Exemption Renewal Form - Exemption 17 Annex IV

Date of submission: **15 January 2020**

Attached documentation:

- **Confidential quantity calculation Renewal exemption 17**

1. Name and contact details

1) Name and contact details of applicant

Company:	**COCIR**	Tel.:	**00327068966**
Name:	**Riccardo Corridori**	E-Mail:	**corridori@cocir.org**
Function:	**EHS Policy Senior Manager**	Address:	**Blvd A. Reyers 80, 1030 Bruxelles**

2) Name and contact details of responsible person for this application (if different from above):

Company:	_____	Tel.:	_____
Name:	_____	E-Mail:	_____
Function:	_____	Address:	_____

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2. Reason for application:

Please indicate where relevant:

- ☐ Request for new exemption in:
- ☐ Request for amendment of existing exemption in
- ☒ Request for extension of existing exemption in Annex IV
- ☐ Request for deletion of existing exemption in:
- ☐ Provision of information referring to an existing specific exemption in:
  - ☐ Annex III ☐ Annex IV

No. of exemption in Annex III or IV where applicable: **17**

Proposed or existing wording: **Lead in solders of portable emergency defibrillators**

Duration where applicable: **Until the end of 2025**

☐ Other: _____

3. Summary of the exemption request / revocation request

Portable emergency defibrillators are used to save lives when people suffer from heart attacks. Patients whose hearts have stopped must be treated within 10 minutes for survival to be possible. Defibrillators must be very reliable as any defects could result in a fatality. There are many types of defibrillator sold in the EU that rely on exemption 17 and manufacturers have been working on substitution for many years, however substitution of lead is not straightforward. Usually redesign is necessary as older designs often include components that contain lead with no lead-free alternative available. Redesign introduces uncertainty over the reliability and usually it is preferable to develop new designs instead, as these can be designed for maximum reliability and also utilise the latest medical science on survival from heart attacks. An added complication is that the Medical Device Directive is being replaced by the Medical Device Regulation, which requires all medical devices sold in the EU to be submitted for re-approval by EU Notified Bodies. Defibrillator manufacturers have estimated that the current work on new models will be completed and approvals granted by the end of 2025, at which time the lead soldered models can be discontinued.

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4. Technical description of the exemption request / revocation request

(A) Description of the concerned application:

1. To which EEE is the exemption request/information relevant?

   Name of applications or products: Portable emergency medical defibrillators

a. List of relevant categories: (mark more than one where applicable)

☐ 1	☐ 7
☐ 2	☒ 8
☐ 3	☐ 9
☐ 4	☐ 10
☐ 5	☐ 11
☐ 6	

b. Please specify if application is in use in other categories to which the exemption request does not refer: _____

c. Please specify for equipment of category 8 and 9:

The requested exemption will be applied in

☐ monitoring and control instruments in industry

☐ in-vitro diagnostics

☒ other medical devices or other monitoring and control instruments than those in industry

2. Which of the six substances is in use in the application/product?

   (Indicate more than one where applicable)

   ☒ Pb ☐ Cd ☐ Hg ☐ Cr-VI ☐ PBB ☐ PBDE

3. Function of the substance: Constituent of solder

4. Content of substance in homogeneous material (%weight): 36 – 40%

5. Amount of substance entering the EU market annually through application for which the exemption is requested:

Estimated total from all manufacturers is about 100kg (estimated using data from manufacturers who contributed data).

Please supply information and calculations to support stated figure.
The calculation includes confidential market data from individual manufacturers and so is provided as a separate confidential annex.

6. Name of material/component: Solder

7. Environmental Assessment: _____

   LCA: ☐ Yes
   ☐ No

(B) In which material and/or component is the RoHS-regulated substance used, for which you request the exemption or its revocation? What is the function of this material or component?

Portable emergency defibrillators are used to restart peoples' hearts when they suffer from cardiac arrest. Cardiac arrest can occur at any time and are usually unexpected. It is essential that patients receive medical attention very quickly for them to survive, so portable emergency defibrillators have been developed to resuscitate patients. These are carried by emergency responders in ambulances, police vehicles, carried by sports trainers in vehicles, as well as being held ready in hospitals, homes and public places such as shops, railway stations, hotels, etc. Defibrillators must be completely reliable because if they were not to function correctly, the patient might die if the defibrillator does not work correctly.

There are many designs of defibrillator, ranging from advanced hospital devices that provide monitoring and defibrillation functions to automated external defibrillation (AED) models that are used in homes and public places. The basic models are designed to be easy to use by untrained passers-by with the

defibrillator instructing the user on how to operate it and resuscitate the patient. The defibrillator monitors the patient's heart rhythm and other parameters to determine the actions required and the appropriate shock energy to use to restart the heart. They provide instructions to users on what to do including how to do CPR (Cardiopulmonary Resuscitation).

More advanced (and more expensive) models can also pace (control heart rate), measure blood pressure, oxygen saturation levels and carry out other functions. These types of defibrillator are used in hospitals and in mobile advanced life support vehicles such as ambulances. Models that may be carried in ambulances will suffer from the most severe conditions as they will experience the most vibration, the largest temperature fluctuations and are most likely to be regularly dropped.

Automated External Defibrillators (AEDs) models are used in many locations, but relatively few are available, even in ambulances and this may be because prices are sufficiently high to prevent more widespread introduction. The UK charity, the British Heart Foundation estimates that only 3% of cardiac arrests happen within the recommended retrieval distance of a defibrillator[1], so anything that discourages potential users from buying a defibrillator (such as increased costs or limited availability) could result in unnecessary deaths in the future.

Portable emergency defibrillators use lead in solders to make electrical connections between electronic components, circuit boards and wires. Experience has shown that lead solders are less impacted by product storage conditions and operational environments than RoHS lead-free materials. Factors such as corrosive atmosphere (for example cleaning agents containing ammonia or chlorides), temperature extremes, temperature cycling, humidity, vibration and mechanical drop can affect RoHS lead-free solder connections more harshly. Furthermore, RoHS lead-free soldered circuits have an increased risk of creating 'Tin Whiskers' where a whisker grows from one surface to another surface causeing an electrical short instide the product. All of these reliability issues must be addressed in new designs; requiring very lengthy research and testing to ensure very high reliability that is required for these safety critical devices.

[1] https://www.bhf.org.uk/how-you-can-help/how-to-save-a-life/defibrillators

(C) What are the particular characteristics and functions of the RoHS-regulated substance that require its use in this material or component?

Potable emergency defibrillators must be very reliable as any malfunction can result in a patient's death. Therefore extremely high reliability is essential and is the most important characteristic of these products.

As the devices are portable, they must survive hostile environments with no effect on their functions. They can be dropped onto hard surfaces, carried in vehicles or helicopters where they suffer from severe vibration, experience large temperature fluctuations, severe environments, such as high humidity and marine environments and if used in factories may be exposed to corrosive chemicals.

As a medical device, they cannot be sold without approval in all of the jurisdictions where they are sold. In the EU, approval by a Notified Body under the Medical Devices Directive (soon to be replaced by the Medical Devices Regulation) is required and separate approvals are needed in other non-EU countries. This can take up to two years after a new design or redesign testing and trials have been completed. With each type or model following the same extensive labour intensive and time consuming compliance procedures. Each manufacture may produce 10 – 20 different types of defibrillator.

The essential combination of required characteristics of solder bonds are:

- Be sufficiently ductile – to avoid damage due to thermal expansion mismatch between laminate and components.
- Melting temperature 160°C to 220°C – to avoid damage to components.
- Suitable for mass production using reflow soldering of surface mount components, as well as wave and hand soldering.
- Solder bonds must be resistant to cyclic thermal fatigue, intense vibration and drop-shock.
- 100% of solder bonds inside defibrillators must not fail.

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5. Information on Possible preparation for reuse or recycling of waste from EEE and on provisions for appropriate treatment of waste

1) Please indicate if a closed loop system exist for EEE waste of application exists and provide information of its characteristics (method of collection to ensure closed loop, method of treatment, etc.)

The more advanced types of defibrillator are collected by manufacturers and some are refurbished, so this may be within closed loops, although COCIR does not know the procedures used by all defibrillator manufacturers. The less complex automated external defibrillators are usually collected for recycling at end of life.

2) Please indicate where relevant:

☒ Article is collected and sent without dismantling for recycling

☒ Article is collected and completely refurbished for reuse (proportion not known, perhaps about 10% of the total).

☐ Article is collected and dismantled:

- ☐ The following parts are refurbished for use as spare parts: _____
- ☐ The following parts are subsequently recycled: _____

☐ Article cannot be recycled and is therefore:

- ☐ Sent for energy return
- ☐ Landfilled

3) Please provide information concerning the amount (weight) of RoHS substance present in EEE waste accumulates per annum:

☒ In articles which are refurbished	about 10kg
☒ In articles which are recycled	about 90kg
☐ In articles which are sent for energy return	_____
☐ In articles which are landfilled	_____

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6. Analysis of possible alternative substances

(A) Please provide information if possible alternative applications or alternatives for use of RoHS substances in application exist. Please elaborate analysis on a life-cycle basis, including where available information about independent research, peer-review studies development activities undertaken

A possible substitute for lead in solders is to use lead-free solders. However, these are not drop-in replacements and experience has shown that substitution can affect reliability, especially when the solder bonds are exposed to hostile conditions that can be experienced by portable emergency defibrillators (see Annex).

Replacement of current models that were originally designed to be made using lead solders with new designs that use lead-free solders is often not straightforward. Manufacturers will usually not be able to use a different (lead-free) solder with the same circuit design because older models will use components that are incompatible with lead-free solders. The components either cannot withstand the higher soldering temperature required, or they contain tin/lead solder inside the components. An example is ball grid array (BGA) integrated circuits, which may contain tin/lead balls which cannot be soldered to circuit boards with lead-free solders as bonds would be unreliable (as well as containing lead). Therefore complete circuit redesign is usually necessary as

lead-free versions of previously used components are often not available and as this will probably mean that newer and different microprocessors are used, the software will also need to be rewritten.

Portable defibrillator manufacturers constantly monitor new developments in medical science as well as electronics design. Based on this research they regularly develop new designs utilising the latest technology and medical knowledge. This means that new models are being continuously introduced to replace old models. Conversion of an existing model from a lead-soldered version to a lead-free version has severe difficulties. Firstly, redesign will usually be difficult for the reasons explained above and the reliability of a redesigned defibrillator will not be known until extensive testing is carried out. The reliability of a redesigned product could conceivably be worse than a new design because the overall design is a combination of the original design with new parts and circuits fitted into the original product.

In practice, due to the very long time required to redesign, the technical difficulties involved and the uncertainty over reliability means that manufacturers focus their effort to develop new products that utilise the latest medical knowledge to improve the likelihood of saving a life rather than substitute lead in existing models. Portable defibrillator manufacturers are already working on new lead-free models, but as the timescale required for each model is quite long and due to resource limitations (i.e. trained engineers), it will take many years to replace all current lead-soldered defibrillator models, although COCIR estimate that this should be complete by the end of 2025.

If this exemption were not to be renewed, most models currently on the EU market could not be sold in the EU and replacement products would not be available for many years (see section 7(B) for the timescale). This would have a severe negative impact on the health of EU citizens as this would prevent new defibrillators being available for use in an emergency. The following are some

published statistics that illustrate the potential harm from the non-availability of portable emergency defibrillators[2,3] :

- 270 children die in the UK every year after suffering a sudden cardiac arrest at school.
- Based on European data, it is estimated that there are approximately 60,000 Out of Hospital Cardiac Arrests (OHCA) every year in the UK and 300,000 heart attacks outside of hospitals in Europe annually.
- In England alone, the Ambulance Service attempts resuscitation in around 30,000 OHCA cases, annually.
- European data shows that portable emergency defibrillators were used in only 1.7% to 12.8% of OHCA.
- Without immediate treatment, 90-95% of sudden cardiac arrest victims will die.
- If a defibrillator is used and effective CPR (cardiopulmonary resuscitation) is performed within 3-5 minutes of cardiac arrest, the chance of survival increases from 6% to 74%.

A UK study into OHCA found that on average, only 8% of people for whom resuscitation is attempted by emergency services in England survive to leave hospital, with each minute without intervention reducing the chance of survival[4]. The use of defibrillators by passers-by is shown to save many lives. The study found that survival rates were much higher, at 53%, for people who had a rhythm that could be treated with a shock from a potable emergency defibrillator by a member of the public. The higher survival rate following bystander assistance was probably due to the shorter response time, although time to intervention was not reported by the researchers of this study.

Published data for the EU is limited, but a US study[5] confirms the above statistics and showed that:

- 95 percent of cardiac arrest victims die before reaching the hospital.
- A heart attack victim's chances of survival are reduced by 7% to 10% for every minute that passes without CPR and defibrillation. Few attempts at resuscitation succeed after 10 minutes.
- The emergency services take on average 6.6 minutes to arrive in mid-size urban communities, which will be too late for some patients.
- Nearly 60% of all cardiac arrests are witnessed, so if a defibrillator were to be located nearby, a patient's chances of survival is significantly

[2] https://www.defibshop.co.uk/facts-and-figures and https://firstaidforlife.org.uk/why-defibrillators-save-lives/

[3] https://bmjopen.bmj.com/content/bmjopen/7/5/e014801.full.pdf

[4] https://discover.dc.nihr.ac.uk/content/signal-000473/use-of-public-defibrillators-linked-to-out-of-hospital-cardiac-arrest-survival

[5] https://ohsonline.com/~/media/CBFA9EAC643F46EEA64F9FA20B896804.pdf

improved. It is estimated that improved access to defibrillators in the USA could save 40,000 lives a year.

The UK charity, the British Heart Foundation's estimate that only 3% of cardiac arrests happen within the recommended retrieval distance of a defibrillator. Demonstrating that many more defibrillators are required in public places in the UK which will be the same or similar for all EU Member States. Therefore limiting the supply of portable emergency defibrillators, especially basic and public models will result in more deaths than if the availability were not inhibited, such as by higher prices or limited availability due to models having to be withdrawn from the EU market.

(B) Please provide information and data to establish reliability of possible substitutes of application and of RoHS materials in application

There is a lot of published research on reliability of lead-free solders that explains why there are no drop-in replacements for lead solder (SnPb) by lead-free solders. Much of this was carried out soon after the RoHS Directive was adopted and clearly demonstrates differences in reliability that depended on solder composition. As well as the environmental factors that affect reliability, in particular temperature fluctuations, drop-shock and vibration. Reliability was shown to depend on many variables including circuit design and materials (such as surface finish), material and size of components and laminate (i.e. due to differences in thermal expansion coefficient which result in stresses when temperatures fluctuate) and solder composition (some alloys have superior thermal fatigue but inferior drop-shock resistances and others are the opposite). The lead-free solders originally developed have since been found to have significant limitations for the more demanding use conditions, which are experienced by portable defibrillators, newer alternative alloys need to be evaluated to determine the most suitable material. These issues are explained in a publication from 2010 and shows that there is no single lead-free alloy that is suitable for all use conditions and so extensive reliability testing is needed[6]. A publication by CALCE describes many of the reliability issues that occur and explains that extensive trials and testing are required when switching from lead solders to lead-free solders[7]. A summary of published research is provided in the Annex to this renewal request.

In recent years, much less research has been published on the comparative reliability of lead and lead-free solders as this work was investigated in the first 10 years of the current millennium. However when a manufacturer designs a new

[6] Second Generation Pb-free Alloys, R. Schueller, et. al., SMTA Journal, Vol 23 (1), 2010)

[7] C14-05 report, Report Title: Considerations for Implementing RoHS Compliant Electronics for Critical Applications Principal Investigator: Michael Osterman, updated October 2014

lead-free medical device, they have to prove that these new designs will be reliable to obtain Notified Body approval under EU medical device legislation before the product can be sold in the EU. The verification and validation process for portable emergency defibrillators is especially extensive taking many years. It is known that older lead soldered designs of defibrillator are very reliable because extensive field data exists. Field data for the few lead-free defibrillators that have been developed is still very limited as very few have been used for more than 5 years. Some defibrillator manufacturers have less than 2 years field data which is limited to a small number of designs, resulting in insufficient field data to be statistically meaningful. As a result, there is uncertainty over the reliability of new products and especially if a product were to be redesigned (no field data exists for redesigned defibrillators).

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7. Proposed actions to develop possible substitutes

(A) Please provide information if actions have been taken to develop further possible alternatives for the application or alternatives for RoHS substances in the application.

Manufacturers have developed a few new defibrillators using lead-free solders since 2014. This required a very large effort in terms of manpower to design the equipment, carry out very extensive reliability assessment and then clinical trials before Medical Device Regulation approval can be obtained. Due the limited number of suitably trained and experienced engineers available to replace all current lead soldered models COCIR estimate that design, test and approvals of new models that can replace all current models will not be complete until the end of 2025.

(B) Please elaborate what stages are necessary for establishment of possible substitute and respective timeframe needed for completion of such stages.

Changes in EU Medical Device legislation are having an impact on the length of time taken to develop new products, as engineers are required to support gaining re-approvals under the new regulation. The Medical Devices Directive 93/43/EEC will be replaced by the Medical Devices Regulation 2017/745/EU on 26 May 2020. As a result, approvals granted previously by EU Notified Bodies will expire and are required to be renewed by 27 May 2024. Medical Device manufacturers are working towards gaining re-approvals with applications for EU MDR approval to be submitted by June 2020 at which time no significant changes can be made to the defibrillators until approval is granted. Replacement of lead solder by lead-free solder may not be regarded as a significant change by Notified Bodies, but where any significant redesign is needed (and is usually the case), such as if an older lead-soldered components (such as BGAs with lead solder balls) has no

lead-free substitute, then extensive redesign would be needed and this is a regarded as a significant change.

It is essential that manufacturers meet the May 2024 re-approvals deadline for the new EU MDR as otherwise, no portable emergency defibrillators could subsequently be sold in the EU. However if re-design is also necessary, the re-approval process is very time consuming because extensive reliability tests and trials will be needed. Manufacturers' resources for this work are limited (due to the shortage of engineers) therefore it is not possible to redesign to replace lead as well as carry out the work to gain re-approval under the MDR. Moreover, under the new MDR, designs submitted for approval cannot be changed after June 2020, which means that if a manufacturer wants to replace lead and gain MDR approval by the 2024 deadline, redesign work, testing, etc. must be complete by 2020 and this will be impossible for all current lead soldered models.

MDR requirements on notified bodies are also shrinking down the number of notified bodies that will be available to recertify equipment. At the time this exemption is being written only 2 notified bodies out of 50+ have completed the certification process. The 20 Notified Bodies that are expected to be available by the end of the year would make it very hard for companies even to get their new equipment certified to be placed on the market.

When a new defibrillator design is being developed, extensive testing, often followed by a clinical trial is needed before approval requests can be submitted and typical timescales are as follows:

Phase	**Elapsed time per model**
Design of new circuit using lead-free solders	1 year
Rewrite software	1 year
Reliability testing – thermal cycling drop-shock, vibration, etc.	1 - 2 years
Clinical trials	1 - 2 years
Gaining global approval	Typically 2 years for all countries

Total elapsed time for redesign of an existing model will be similar to the above timescale. Although the above timescale is a total elapsed time of 6 - 8 years for one defibrillator model, all defibrillator manufacturers produce many types and designs. As the design and testing process is very labour intensive, with limited numbers of suitably trained and experienced engineers, each manufacturer is usually able to work on only one or two models at a time. Therefore the total elapsed time needed to replace all lead solder models will be much more than 8

years. Research and re-design work originally started before 2014 when Medical Devices entered scope of RoHS and is expected to be complete by the end of 2025.

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8. Justification according to Article 5(1)(a):

(A) Links to REACH: (substance + substitute)

1) Do any of the following provisions apply to the application described under (A) and (C)?

☐ Authorisation

- ☒ SVHC
- ☒ Candidate list
- ☐ Proposal inclusion Annex XIV
- ☐ Annex XIV

☐ Restriction

- ☐ Annex XVII
- ☐ Registry of intentions

☒ Registration

2) Provide REACH-relevant information received through the supply chain.

Name of document: Lead metal registration – see https://ila-reach.org/our-substances/lead-metal/ and https://echa.europa.eu/registration-dossier/-/registered-dossier/16063

(B) Elimination/substitution:

1. Can the substance named under 4.(A)1 be eliminated?

☐ Yes. Consequences? _____

☒ No. Justification: A lead-free soldering process may not be technically possible without redesign. Reliability of new designs and especially redesigned products is not ensured.

2. Can the substance named under 4.(A)1 be substituted?

☐ Yes.

☐ Design changes:
☐ Other materials:
☐ Other substance:

☒ No.

Justification: A lead-free soldering process without redesign may not be technically possible and reliability of new designs and especially redesigned products is not ensured

3. Give details on the reliability of substitutes (technical data + information): This explained in Section 6 and the Annex.
4. Describe environmental assessment of substance from 4.(A)1 and possible substitutes with regard to
    1) Environmental impacts: Not applicable
    2) Health impacts: See above
    3) Consumer safety impacts: Not applicable

⇨ Do impacts of substitution outweigh benefits thereof? Not applicable
Please provide third-party verified assessment on this: _____

(C) Availability of substitutes:

a) Describe supply sources for substitutes: Lead-free solders are widely available but as described in Section 6 these are not suitable as drop-in replacements currently
b) Have you encountered problems with the availability? Describe: No
c) Do you consider the price of the substitute to be a problem for the availability?
☐ Yes ☒ No
d) What conditions need to be fulfilled to ensure the availability? Availability is not the reason for needing this exemption

(D) Socio-economic impact of substitution:

⇨ What kind of economic effects do you consider related to substitution?

☐ Increase in direct production costs

☒ Increase in fixed costs – The costs of redesign, testing, trials and gaining approvals can be very significant. As all defibrillator manufacturers are affected in the same way, all will pass on these costs to their customers.

☐ Increase in overhead

☒ Possible social impacts within the EU. Many people die in the EU each year from heart attacks. Some could be saved if portable emergency defibrillators are available and are accessible within a few minutes. Currently, only 12.8% at best and 1.7% at worst of heart attack victims are treated with defibrillators in EU Member States. As a result a high proportion of the 300,000 heart attack victims in the EU die annually. This death rate could be reduced

by an increase in the availability of defibrillators which will occur if prices are as low as possible and there are no supply shortages, but this would not occur if most models could not be sold in the EU because this exemption is not renewed.

☐ Possible social impacts external to the EU

☐ Other: _____

⇨ Provide sufficient evidence (third-party verified) to support your statement: _____

9. Other relevant information

Please provide additional relevant information to further establish the necessity of your request:

_____

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10. Information that should be regarded as proprietary

Please state clearly whether any of the above information should be regarded to as proprietary information. If so, please provide verifiable justification:

The method used to calculate the amount of lead used annually uses confidential market information from individual manufacturers and so is provided as a separate confidential annex.

Annex

Reliability research summary into lead-free solders.

Lead-free solders have been widely used by the electronics industry since 2006. Research into long term reliability of lead-free solders subjected to the types of hostile environmental conditions experienced by defibrillators has been carried out and is discussed below:

Vibration:

Vibration can cause solder bonds to fail by cracking and this phenomenon is also known as high cycle fatigue. The susceptibility to high cycle fatigue is dependent on the g-force, whether the vibration is random or directional, frequency, design,the composition of the solder alloy and other variables such as the terminal coating composition and type of laminate material. Defibrillators carried in vehicles can experience severe vibration.

Research published by the National Physical Laboratory (NPL) with solder bonded to copper plates in order to eliminate the effect of design showed that tin/lead solder was superior to the lead-free alloys tested comprising of tin, silver and copper (SAC0305 and SAC387), especially at higher frequencies[8]. NPL's tests showed that for all frequencies, SnPb had a lower probability of failure than any of the four SAC alloys they tested and this was especially the case at the higher frequencies of 400 and 800Hz that were assessed. The numbers of vibration cycles to 20% probability of failure from Wiebull plots were:

Table 1. 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	-

A comparison of SnPb and SAC solder bonds to SnPb and SAC alloy ball grid array (BGA) package on FR4 laminate at vibration g-forces of 10g and higher by CALCE showed that Sn37Pb solder is more reliable than SAC solder[9]. Another publication also shows that at high vibration load (30g) with chip resistors on a laminate circuit board, the lifetime of SnPb solder bonds is considerably longer than SAC305 and SN100C (Sn-0.7Ni-0.05Cu+Ge) solders.

Often research has given contradictory results but the reason was demonstrated by research carried out by JGPP[10] which showed that susceptibility depends on:

- The solder alloy composition;
- Type of component;
- Position on circuit board (as this affects the g-force); and
- g-force

[8] High-Frequency Vibration Tests of Sn-Pb and Lead-Free Solder Joints, D Di Maio and C Hunt, NPL report MAT 2, August 2007

[9] Vibration Durability Investigation for SAC and SnPb Solder: Based on JCAA/JG-PP Lead-Free Solder, Project Test Results, CALCE Electronic Products and Systems Centre, 2006.

[10] T. Woodrow, JCAA/JG-PP Lead-free solder project: Vibration and Thermal Shock Tests", April 2006. http://www.cirvibe.com/WoodrowVibBoston2007Rev.F.pdf

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 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 2. 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.

Research for a Ph.D. thesis compared SnPb with various SAC alloys and tin/copper/nickel (SnCuNi) solder[11]. This showed that SAC305 and SnCuNi were substantially inferior to SnPb in the range of stresses assessed.

Large temperature cycles:
Large cyclic temperature changes can occur with defibrillators, for example when used in vehicles, such as ambulances. The inside of a vehicle in Northern Europe at night in the winter when the engine is not in use will reach very low ambient and temperatures below -20°C are not unusual in Northern Sweden and in Finland -45 to -50°C is recorded fairly regularly[12]. In summer inside vehicles the temperature can exceed 40°C. This large temperature range can result in large stresses being imposed on solder joints due to differential thermal expansion and contraction of the component and substrate which have different thermal expansion coefficients. This is especially a problem with larger ceramic components (such as chip resistors and ceramic ICs, but this can also be an issue with many other types of component) on polymer laminate PCBs. Ceramics (and silicon die) have typically much lower thermal coefficient of expansion (TCE) than polymeric PCB laminate materials.

[11] Lead-free Solders for High-Reliability Applications: High-Cycle Fatigue Studies, N. Barry Ph.D thesis 2008, http://etheses.bham.ac.uk/198/1/Barry08EngD.pdf

[12] http://en.ilmatieteenlaitos.fi/seasons-in-finland

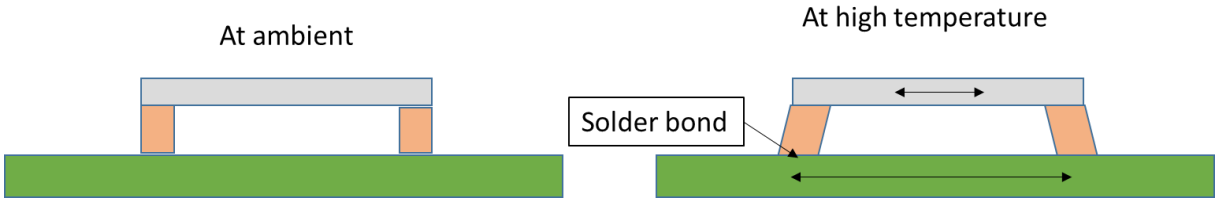

Figure 1. Strain imposed on solder bonds due to heating laminate with a larger TCE than the TCE of the component

There are many publications that compare SnPb with a variety of lead-free solder compositions. These show that thermal fatigue performance of lead-free solders is different to SnPb and it can be superior or inferior depending on:

- Alloy composition; and
- Stress imposed on solder bonds, which is dependent on component and laminate design, dimensions, materials used and the size and rate of the cyclic temperature range.

Due to the many parameters that can affect stress level, it is very difficult to predict service lifetimes. It is also difficult to estimate lifetimes from accelerated testing as acceleration factors for tin/lead and lead-free solders are different. However, research has shown that overall, lead-free alloys tend to be superior to SnPb at low stress levels, whereas SnPb is superior overall at higher stress levels. However the difficulty and uncertainty of predicting lifetimes and reliability is a problem because it is necessary to prove long term reliability to gain Medical Device Regulation approval from an EU Notified Body.

Drop shock performance

Early research with lead-free solders showed that these had inferior drop shock performance compared with SnPb solder. This was a concern with portable devices that are often dropped such as mobile phones, but is especially a concern with defibrillators that are likely to be dropped when the paramedic reaches a very ill patient.

Research published by Heaslip et al[13] in 2005 compared the drop performance of printed circuit boards (PCBs) having ball grid array (BGA) devices made using SnPb compared with SAC305 solders. Drop performance of PCBs made with SnPb and Sn3.8Ag0.7Cu BGA balls and solder pastes were compared using drop heights of 406 and 610mm. Two types of failure were noted; “hard” faults where permanent open circuits occurred and “soft” faults where brief periods of high electrical resistance occurred (presumably due to cracks). Brief periods of high electrical resistance are sufficient to cause the defibrillator to malfunction and transmit an incorrect signal that could detrimentally affect its function, potentially fatally. A selection of Heaslip’s results is shown in the table below which shows when the first soft failures occurred after the specified numbers of drops:

[13] Heaslip, Ryan, Rodgers & Punch Stokes Research Institute and University of Limerick, “Board Level Drop Test Failure Analysis of Ball Grid Array Packages”

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 (possibly due to a solder defect)	All failed after <20 drops

This research clearly shows that SAC305 solders have significantly inferior drop performance than SnPb. As a result of these results, which has been confirmed by other researchers, alternative types of lead-free alloys have been evaluated for comparison with SnPb solder.

Research published in 2007 compared the drop performance of simulated BGA assemblies soldered using a wide range of solders[14]. This research used 17 lead-free solder alloy compositions including three alloys with ~3% silver (Ag), the rest with lower amounts of silver and these were compared with 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 that contained ~1% Ag plus certain additives gave slightly superior drop performance to SnPb when tested in the "as reflowed" condition. This condition is however unrepresentative of electrical equipment as all solders "age" in use and this changes their microstructure so that they perform differently. This research also compared drop test performance of more representative 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 about 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 its rather high melting temperature for use in solder pastes (this melts in the range 217 - 227°C) and as this alloy is not available commercially, it cannot be considered as a practical substitute.
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 SAC305 solder[15]. Solders with low silver content have however been found in comparative testing to give inferior thermal fatigue performance[16], so choice of solder has to be a compromise and manufacturers need to consider which failure modes are the most significant – due to thermal cycling or being dropped. This is a problem for portable defibrillators as both occur.

[14] 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

[15] 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

[16] Comparison of Thermal Fatigue Performance of SAC105 (Sn-1.0Ag-0.5Cu), Sn-3.5Ag, and SAC305 (Sn-3.0Ag-0.5Cu) BGA Components with SAC305 Solder Paste, Gregory Henshall, et. Al, published IPC APEX EXPO Proceedings. Downloaded from http://www.circuitinsight.com/pdf/comparison_thermal_fatigue_ipc.pdf