Public version

Questionnaire for Further Clarification

Exemption Request"*Leaded solder used to create stacked, area array electronics within ionizing radiation detectors used in CT and X-ray systems until 31 December 2019 and in spare parts for CT and X-ray systems placed on the EU market before 1 Jan 2020*"

Background

The Öko-Institut together with Fraunhofer IZM has been appointed within a framework contract for the evaluation of applications for granting, renewing or revoking an exemption to be included in or deleted from Annexes III and IV of the new RoHS Directive 2011/65/EU (RoHS 2) by the European Commission.

You have submitted the above mentioned request for exemption which has been subject to a first completeness and understandability check. As a result we have identified that there is some information missing and a few questions to clarify before we can proceed with the online stakeholder consultation on your request.

Questions

1) You explain that stacked area array detectors allow reducing the X-ray dose compared to silicon detectors. Please quantify the reduction effect.

This stacked area array design, as explained in section 2 of the application, has the advantage that the low level analogue circuit paths are shortened. This is the path between the photo diode, which acts as a very small current source, and the digitizing electronics. Shortening these signal paths reduces the capacitance present at the input of the digitizing electronics. This lower input capacitance and the state-of-the-art ASIC technology employed in the digitizing electronics minimizes the electronic noise in the data acquisition system. When the number of photons from an X-Ray beam are reduced to the level where the detected signal is as small as signal from electronic noise in the acquisition system, the images will have significantly degraded image quality. Therefore, it is desired to reduce the electronic noise in order to improve image quality in low dose examinations. Low dose examinations are typically seen when large patients block the X-Ray beam. In this application a reduction in e-noise improves the SNR by approximately Confidential which leads to approximately Confidential reduction in radiation dose to achieve equivalent image quality.

2) GE applies for this exemption, but GE is not the only medical equipment manufacturer offering digital detectors for diagnostic systems based on X-ray.
   a) Will other medical equipment manufacturers use this exemption as well?
   b) If not, how do other manufacturers construct and manufacture their digital detectors?
   c) If other manufacturers have designs that do not require the use of lead, please justify and explain why the GE-solution is required.

Detector architecture, interconnect implementation and associated manufacturing processes are generally regarded as proprietary information in the medical industry.

3) You have submitted the below figure illustrating the construction and the different parts of the detectors.

GE Confidential

Please indicate in the above figure where the different types of solders are used.

GE Confidential

4) In the below cross section of the detector, conductive epoxy is used between the scintillator unit and the pass-through-ceramic.
   a) Why can't conductive adhesives be used at other levels as well as to replace the solders, or at least the lead-containing solder?

There are many challenges to overcome to use conductive adhesives successfully at other "levels" of the microelectronic assembly. For the "level" with lead solder there are several reasons why conductive epoxy could not be used. The first is a large variation in the surface topology of the components. The components vary in thickness from part to part and lot to lot and they have a natural non-flatness (curvature) that adds to the mechanical gap variation between the components (as seen in the photo).

Proper conductive epoxy area array interconnects require uniform deposits of material that are nearly equally displaced (compressed) during assembly so as to not create a short (over compression) or an electrical open (under compression). Another challenge with high and low gaps is the resultant electrical resistivity variations from one interconnect to another which is attributed to the intrinsic high electrical volumetric resistivity in conductive epoxies. Large variations in electrical resistances make it very difficult to calibrate the device and could compromise the performance.

Additionally interconnects at the “levels” below the components are not suited for conductive epoxy because they include power and ground with significantly higher current requirements. Again the intrinsic high resistivity of conductive epoxies won’t work for the milli-amps of current required for these interconnects. The voltage drop would greatly compromise the module performance.

b) In an earlier exemption request, the applicant had claimed that conductive adhesives cannot be used in an x-ray environment, as they deteriorate quickly. Why is it possible to use it in this case in between the scintillator and the PTC?

This module architecture is such that conductive epoxy is shielded from ~98% of the incident x-ray energy because the scintillator material in front of it blocks it. Therefore, in this case, the conductive epoxy will not deteriorate from x-ray.

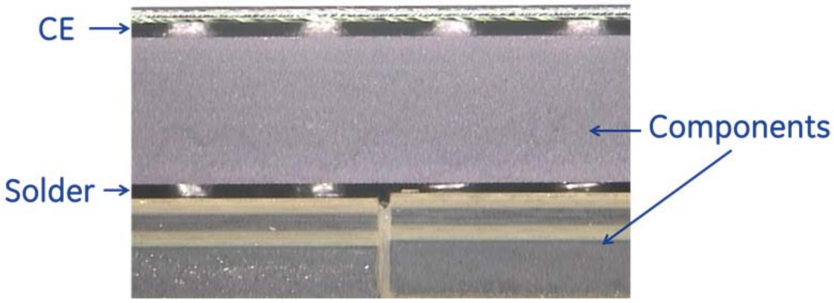


Figure 1: Section of the detector

5) In your application you mention research demonstrating that the use of SnPb solder across the large analogue area array is necessary. Reasons are its lower melting temp of 183°C, its eutectic behavior with a single melting point (i.e. no pasty range) and its superior ductility compared with most lead-free solders. Can you please make these results available?

Solder alloy properties will have a significant effect on the long term reliability of solder bonds between the components. The thermal expansion coefficients (TCE) of these two parts are different and there regular temperature changes that will cause differential expansion and contraction, resulting in the solder bonds being subjected to cyclic stresses. A lot of research has been carried out to predict the lifetime of lead-free solder bonds under cyclic stesses but at very high stresses that will occur with large-size devices such as large TCE difference between the components, failures can potentially occur due to damage to the solder pads on the surfaces of the components. This type of damage can be avoided by using ductile solders that distort so that the stress imposed on the component pads is reduced. All of the commonly used lead-free solders are less ductile than tin/lead and so where high stresses are imposed, the stress will not be relieved by deformation of the solder so that there is a higher strain loading on the solder pad/device bond. Solder hardness depends on its thermal history so it is not always straightforward to compare published hardness values. Published values for a selection of solders include[1]:

Solder alloy	**Vickers hardness** (not annealed)
SnPb	12.9
Sn3.5Ag	17.9
Sn3.8Ag0.7Cu	21.9
Sn3Ag3Zn	21.9
Sn3Ag3In	21.3

Hardness depends on thermal history and annealing reduces hardness however it is clear that most commonly used lead-free solders are harder and so less ductile than SnPb. SnAgZn and SnAgIn are included (although neither is a standard alloy) in the above table because these are lower melting point alloys but they are equally hard as SnAgCu and SnAg.

Lower melting point solders are available but these are not suitable for a variety of reasons. Some are susceptible to corrosion and some are too hard and brittle. The melting points of some alloys are too low and so could melt in service. Low melting point solders include (with SnPb for comparison):

Table of alloys with low melting point compared with SnPb.

[1] From http://www.boulder.nist.gov/div853/lead_free/props01.html except Sn3.9Ag0.7Cu which is from Elfnet

Alloy	**Melting point °C**
63Sn37Pb	183
52In48Sn	118 (too low m.pt.)
58Bi42Sn	138 (m.pt. too low and also hard and brittle)
Sn9Zn, Sn8Zn3Bi	189 – 199 (very susceptible to corrosion)
Sn20In2.8Ag	175 – 187 (wide pasty range and susceptible to corrrosion)

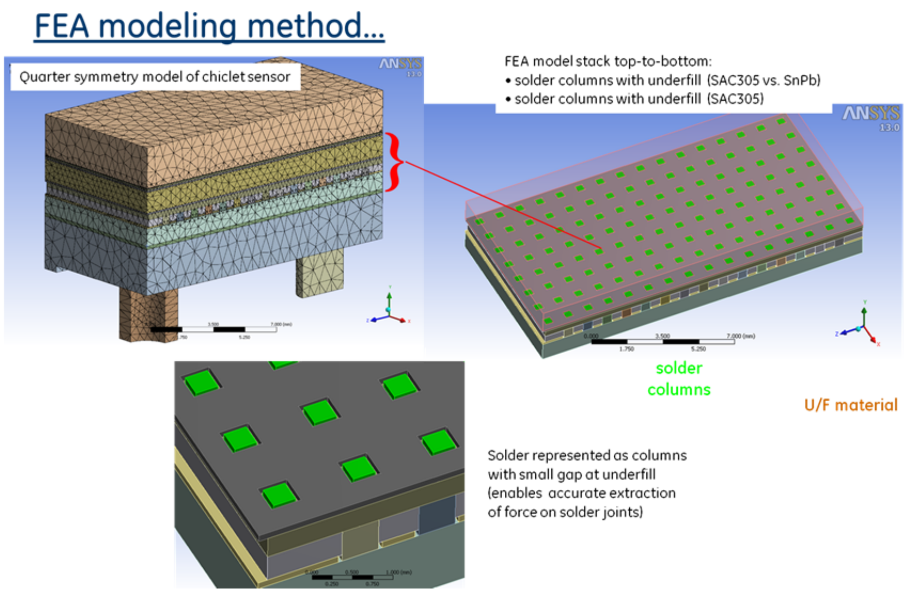
Temperature increases and decreases will repeatedly occur and the cyclic strain this causes can cause thermal fatigue cracking of the solder joints. Thermal fatigue failure occurs with both SnPb and lead-free solders but the time to failure depends on many variables including the size of the temperature 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 but where there are high strain levels, lead-free solders fail sooner than tin/lead. The solder bonds between the components could suffer from relatively high strain levels and so manufacturers will need to carry out lengthy testing with lead-free solders before these can be used in medical products that can be put onto the EU market. Medical devices must be approved by a Notified Body under the Medical Devices Directive and as it is not possible to accurately predict lifetimes of lead-free solder bonds, lengthy testing and trials of the new designs will be required to find solder alloy / design combinations that can be demonstrated to have suitable reliability. Prediction of lifetimes of lead-free solder bonds is possible because this alloy has been in use for many decades but there is still very little data for lead-free solders. It is therefore possible to ensure an adequte lifetime with tin/lead solder and so gain Medical Device Directive approval but this is much more time-consuming with alternative alloys.

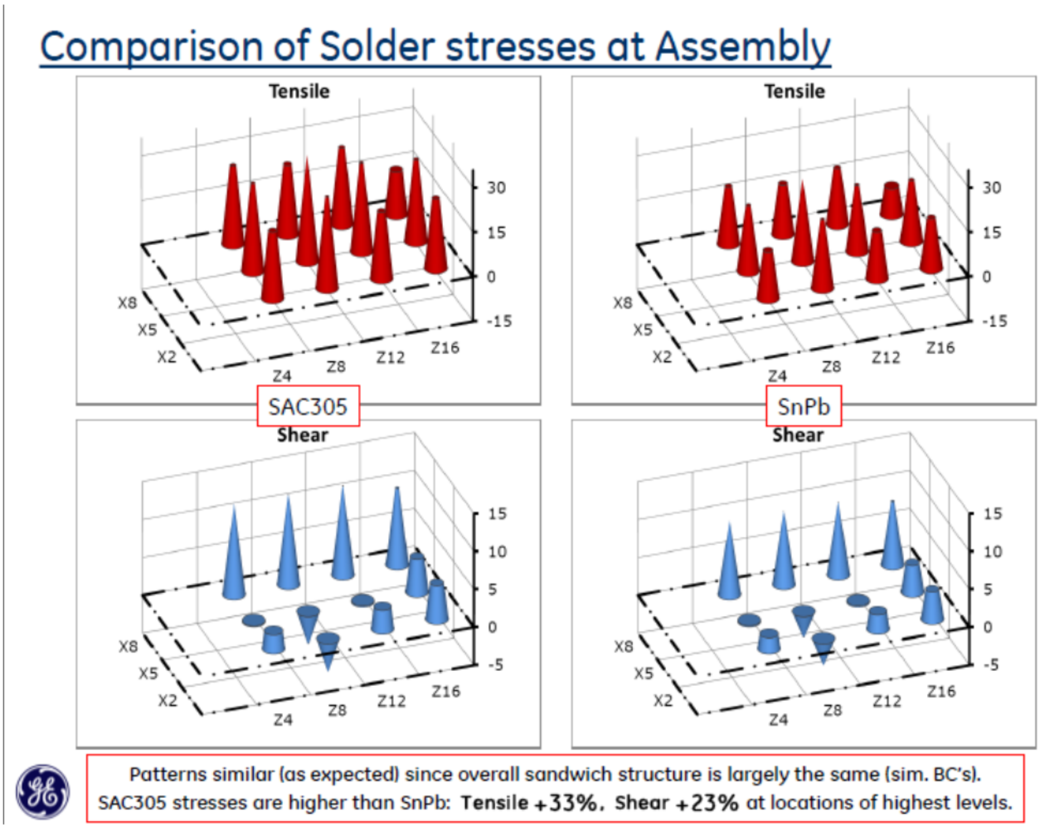
6) You state that utilizing the lower temperature of SnPb at the area interconnect has been found to greatly improve the manufacturability and reliability, especially in the outer region of the large analogue array where stresses due to the TCE mismatch are the greatest. Can you please provide evidence for these findings?

This module architecture includes a continuous structure with a large area array of interconnects at the interface. The two mating parts in this case have a CTE mismatch and the resulting peak stress will generally occur at the extremes which in this case are opposite corners. For this assembly the corner to corner distance is ~14mm. Since the distance and CTE mismatch can't easily be reduced the lower Pb/Sn solder reflow temperatures will significantly lessen (~20% lower temperature) the interconnect stresses between the components. The Pb/Sn solder also provides additional design and manufacturing robustness because of the higher ductility (ability to strain without fracture) with Pb/Sn solder. The SAC305 essentially produces a stiffer joint that pushes more of the strain-energy into the solder pad interface.

The failure with SAC305 and success with Pb/Sn solder was demonstrated through manufacturing DOE's on re-flow settings. The specific details of this DOE are not available because they are considered proprietary by the third party i.e. the micro-electronic manufacturer that completed this work for GEHC. However in this DOE SAC305 was compared against Pb/SN solder for greater than 20 parts for a range of temperatures, ramp, dwell and cool-down times. For all trials with SAC305 a large percentage of interconnects failed during the cool down of the reflow process regardless of the parameters selected. No solution "space" was found that would produce acceptable yield with SAC305 so it was abandoned in favor of Pb/Sn. The Pb/Sn solder on the other hand produced a high yield and demonstrated robustness to the manufacturing re-flow settings of time and temperature.

Additionally the peak stressed in the solder joints for SAC305 and Pb/Sn was compared with an FEA analysis. This work demonstrated that stresses from the re-flow process were significantly greater with SAC305 vs. Pb/Sn solder where the peak shear and tensile stress is 23% and 33% greater respectively. A snap shot of the analysis and results is included below.




Comparison of Solder stresses at Assembly
Tensile
Tensile
30
15
0
-15
X8
X5
X2
Z4
Z8
Z12
Z16
SAC305
SnPb
Shear
Shear
15
10
5
0
-5
Patterns similar (as expected) since overall sandwich structure is largely the same (sim. BC's).
SAC305 stresses are higher than SnPb: Tensile +33%, Shear +23% at locations of highest levels.

Conclusions / Recommendations

- Observations
  - stress in component solder joints always higher with SAC305 than SnPb
    - at Assembly: Tensile +33%, Shear +23%
    - at 40°C operating: Tensile +13%, Shear +23%
    - Assembly stresses are much higher than at operating temp:
      ~6× higher for Tensile stress, ~3 × higher for Shear stress
    - stress patterns are very similar
    - strength of SAC305 vs. SnPb is +17-21% (tensile) and +39% (shear)
- Conclusions
  - SnPb solder preferred over SAC305
    - SAC tensile stresses +33% higher but its strength is only 17-21% higher
    - highest stress due to assembly is expected to be a critical consideration in overall fatigue life (mean stress preload)
- Recommended next steps for Stress Analysis
  - quantify fatigue using these estimated mean & operating stresses
  - continue to refine FEA model (mesh, properties, etc.)

7) You present the below figure in your exemption request.

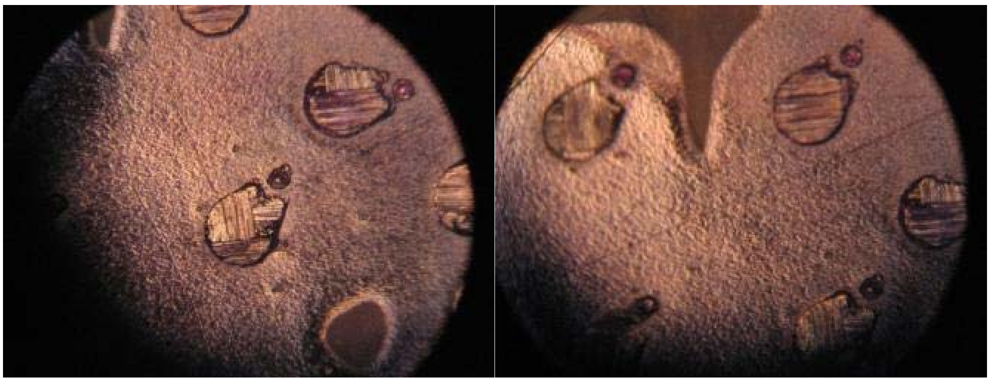


Figure 2: Dye & Pry analysis of SAC305 lead-free solder joints used in the analogue solder array interconnect

You state that dye penetration across tear shaped 2SP BGA pads indicates a lack of solder joint integrity. Please explain in more detail the terms “dye penetration” and how it indicates poor solder joint quality.

Identifying very small solder defects through a microscope is very difficult. To improve visual detectability of solder defects the dye and pry technique is used. Dye is applied to the edges of the solder interfaces. The dye penetrates into existing micro cracks or opens (voids) and is allowed to dry. Then the assembly is pulled (pried apart). The solder interfaces (joints) are inspected for the presence of the dye which reveals inter-facial connection defect areas (poor solder joint quality).

8) You submit the below cross section image.

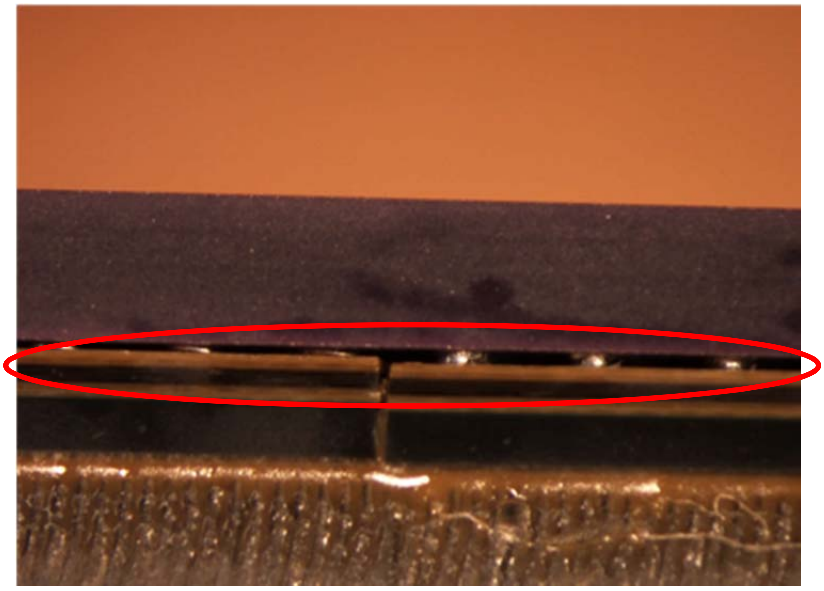


Figure 3:Cross section illustrating analogue interconnect array solder height variation challenge

Can you please submit a reference picture showing the situation with lead solder?

We do not have a cross-sectional photograph of the assembly with the SAC305 solder. Figure 5, as well as the photograph in Figure 1, show a cross-section through a detector assembled with tin/lead solder. This image clearly shows that the gap on the left side is smaller than the gap on the right side due to variation of part sizes and previous assembly process steps. This difference is acceptable as it has allowed for the tolerances of the dimensions of the various parts in the completed detector and has enabled a stress-free assembly to be made. The detector assembly is quite complex and so it is difficult to avoid these dimension differences. Tin/lead solder is an ideal material for this because of its ductility (it can deform to allow for dimension differences) and it has superior wetting properties to lead-free solders such as SAC305. Good wetting is important because it is essential that the solder flows across the surfaces of all of the pads of the components devices simultaneously to create good bonds. It is quite common when large area circuits are soldered that there are thermal gradients that result in solder melting in one area before others. If this were to cause solder to melt and wet the pads of one of the components only, when these bonds are formed, this can potentially cause movement as the part “floats” on the liquid solder and the gap can change. This movement could cause some of the unmelted solder paste or solder that has not yet wetted on the second component's solder pads so that the solder does not touch one or more pads. If movement causes the gap to increase too much, when the solder melts, some bonds between the components may not form and the detector will not function. The likelihood that this effect could occur will be proportional to the length of time that wetting occurs, being more likely with longer wetting times.

Research into solder wetting rates has been carried out that shows that SAC alloys wet much more slowly than SnPb and so wetting times are longer.

Solder alloy	Copper dissolution rate (wave soldering) at specified temperature*
SnPb	~1.38µm/sec at 255°C (72°C above m.pt.)
SnCu	3.28µm/sec at 275°C (~48°C above m.pt.)
SnAg	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.)

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

Comparative wetting time tests have been published by Asahi (a solder manufacturer)[2] in which a variety of alloys were compared by wave soldering a standard PCB using a soldering temperature of 245°C.

Alloy composition	Wetting time (seconds)
Tin / lead	0.6
Sn0.7Cu	1.0
Sn3.5Ag	1.4
Sn3.5Ag3.0Bi	1.7
Sn4Ag0.5Cu	1.9

Temperature also affects wetting times by a solder alloy. It is unrealistic to compare tests at 245°C because SnPb is typically soldered at ~235°C whereas lead-free alloys may be at

[2] http://www.asahisolder.com/Publication/Comparative.pdf

~255°C. However at these temperatures, Asahi's test results show that SnPb has the shortest wetting time.

SnPb at 235°C	~0.77 seconds
SnAgCu (SAC) at 255°C	~1.28 seconds

These results show that SAC wetting is slower than SnPb and so the risk that a bond will form to one component before the other is higher with lerad-free solders than with SnPb and therefore missing bonds would be more likely. Research using SAC305 and other lead-free solders to build these detectors is at an early stage and so the extent of this issue and how faults can be avoided is not yet known. It is planned to carry out this research in the timetable described in our exemption request.

IMPORTANT REMARK:

The pictures were taken from your GE proprietary submission document. We understand that you wish these photographs to be confidential. We will, of course, respect this and refrain from any publication. We would nevertheless kindly ask you whether it is not possible to make these illustrations publicly available. They greatly contribute to the understanding and transparency of your exemption request. We believe that it is important that exemption requests, even highly technical ones, are understandable for the responsible desk officers in Brussels and for the interested public. You could possibly alter those parts in the illustrations which you consider as sensitive, if this is possible, and allow the publication. In case you have any questions or concerns, please let us know.

Note: Please only use this "Public Version" of our responses.