Questionnaire 5 Exemption 14 of RoHS Annex IV

Lead in single crystal piezoelectric materials for ultrasonic transducers

Acronyms and Definitions

US	ultrasonic

1. Background

Bio Innovation Service, UNITAR and Fraunhofer IZM have been appointed[1] by the European Commission through for the evaluation of applications for the review of requests for new exemptions and the renewal of exemptions currently listed in Annexes III and IV of the RoHS Directive 2011/65/EU.

You submitted information to substantiate your request for the renewal of the above-mentioned exemption. This information was reviewed and as a result, we ask you to kindly answer the below questions for further clarification of your request until 8 July 2021 latest.

2. Questions

1) Are there product examples for use of cMUTs or pMUTs in endoscopic probes?

   We are only aware of limited research and development activities which have been undertaken, which have not been developed beyond an academic study. These would have to undergo multiple stages of development for them to be at a level of development where products could be marketed, if at all possible.

   For some applications, such as Intravascular Ultrasound, additional hardware items would also be required to be developed to allow the technology to be potentially implemented. This would take a significant length of time to be developed, and certainly beyond the maximum validity period potentially granted for the exemption as some development activities need to occur sequentially.

2) We understand that pMUTs are a technology based on piezoelectric ceramics as well.

It is important to note that due to the fundamental differences in pMUT and single crystal piezoelectric materials that there is an inherent difference in diagnostic capability that each solution offers, with single crystal piezoelectric materials offering a higher diagnostic imaging capability.

   a) Do pMUTs use lead in the piezoelectric ceramics?

      pMUTs can be fabricated from polycrystalline lead zirconium titanate (PZT) based ceramic materials and therefore would be covered by exemption 7c-I of Annex III of the RoHS Directive (so are not in scope of IV-14), however other polycrystalline compositions not including lead are also utilised. Aluminium nitride is an example of a lead-free alternative used in pMUT devices, however it is not used in applications medical imaging applcations

[1] It is implemented through the specific contract 070201/2020/832829/ENV.B.3 under the Framework contract ENV.B.3/FRA/2019/0017

where a high degree of performance is required, rather in applications such as air flow measurements.

b) What would be the volumes of lead used in transducers for applications like a catheter if produced with pMUTs compared to those with single crystal piezoelectric materials?

A rough estimate could be compared in the following manner: if a bulk PZT device used 100µm thick PZT ceramic single crystal, an equivalent pMUT device would use membranes about 1.5µm thick, so about 1.5% of the bulk ceramic volume. The pMUT "drums" are populated at a maximum of 60-70% of the surface area of each element, so the 1.5% estimate would be reduced to 60-70%. Therefore, as an estimate only about 1% of the ceramic volume is required for a pMUT device compared to a bulk ceramic device.

The above estimation only accounts for the comparative amount of lead in each product, without consideration for the potential difference in service life. For example, some catheters utilising non-single crystal solutions are designed to be single use, whereas other catheters which utilise single crystals can have an expected product life for 10 years. This would of course significantly impact the amount of lead utilised for each solution.

Although there are differences in the amount of lead used in pMUTs compared to those with single crystal piezoelectric materials, they cannot be an accurate point of comparison due to the different diagnostic capability each of them offers.

3) Due to the information you provided so far, we are aware that cMUTs or pMUTs cannot (yet) be considered as a technology to eliminate the use of lead for all uses of single crystal transducers, but for (some) specific applications within the fields you had indicated (catheters, etc.). You commented on the products[2] already placed on the market that proof of equivalency to single crystal transducers cannot be overstated, that months or even years will be required for a full analysis, that pMUTs used in catheters are inferior to cMUTs, etc.

a) We assume that each of these products passed a qualification and certification according to the legal requirements. We further assume that medical products which are insufficient and inadequate for their foreseen uses would endanger patients' lives and thus hopefully would not be able to acquire the certificates necessary for placing them on the market.

Could you please comment your concerns as to the above products in the light of our assumptions?

Differing levels of diagnostic capability and performance are required depending on the medical procedures being undertaken using the specific type of ultrasound imaging equipment. For example initial pregnancy assessments can be undertaken with cMUT-based products as their clinical imaging is sufficient for this use. However, when a higher diagnostic capability is required for procedures, such as the following examples, cMUT based products would not provide sufficient resolution and penetration depth:

- 1st and 2nd trimester fetal imaging and assessment,
- Intravascular Ultrasound in peripheral vessels.

  For sectors such as intravascular diagnostics, the size of the transducer is especially important, with a trend between a smaller size of transducer resulting in a lower diagnostic capability. cMUT based products would not be able to provide sufficient

[2] https://www.butterflynetwork.com/; https://www.hitachi-medical-systems.co.uk/products/ultrasound/transducers/4g-cmut.html; https://www.exo.inc/; https://verasonics.com/ge-transducers-for-vantage-systems/; https://verasonics.com/cmut-hf-transducers/

resolution and penetration depth in many of these procedures due to the limitations on size.

In addition to size constraints, developing and establishing associated manufacturing processes for an acoustic window that performs optimally, while functioning as a biocompatible protective mechanical barrier and fluid-tight seal would require a significant amount of design iteration and testing.

- Deeper diagnostic applications, such as deep abdominal liver quantification and associated needle guidance and biopsy procedures, due to cMUT's having insufficient power output and therefore penetration capability.

As stated in the IV-14 exemption request, single crystal transducers provide the best possible performance and so is used when this capability is needed. The certification necessary for placing each type of medical device on the market does not differentiate between performance levels offered by different product types but on an assessment of whether the equipment is safe for its intended uses and is capable of safely carrying out the procedures for which they are specified.

It is worthwhile keeping in mind that a large number of the ultrasonic transducers currently on the market are designed and required to provide multiple diagnostic capabilities, rather than being suited to a single procedure type. cMUT transducers lack the capability to provide some of the most commonly used imaging modes on modern ultrasound systems, because the response from cMUT to these ultrasound systems transmit pulses is much worse than PZT/single crystal transducers. Therefore, any trade off of technical capability a cMUT based product would result in, would have to be considered for all diagnostic capability the ultrasonic transducer offered.

b) You claim that proof of equivalency with single crystal based transducers is required. In a previous questionnaire you state that transducers for the application fields which these cMUT and pMUT based products cover are difficult to manufacture, and that cMUTs are used where they can play their strengths while their weaknesses are acceptable.
We conclude from this that equivalency of performance of these products with single crystal transducers is not the overall objective in these cases but that these applications are cases where cMUTs and possibly pMUTs are the best solution taking into account all aspects. Would you agree to these conclusions?

Yes, as cMUTs and pMUTs play a role in providing sufficient technical function in specialised applications.

c) Are products comparable with those based on cMUT/pMUT still placed on the market with transducers manufactured with single crystal materials? If so, could you please give us some examples and explain why they could or could not be replaced by cMUT-based transducers?

COCIR is not aware of any products utilising single crystal materials which could be replaced with cMUT/pMUT, as cMUT technology does not match the high efficiency out pressure of lead based single crystal transducer. As such there are no known cMUT/pMUT transducers that provide image quality adequate for the requirements of high-quality ultrasound diagnostics.

The advantages of cMUT/pMUT, such as the ease of fabrication, would offer manufacturers significant cost savings due to the ease of which higher volume production could be undertaken. This financial incentive would automatically ensure that for applications where this is acceptable, the transition takes place.

Please note that answers to these questions may be published as part of the evaluation of this request. If your answers contain confidential information, please provide a version that can be made public along with a confidential version, in which proprietary information is clearly marked.

It would be helpful if you could kindly provide the information in formats that allow copying text, figures and tables to be included into the review report.