing to simulate field conditions. To further confound these difficulties, before meaningful testing can begin the grain boundaries must be allowed to rearrange themselves and reach an equilibrium condition. It is not clear how or if isothermal aging accurately simulates the normal aging process. According to research by Dr Werner Engelmaier, much worse test results can be expected from an assembly that has been aged for 12-months than from an assembly that has been freshly assembled[5].

Unfortunately for lead-free solders, it is still unclear how to accurately predict field reliability from accelerated test results because there has been so far very little electrical equipment built with lead-free solders and used in the relatively severe environmental conditions experienced by MMD medical products and used for sufficient periods of time in the field, i.e. more than 10 years. There is recent field failure data for some types of consumer products but this does not differentiate SnPb and lead-free products. For example, the insurer "Squaretrade" reported in 2009 that 31% of laptop PCs fail within the first three years and 10.6% was due to accidental damage, e.g. being dropped. Laptop PCs are relatively complex products and so are comparable to medical devices but this high rate of failures would not be acceptable for safety critical products. This data is for computers made since 2006 and so would be produced using lead-free solders showing that complex lead-free equipment is susceptible to accidental damage. In order to justify this exemption request, a thorough search for field data that compares tin/lead and lead-free versions has been made but no data could be found and may not exist. There is evidence of poor reliability of lead-free products such as the case of the Microsoft X-Box which appears to be due to poor design and selection of an unsuitable lead-free solder but not due solely to the choice of lead-free solders[6]. There have been many incidents where failures have occurred due to tin whiskers including in Toyota vehicles which has recently been discovered and studied by NASA engineers[7]. Although the cars that failed were built in 2003, research since RoHS was adopted has not found solutions that guarantee that no whisker failures will occur. Commercial component tin coatings provide a small but not insignificant risk for equipment with long field lives particularly which can be used in humid environments but tin/lead solders reduce this risk by providing better wetting than SAC alloys so that less exposed tin plating remains.

Gartner[8] found that tin/lead soldered laptop PC reliability improved between 2003 and 2005 (pre-RoHS directive). They found that in 2005 – 2006, laptop failures were 22% over four years. These figures are for all failures (hardware and accidental) and are lower than the 31% over three years published by Squaretrade in 2009 which corresponds to lead-free laptop PCs. This difference could be due to the change from SnPb to lead-free but other variables such as design (complexity will have increased) and the way the data in the two

[5] *Opening remarks at the IPC Conference on Lead-Free Reliability in 2005.*
[6] *http://en.wikipedia.org/wiki/Xbox_360_technical_problems*
[7] *H. Leidecker, L. Panashchenko and J. Brusse, "Electrical Failure of an Accelerator Pedal Position Sensor Caused by a Tin Whisker and Discussion of Investigative Techniques Used for Whisker Detection", 5th International tin Whisker Symposium, 2011.*
[8] *Gartmore press release, 2006 from http://www.gartner.com/press_releases/asset_154164_11.html*

studies were collected were different (Gartmore data is from mainly business users whereas Squaretrade is all users). However there does appear to be more failures with lead-free than SnPb laptop PCs from this data.

There is a lot of research into lead-free solders which shows their limitations and this is described below but evidence of field failures is very limited for certain specific reasons:

- Most lead-free products sold in the EU since RoHS was adopted have been lower value IT, consumer and household appliances. If failures due to the reliability of lead-free solders were to occur, this would be after the warranty had expired and so would not have been investigated.
- If a manufacturer discovers a reliability issue they never publicise this because it could harm their business. Reliability is important to all manufacturers and so they would never admit publically to defects in their products, unless forced to by regulatory requirements for full disclosure[9].

There have been a few publicised examples of failures of lead-free soldered products such as the X-Box mentioned above but few details are available due to an unwillingness of manufacturers to admit to the cause.

Very large numbers of electrical products have been constructed since RoHS was adopted in 2006 and gross reliability problems have not been encountered. However medical devices need to be much more reliable than consumer and office equipment. Comparative field data for most types of equipment is however not available for the following reasons:

- Most manufacturers will not publish field failure rates as they regard this as confidential.
- Most consumer products are not exposed to severe environments and have fairly short lives and so solder failures are not an issue.
- If a lower priced product fails after 3 years, failure investigations are rarely carried out and so the cause is not identified.

Medical devices are however different; they can be relatively complex, have lives of over 20 years and mobile types are exposed to severe conditions that impose significant stresses on solder bonds. One manufacturer of mobile medical devices has collected field data that shows that the likelihood of failure of mobile products used outside hospitals is double that of products used only within hospitals. This exemption is therefore justified for two reasons:

- Reliability concerns from lead-free solders and
- Reduced reliability would cause a greater negative impact on human health (patient's health) with lead-free products than with SnPb soldered products.

[9] *In 2009 the FDA forced Physio-Control portable defibrillators to disclose the root cause of four field failures. In each case it was found to be a tin whisker associated with a lead-free tin coated component finish.*

5. Analysis of possible alternatives

The potential alternative to the use of lead in solders is lead-free solders and this exemption is being requested due to concerns over the long-term reliability of mobile medical devices made using these alloys. The long-term field reliability of lead-free solders is uncertain as they are relatively new and so manufacturers have not been able to collect sufficient field data to reliably predict product lifetimes (for products with long service lives). Methods of estimating product lifetimes are being developed but there is some uncertainty because field data is not yet available to validate these predictions.
The potential risk of failure is greater with (MMD)than in equipment that is not intended to be moved because there are two additional failure modes – vibration as a result of transportation and impact from being dropped onto the floor. These are in fact related because when equipment is dropped onto a hard surface, it experiences a brief very high g-force whereas vibration imposes many repeated but smaller g-forces. The MMD equipment may also be exposed to large temperature changes and to high humidity. Research into these four potential failure modes is described here.

Before describing the failure modes that can occur, it is worth first explaining the reasons why failures occur as a result of severe vibration and temperature cycling. Failures often occur at the interface with brittle intermertallic phases or within these phases although failures as a result of damage to the PCB laminate can also occur. Intense vibration causes PCBs to flex and this imposes strain on solder bonds and the internal structures within the laminate.

5.1. Intermetallic phase formation with solders

SnPb solder interacts with the substrates to create a layer of intermetallic phase. This phase is produced as a result of chemical reaction between the tin in the solder and the metal surface of the PCB pad or the component's terminals. If copper is used, a SnCu intermetallic is produced whereas if there is a nickel layer then SnNi is formed. SnCu forms more quickly than SnNi but both continue to grow after the solder bond has been produced due to "aging". The rate depends on temperature and at higher temperatures the intermetallic phase grows more quickly and this effect can be used to simulate accelerated aging. With SnPb solders, the available tin close to the interface is depleted so that this zone becomes lead-rich which retards intermetallic growth as tin is less accessible. Also, the residual lead is relatively flexible unlike tin/copper and tin/nickel intermetallic phases. Lead-free solders contain mostly tin and so a tin-depleted zone does not form. A second effect also occurs with aging. SnPb solder consists of two phases, one tin-rich and the other lead-rich. These are separate grains which gradually grow especially where there is high imposed stress. Grain growth within SnPb does not affect bond reliability unless they become particularly large in stressed regions when thermal fatigue failure can occur after many stress / relaxation cycles.

Most lead-free solders are mainly pure tin with a dispersion of irregularly shaped SnAg and SnCu intermetallics. When a solder bond is formed on a copper substrate, SnCu forms at the interface and on nickel, SnNi intermetallic is formed. These layers tend to be thicker than with SnPb solder because of the higher soldering temperature and because tin is not depleted close to the interface. Sn_3Ag and SnCu intermetallic crystals form within the solder as soon as the bond is formed and grow in size due to thermal aging. Sn_3Ag crystals

are a particular problem as they are needle shaped and can be quite long. In very small solder ball bonds used for micro-BGAs and CSP, large intermetallic crystals can occupy a significant proportion of the ball volume whereas this is not possible with SnPb as lead occupies half of the volume and does not react with copper or nickel. An additional failure mode that has been found with lead-free ball bonds is where the solder is bonded to a copper PCB pad with a nickel barrier layer that is not completely non-porous. If a small amount of copper reaches the solder, the intermetallic that forms is SnNiCu which has been found to be very brittle and fractures easily. This is a very uncommon failure mode with SnPb because of the lower soldering temperature but has been frequently found with lead-free products.
Research has shown that improved resistance to failure of bonds to BGAs and CSPs when dropped is achieved with under-fill materials. These are materials that are types of adhesives that are injected between the device and PCB laminate and was used by Microsoft to resolve their high failure rates that were experienced with BGAs in their X-Box devices. Under-fills compatible with SnPb have been available for many years but lead-free compatible under-fills are newer. Drop-test performance of lead-free BGA and CSP is greatly improved by the use of suitable under-fill materials but selection of the correct type of underfill and how best to use it is not yet routine for lead-free assemblies. Research in the USA is being carried out to determine guidance on how to select and use underfill with lead-free BGAs, CSP and QFN[10]. Research has shown that under-fill performance varies considerably with many providing little or no benefit. One reason for poor performance is the increased use of "no clean" fluxes. The residue interferes with the underfill's ability to adhere to the board which severely limits its effectiveness to support the component. To further complicate things, components such as QFNs nearly always mandate the use of "no clean" fluxes. Thermal coefficient of expansion (TCE) of the under-fill is important with low TCE materials appearing from research to give improved drop-test performance.

5.2. Kirkendall voiding

The use of lead-free solders has introduced other complicating factors. Lead-free processes have been shown to increase the risk of "Kirkendall voiding". This is a process that creates many very small voids at the solder-substrate interface and is believed to be related to the plating process although it is not fully understood. Research has shown that Kirkendall voiding is more likely to occur with lead-free processes than SnPb due to the higher soldering temperature. The latest theory is that electroplating processes trap organic substances within the metal coating and these decompose to give gases during soldering and these gases create the small voids. Due to the higher melting point of lead-free solders, the 20 – 30°C higher temperature increases the risk that the organic substances will decompose to form gases and also increases the volume of the gas as they are hotter. Normally these voids have little effect but they will increase the risk of failure when the equipment is dropped or subjected to stresses such as vibration.

Vibration research
Solder bond reliability is of concern with this application because the circuits are exposed to very severe vibration for long periods as well as from being dropped and large temperature changes. There are several research publications which compare the vibration performance of SnPb solder with lead-free solder although some of the results appear contradictory. The

[10] *For example http://www.inemi.org/project-page/advanced-si-node-pb-free-underfill-reliability*

reasons for contradictory results were demonstrated by research carried out by JGPP[11] which showed that susceptibility depends on:

- The solder alloy composition
- Type of component
- Position on circuit board
- g-force

Later research described below also showed that vibration frequency is an important variable.

The JGPP research used test boards having several types of components each attached at several positions. Three lead-free solders and SnPb solder were compared. At lower g-forces, no failures occurred during the 7 hour period of the test but at moderate to high g-forces, there were many failures. The most susceptible type of component to fail was the ball grid array (BGA). The test board had several of these and most of BGAs had bond failures before other types of component although the time to failure was strongly dependent on the location on the PCB. Results with BGAs showed that during the tests, failures were significant at g-forces above 9g and that the lead-free solders tested failed before SnPb. In these tests, g-forces were increased once every hour. Results for two of the BGAs are shown below (BGAs U4 and U6 were of the same type).

Table 1. Proportion (%) of BGAs with failed bonds during vibration testing comparing SnPb with SAC and SACB solders

	BGA U4			BGA U6		
g-force	SnPb	SAC	SACB	SnPb	SAC	SACB
9.9	40	80	100	0	20	0
12	80	100	100	20	60	40
14	100	100	100	40	100	60
16				60	100	100
18				60	100	100
20				80	100	100

SAC = Tin, silver and copper
SACB = Tin, silver, copper and bismuth

As component location affects vibration failure it is difficult to compare different types of component but most of the other types of components at locations adjacent to U4 and U6 and so experiencing similar vibration force and amplitude, failed after longer periods than these BGAs. This is a concern to manufacturers of mobile medical device because BGAs are commonly used.

The test results reported from the JGPP research are from highly accelerated testing using very high g-forces. The test duration was only 7 hours whereas many types of medical device have lifetimes of over 25 years and will be in use many hours per day. Clearly if the electrical device, irrespective of which type of solder was used, were to be exposed to 9.9g or more, it would not survive 25 years. Accelerated testing is useful to identify potential failures during the normal lifetime of the equipment based on known characteristics of the equipment such as the level of vibration.

[11] *T. Woodrow, JCAA/JG-PP Lead-free solder project: Vibration and Thermal Shock Tests", April 2006. http://www.jgpp.com/projects/lead_free_soldering/April_4_Exec_Sum_Presentations/040406WoodrowVibThShock.pdf*

The maximum vibration force experienced in service is relatively large for mobile medical devices although is less severe than accelerated test conditions. Some electrical component bonds failed after less than 2 hours in the JGPP tests whereas medical device PCBs must for 25 years and may regularly experience severe vibration for long perods. Medical device manufacturers have many years of field experience with SnPb solders at high levels of vibration and so can expect that PCBs made with SnPb solder will survive 25 years. As the JGPP tests show that bonds made with lead-free solders will have shorter lifetimes, there can be no certainty that the same PCBs when made with SAC lead-free solders will survive the 25 years. Unexpected early failure could be harmful to patients due to the equipment not being available when needed and early failure would also create more waste electrical equipment (accelerated testing is discussed below).

Research published by the National Physical Laboratory (NPL)[12] showed that vibration testing of assembled PCBs cannot be used for comparison of solder alloys because solder joint shape, vibration amplitude, frequency, etc all affect the time to failure for a specific type of component. This was clear from the JGPP research which showed that for a few types of components, lead-free solders gave superior performance to SnPb. NPL's research compared SnPb with four SAC alloys (including one with only 0.3%Ag) using piezoelectric actuators to impose controlled vibration forces. Vibration amplitude and frequency were controlled in these tests. The main result was that at all frequencies, SnPb had a lower probability of failure than any of the four SAC alloys. This was especially the case at higher frequencies as 400 and 800Hz were compared. The numbers of vibration cycles to 20% probability of failure from Wiebull plots were:

Table 2. NPL vibration results – cycles to failure

Solder alloy	20% probability at 400Hz	20% probability at 800Hz
SnPb	200,000	20,000
SAC305	100,000	2,000
SAC387	60,000	8,000
SAC 0305	40,000	4,000
Annealed SAC305	9,000	-

Tests carried out by one mobile device manufacturer shows that their PCBs experience vibrations at frequencies from low frequency up to and beyond 2000Hz and so the performance in table 2 at 800Hz is applicable to mobile medical devices. For surface transport (ambulances), the vibration frequencies are lower but the G-levels are higher. MIL STD 810F contains power spectral density plots for both surface (ambulance) and air transport (helicopter) and the frequencies used for the NPL results are relevant to both of these forms of transport.

5.3. Comparison with SnCuNi solder

The JGPP research also compared Sn0.7Cu0.05Ni (often referred to as SN100C) wave soldering with the two SAC lead-free solders and with SnPb. This could be used only for some types of components and appeared to give superior performance to SnPb with one

[12] *NPL Report MAT 2, D Di Maio and C Hunt, "High-frequency vibration tests of Sn-Pb and lead-free solder joints", August 2007 http://publications.npl.co.uk/npl_web/pdf/mat2.pdf*

type of DIP component. The detector and DAU PCBs used for PET/MRI are all surface mount types with BGAs and so SN100C cannot be used. This is because BGAs are made using SAC balls and the solder used to attach these should have a similar melting temperature to avoid reliability problems. Standard SAC that is used for BGA balls melts at 217°C whereas SN100C melts at 227°C. This would result in the BGA ball melting before the SN100C and this would allow flux volatiles from the solder paste to form large voids inside the BGA balls before the SN100C melts. It has been shown that large voids inside BGA balls affects bond reliability[13]. For this reason, manufacturers always use solder pastes with similar alloys to the BGA ball alloy. Another issue is that BGAs are temperature sensitive devices and so are more likely to be damaged by the higher reflow temperature needed for SN100C solder. Too high a reflow temperature can cause delamination or cracking of the circuits of the BGA package.
SnCuNi was also assessed by Barry (as well as SAC305) who tested solders in a more consistent way as was also performed by NPL (described above)and this research showed that SnPb has superior vibration performance to both the SAC305 alloy and SnCuNi with SnCuNi being inferior to SAC305[14].

5.4. Drop / shock research

Manufacturers test results with medical devices: Research into the reliability of equipment constructed with lead-free solders when dropped onto hard surfaces has been carried out. The performance of SnPb solders has been established over many years so that mobile medical devices do not fail in normal use which includes being repeatedly dropped. Lead-free soldered versions are also drop tested and preliminary test results with a mobile medical CO2 sensor has indicated that lead-free solder joints are more susceptible to damage when dropped. One type of CO2 sensor constructed with SnPb solders has been designed to successfully survive being dropped fifty times from a 2 meter drop onto concrete although field failures do occur due to abuse by users. This performance is superior to most types of mobile consumer product as they are designed to be very reliable. Lead-free versions of a similar medical device have been constructed and early drop test results indicate that failure occurs after less than fifty two meter drops indicating that lead-free versions would have inferior reliability.

Published drop-test research: Research that has been carried out to compare SnPb and lead-free solders is described here.

Research published by Heaslip et al[15] in 2005 compared SnPb with SAC305 solders. This compared the drop performance of printed circuit boards (PCBs) having ball grid array (BGA) devices that are similar to those used in mobile defibrillators, PWDs and many other types of mobile device. Drop performance of PCBs made with SnPb and Sn3.8Ag0.7Cu BGA balls and solder pastes were compared using drop heights of 406 and 610 mm. Two types of failure were noted, "hard" where permanent open circuits occurred and "soft" where brief periods of high electrical resistance occurred. Brief periods of high electrical resistance are

[13] *M. Yunus, et. Al., "Effect of voids on the reliability of BGA/CSP solder joints", Microelectronics Reliability, 43 (2003), 2077, http://www.atv-tech.com/en/pdf/Effects%20of%20voids%20on%20the%20reliability%20of%20BGA%20and%20CSP%20solder%20joints.pdf*
[14] *N. Barry, University of Birmingham, UK, Ph.D thesis October 2008.*
[15] *Heaslip, Ryan, Rodgers & Punch Stokes Research Institute and University of Limerick, "Board Level Drop Test Failure Analysis of Ball Grid Array Packages" …….*

sufficient to prevent some types of medical device from functioning and as a result posing a health risk to patients. This is often due to the significant functionality that is provided by embedded CPUs where even a momentary loss of communications can result in the system locking up or spontaneously rebooting. This could have serious implications with a portable ventilator or the types of equipment used by patients away from medical staff. Heaslip's research showed that there were failures after the following numbers of drops:

Drop height mm.	Number of drops until soft failure	
	SnPb	SAC
406	Best 200, worst 70	Best ~40, worst 10
610	Between 30 – 70 drops + one test after only 10 (solder defect?)	All failed after <20 drops

This research clearly shows that SAC305 solders have significantly inferior drop performance than SnPb and so if mobile medical devices were to be made with SAC305 solder, they would be significantly more likely to fail than SnPb versions. As a result of this finding which has been confirmed by other workers, alternative types of lead-free alloys have been evaluated and compared with SnPb.

Research published in 2007 compared the drop performance of simulated BGA assemblies soldered using a wide range of solders[16]. This research used 17 lead-free solders including three with ~3% silver, the rest with lower amounts and SnPb solder. All of the SAC alloys with ~3%Ag gave significantly inferior performance to SnPb confirming Heaslip's results. However several of the SAC alloys containing ~1% silver plus certain additives gave slightly superior drop performance to SnPb when tested in the "as reflowed" condition. This condition is however unrepresentative of medical devices as all solders "age" in use and this changes their microstructure so that they perform differently. This research also compared drop test performance of aged samples and this showed that only one lead-free solder was superior to SnPb. This alloy contained 1.1%Ag and 0.13% manganese (Mn) which survived after a minimum of ~15 drops whereas SnPb survived a minimum of 10 drops in these tests. It would appear therefore that if drop performance were the only important criteria Sn1.1Ag0.64Cu0.13Mn could be used but due to other performance limitations such as rather high melting temperature for use in solder pastes (this melts in the range 217 - 227°C) and this alloy is not available commercially and so cannot be used.
Some manufacturers are now however using commercially available SAC105 solders in applications where being dropped is likely such as for mobile phones and it is clear that these have superior drop performance to SAC 305 solder[17]. Solders with low silver content have however been found in comparative testing to give inferior thermal fatigue performance. Because of this finding, these solders would not be suitable for use in mobile medical devices that experience significant temperature fluctuations. Mobile phones may occasionally experience large temperature fluctuations such as when left in an automobile but as their expected life is relatively short, thermal fatigue failure is not a concern as this

[16] *Weiping Liu and Ning-Cheng Lee,*
"The Effects of Additives to SnAgCu Alloys on Microstructure and Drop Impact Reliability of Solder Joints", Journal of Materials, July 2007
[17] *Zhang, Cai, Suhling & Lall, "Aging effects on the mechanical behaviour and reliability of SAC alloys", Proceedings of the ASME 2009, July 19-23, 2009, San Francisco, California, USA*

type of failure within normal lifetimes are unlikely. Medical devices however need to function for over 20+ years and so thermal fatigue does need to be taken into account when selecting a suitable solder alloy.

5.5. Accelerated vibration and drop testing

The reliability of electrical equipment is demonstrated using standard accelerated test methods that have been developed and validated over many tears because manufacturers cannot wait 20 – 25 years to find out how their new designs will perform in the field. Standard accelerated test methods exist for vibration, drop testing, thermal cycling etc. and the test conditions are selected to be realistic for the way that the equipment is used. Acceleration factors are known so that if a product survives the test, it can be assumed it will survive 20+ years in normal use. However, these tests have been developed and validated with equipment made with tin/lead solders. The same acceleration factors will not apply to lead-free solders and the test conditions may be inappropriate because of the differences in physical properties. All medical devices must be approved by a Notified Body in the EU before they can be used and one way of assessing reliability is to use industry standard accelerated test data. As this is not reliable for lead-free equipment, this creates a problem obtaining approval.

5.6. Research into temperature fluctuations

A considerable amount if research has been carried out into the effects of temperature fluctuations on solder reliability. Temperature increase causes materials to expand and PCB laminate expansion on heating is different and usually larger than component expansion, especially for ceramic components. This differential expansion imposes strain on solder joints. Where temperature increases and decreases repeatedly, failure can occur as a result of the cyclic strain causing thermal fatigue cracking of the solder joints. Thermal fatigue failure occurs with both SnPb and lead-free solder joints and the time to failure depends on many variables including the size of the temperature variation, the rate of temperature change, the stress level and the solder alloy composition. Research has shown that where strain is low, lead-free solders are superior to SnPb whereas at high strain levels, lead-free solders are inferior to SnPb. This rather complex result means that PCB designers try to avoid using components that will suffer from large strain such as large ceramic components but this is not always possible. Some of the large BGAs used on mobile medical device PCBs will suffer from large strains when temperatures fluctuate and so this difference in performance is a concern for mobile medical devices as they can experience many repeated large temperature changes.

The field life of SnPb PCBs can be reliably predicted from the results of accelerated thermal cycling tests because many decades of field behaviour is available. The designers of SnPb PCBs can therefore predict product lifetimes and so can be certain that they will survive the expected lifetime of the equipment but this is not yet possible with lead-free solders. If high strain is likely, lead-free solder product lifetime will be shorter than the SnPb equivalent but there can be no certainty of how long because no 20+ years field data exists to validate theoretical prediction models.

It is expected that in the near future, prediction models for lead-free solder will be developed that can be trusted and so will be used but currently this is not possible.

One dilemma for mobile medical equipment manufacturers is that to achieve good drop resistance, research has shown that SAC alloys with low silver content are superior as described above. However, low silver content lead-free solders (e.g. with <1% silver) has inferior thermal fatigue resistance to SAC alloys with 3 or 4% silver[18]. This research showed that failures occur with SAC having 1% silver after less than half the number of thermal cycles than occur with SAC with 3% silver and this has been confirmed by other researchers. Therefore equipment that is dropped and experiences significant thermal fluctuations is at a high risk of failure if lead-free solders are used. Low silver content SAC alloys are now widely used for mobile phones because they are often dropped but due to the small component size and limited temperature changes, strain is too small for rapid thermal fatigue failures to occur.

5.7. Copper dissolution rates

When a printed circuit board is soldered by wave soldering, the copper pads and through-holes are in contact with liquid solder for a fairly short time but some of the copper dissolves in the solder. This is not usually a problem unless rework or repairs are needed when the copper will be in contact with liquid solder for much longer. Research has shown that the rate of copper dissolution is much faster with SAC alloys than with SnPb solder although SnCuNi solder appears to be OK. Measurements by NPL (UK) show the difference in copper dissolution rate.

Solder alloy	Rate of dissolution of copper immersed in solder bath*	Copper dissolution rate (wave soldering) at specified temperature**
SnPb	1.8µm/sec at 275°C	~1.38µm/sec at 255°C (72°C above m.pt.)
SnCu	2.7µm/sec at 275°C	3.28µm/sec at 275°C (~48°C above m.pt.)
SnAg	4.4 µm/sec at 275°C	3.28µm/sec at 275°C (~54°C above m.pt.)
Sn3.7Ag0.7Cu	-	2.3µm/sec at 275°C (~58°C above solidus.) or 3.3µm/sec at 300°C (~80°C above solidus.)

* *D. Di Maio, C. P. Hunt and B. Willis, "Good Practice Guide to Reduce Copper Dissolution in Lead-Free Assembly", Good Practice Guide No. 110, 2008, National Physical Laboratory, UK.*

** *C. Hunt and D. Di Maio, "A Test Methodology for Copper Dissolution in Lead-Free* Alloys", *National Physical Laboratory, UK.*

These results show that the risk of complete loss of copper is higher with lead-free solders than with tin/lead solder. This issues impairs rework and repairs so that additional waste would be created.

5.8. Research into high humidity

[18] *S. Terashima, et al., J. Elec. Mater., Vol. 32, No. 12, p.1527 (2003).*

High humidity increases corrosion rates of materials and this could affect the reliability of mobile devices. Corrosion of most types of lead-free solder is not a concern as most types are less susceptible to corrosion than SnPb. The only exception is Sn-Zn alloys which have been found to corrode and fail after fairly short periods. High humidity can however have the following effects:

- Tin whiskers of electroplated tin coatings
- Corrosion of edges of solder pads and tracks
- Corrosion of metallic parts, e.g. of components on the PCB, due to corrosive flux residues.

Tin whiskers

Tin whiskers form on electroplated tin coatings which are used for electronic component terminations. Tin whiskers are thin rods of tin that grow spontaneously from electroplated tin coatings. These have been known for many decades and have caused the failure of a wide variety of electrical equipment as a result of short circuits. Only since the introduction of the RoHS directive has intensive research been carried out to determine its causes and identify measures to minimise the risk. This research has shown that whiskers form where the tin has compressive stress which can have many different causes. The US organisation International Electronics Manufacturing Initiative (iNEMI) has co-ordinated a lot of research and published guidance on methods to minimise whisker formation, however these recommendations cannot all be adopted with non-magnetic circuitry. One source of stress is due to the formation of tin/copper intermetallic phases that grow between copper substrates and tin plated coatings. The risk of whisker formation from this source of stress can be significantly reduced by the use of nickel barriers between copper and tin but this is not possible with MRI circuits. A possible alternative is to heat the components to 150°C but this must be carried out within 24 hours of electroplating to be effective. This treatment creates a thin SnCu intermetallic barrier that has been shown in some research to hinder or even prevent tin whisker formation although research disputes these results. This option relies on the component manufacturer but very few use this process, so many of the components needed are not available with this heat treatment. By the time the medical equipment manufacturer receives the components, it is too late.
High humidity causes surface corrosion which affects the grain boundaries at the surface imposing strain on these grains. This has been shown to grow long tin whiskers with no mechanism for this stopping (unless the tin is consumed). Many off-the shelf components are available only as lead-free versions usually with tin plated terminations so that manufacturers have no other choice. However the risk of tin whiskers can be limited with tin/lead solder by ensuring that it coats as much of the coating as possible. Lead-free solders wet tin less well so that it is common for a larger area of termination coating to remain uncoated.

Conformal coating option

Research has been carried out to determine whether conformal coatings can reduce the risk of tin whiskers causing short-circuits. There are several types of conformal coating available and all have been evaluated. Research has shown however that they do not stop the formation of tin whiskers, they merely delay their formation, some types for longer than others[19]. Whiskers will eventually grow through many types of conformal coating but as they are flexible, once they emerge they cannot penetrate the coating over an adjacent

[19] *http://nepp.nasa.gov/whisker/reference/tech_papers/2006-Woodrow-Conformal-Coating-PartII.pdf*

termination. There are however three ways that short circuits can occur with conformal coatings:

- Most types of conformal coating give fairly thick coatings and these tend to be more effective than thin coatings which can leave gaps. However, when used on fine pitch components, the coating bridges between terminals. If a whisker grows from one terminal, it is supported by the coating and will eventually reach the adjacent terminal (as there is no air gap) and cause a short circuit. This will however take a longer time than without conformal coatings and to date no examples of failures due to this have been reported (although they would be very difficult to detect).
- Whiskers can grow beneath coatings across the surface of PCBs or components to the adjacent electrical conductor. Poor adhesion of the conformal coating will make this more likely to occur and no-clean soldering fluxes are known to cause inferior adhesion. No-clean fluxes are designed not to be removed and so when they cannot be completely removed poor adhesion occurs. As lead-free solders require higher temperature, this usually makes flux removal with solvents more difficult. Some types of components such as QFNs and vented BGAs (both of which are used in mobile medical devices) must be soldered with no-clean fluxes and they should not be cleaned.
- If two whiskers grow through the coatings of two adjacent terminals into the air, they may touch each other causing a short circuit. This is likely to occur only if there are many whiskers formed although this is fairly common.

The likelihood of a short circuit caused by tin whiskers when a conformal coating is used is much less than without the conformal coating but clearly the long term risk is not completely eliminated.

Corrosion of edges of solder pads and tracks

As lead-free solders wet less well than SnPb, it is often found that component solder pads are not fully wetted by solder. Corrosion of these uncoated areas has been observed in hostile environments when the PCBs have OSP or silver coatings but is not an issue with ENIG or HASL coatings and so this can be avoided.

Corrosion of metallic parts, e.g. of components on the PCB, due to corrosive flux residues. – Some lead-free solder fluxes must be more aggressive than those used with SnPb solders due to the inferior wetting properties and the higher solder melting point. This is alloy dependent with some fluxes being particularly corrosive. Ideally no-clean fluxes are used to avoid the production of waste washing solutions but for many types of mobile medical device, high surface insulation resistance (SIR) is essential for the equipment to function correctly and so these fluxes must be removed by washing. Lead-free flux residues tend to have a higher ionic content and are more difficult to dissolve due to the higher reflow temperature and so manufacturers can experience difficulties achieving the required level of cleanliness.

High humidity combined with a higher ionic content of fluxes can also cause the Surface Insulation Resistance (SIR) between tracks and pads to increase to a level that causes some types of equipment to malfunction. For example, biometric measurement circuits must have high impedance and so humidity and higher lead-free ionic content fluxes can cause malfunctions which result in false alarms or worse, no alarm when a serious incident occurs. Excessive ionic material with high humidity can also cause corrosion of metals and dendrite growth which is an electrochemical corrosion process that causes short-circuits and is found to occur faster with solders containing silver. Overall therefore, manufacturers find that

using lead-free solders is more difficult than SnPb and so will need sufficient time to resolve these issues.

5.9. Comparison of solders

The table below summarises the reliability performance due to the three main risk factors and reparability of the three main types of lead-free solder with SnPb.

Variable	SAC alloys with ≥3%Ag	Low Ag SAC alloys with <1%Ag	Sn100C, etc (no silver)
Temperature fluctuations	OK unless high strain	Inferior to SAC305 and SnPb	Inferior to SAC305 and SnPb
Vibration	Inferior to SnPb	Inferior to SnPb	Inferior to SnPb
Drop / shock	Unsuitable	Probably OK, used for mobile phones	Probably OK
Copper dissolution	Faster than SnPb	Faster than SnPb	Faster than SnPb but may be OK

Re-use and recycling of materials from waste EEE

At end of life, most medical equipment is recycled as it often has a high value due to its metals content. Printed circuit boards are separated for separate recycling as required by Annex II of Directive 2002/96/EC before being recycled. In the EU and in many facilities elsewhere, PCB scrap is recycled using smelters which are large furnaces that melt some metals such as copper and convert others including lead into oxides which are collected then converted into metals for re-use. Lead is recovered with a very high efficiency and emissions are extremely low and meet EU environmental limits. PCB scrap is only one of many materials processed in large smelters and so removal of lead from solder will not affect this process as other materials including ores used may contain lead.

Unsafe recycling of WEEE is carried out in some developing countries but this is mostly with IT, telecom and consumer equipment. Waste medical equipment is very unlikely to be recycled except by professional recyclers using well controlled safe processes.

Lead: Large quantities of recycled lead are produced from lead scrap including printed circuit boards. No lead is released in the circuit board fabrication phase or the use phase of the life cycle. At end of life, PCBs in mobile medical devices contain some valuable metals and so they are nearly always recycled.

Silver: If solders containing silver are used, recyclers will want to recover the silver from equipment at end of life. There are safe and efficient processes used by professional recyclers in the EU to recover silver with a high yield but if this equipment is exported to second users in developing countries, when it reaches end of life, unsafe recycling methods using very hazardous chemicals such as nitric acid and cyanide might be used and these chemicals are known to cause harm to local populations and the environment.

Other solder constituents including tin (Bi, In and Zn) may also be recovered by modern efficient recycling processes but are very difficult to recycle without suitable processes.

6. Other information

The quantity of lead in the solder required for these applications will be 3.27 tonnes in the EU annually.

6.1. Proposed plan to develop substitutes and timetable

The only potential alternative to lead in solders is lead-free solders. Manufacturers are carrying out research to find alloys and processes that give high reliability. It is likely that high reliability will be possible by a combination of selection of the correct alloy and suitable design to minimise the risk from shock, vibration and temperature changes. This is time-consuming work because each type of equipment will need to be considered separately. Reliability testing of new alloys and designs must be thorough for medical devices as this data is needed before applying for approval under the Medical Devices Directive. Professor Cedar[20], has commented that in order to fully establish any new alloy or materials' characteristics and properties, it will take up to 18 years of effort and data collection, so that changes can be made appropriately to improve the materials, thus making the new materials close to problem free and more reliable when serving the industries. To gain approval, it will be necessary to show that the alternative alloy and every new design is no less reliable than with lead-based solders and so do not pose a risk to patients. The likely time-scales are:

Evaluation of alternative alloys and designs	up to 5 years
Reliability testing of new designs	at least 2 years
Submission for MDD approval	1 year
Total timescale	minimum 8 years

This exemption is therefore likely to be needed until 2020 at least. The reason that manufacturers expect to need 5 years for evaluation of alternative alloys and designs for all types of mobile medical equipment is to resolve technical issues due to lead-free solders, for example:

- Lead-free processing (with SAC) limits the maximum allowable deflection of the circuit boards by about 35%. This is presumably the result of greater SAC erosion of copper plating especially at vias in pads in reflow processes. Through hole components requiring wave soldering will cause even more copper erosion where ever copper sees the wave.
- Currently, the only solutions to copper erosion relate to wave soldering of through-hole components. For surface mount components that utilize vias-in-pads there currently no solution to the erosion problem that we are aware of. SN100C solder reduces copper erosion but is suitable only for wave soldering only. For SMT it is still a problem (see section below on SnCuNi comparison).
- ENIG can cause problems, most notable of which is "black pad" although this can also occur with SnPb. The electroless plating of nickel introduces phosphorus which can collect and cause plating failure at the collection points. The solder dissolves the gold and bonds to the nickel, but the nickel is not secured to the copper. Therefore time is required with any new design to ensure that reliability and quality issues do not occur.

[20] *Private communication from Professor Cedar, MIT, Material Science Department*

- Some lead-free alloys such as SAC305 have been comprehensively studied and used for up to 10 years. For the reasons explained here, more research is needed but this has been a trend in recent years to use lower cost alloys with low silver content such as SAC0807 and SAC0307 (which have much higher melting temperature than SAC305). There has much been less research and field experience with these new alloys but they are cheaper and have a few technical advantages. Medical equipment manufacturers are able to select whichever alloy they need to ensure high reliability but if most of the electronics industry switches to new alloys, this will severely limit the number of collaborative research studies into SAC305 and other alloys that medical equipment manufacturers have been evaluating and already have some experience. Collaborative research is useful as a lot more research is carried out and shared than could be carried out by a single manufacturer in the same period of time. Switching to new alloys for consumer products and that may not be suitable for mobile medical devices will mean that medical equipment manufacturers will need to carry out much more research themselves and this will require more time than if all of the electronics industry were investigating the same few alloys.

7. Proposed wording for exemption

It is suggested that the following wording is used:

Lead in solders used in Directive 93/42/EEC Class IIa and IIb portable and mobile medical devices where the medical devices need to be transported on a cart or trolley, hand-held diagnostic devices, hand carried devices such as portable ventilators, those transported in a vehicle such as an ambulance or helicopter to the designated location of use and medical devices that are operated while being carried such as patient worn devices.