1st Questionnaire Exemption Request No. 2013-4

Exemption for Mercury used in high speed rotating electrical connectors (slip ring) with electrical conduction paths that have sealed liquid mercury, molecularly bonded to the contacts

Abbreviations and Definitions

ACIST – Acist Medical Systems

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.[1]

ACIST has submitted the above mentioned request for exemption which has been subject to a first evaluation. The information you have referred has been reviewed and as a result we have identified that there is some information missing and a few questions to clarify concerning your request.

Questions

1. The request has been made for an exemption for "Electro-mechanical component containing mercury for specialized low noise, low/high voltage interconnect used in medical device applications for intravascular ultrasound imaging"

   a) Please name some examples of medical applications for intravascular ultrasound imaging in which this component is in use or an exhaustive list of all applications if possible.

[1] Contract is implemented through Framework Contract No. ENV.C.2/FRA/2011/0020 led by Eunomia

To ACIST Medical Systems' knowledge, the mercury slip ring component is not currently used with any other intravascular ultrasound imaging system. All currently marketed IVUS systems utilize rotary inductive couplers (rotating transformers) which have, compared to mercury wetted slip rings, the following limitations:

- Reduced bandwidth: Broadband transformers utilize capacitive coupling between the input and output windings to extend the upper frequency response. Rotary transformers cannot utilize this technique because of the required air gap between the rotating and non-rotating primary and secondary windings.
- Reduced peak power handling due to magnetic core saturation:
  - Amidon ferrite material type 43 is useful in wideband applications across the 1-50 MHz band and has an initial relative permeability of 850. This material is in use in existing IVUS system rotary inductive couplers but is not usable for the ACIST IVUS system because of the limited frequency response.
  - Amidon ferrite material type 61 is useful in wideband applications across the 10-200 MHz band but has an initial relative permeability of only 125. This material has the appropriate frequency response for the ACIST HD-IVUS system, but is not suitable because of the relatively low initial permeability which is expected to saturate during the high peak power (~180 watts) transmit pulse.
- Reduced high frequency performance due to available ferrite materials (see above)
- Higher insertion losses
  - Existing IVUS rotary inductive couplers have -3dB of insertion loss at 47MHz with increasing loss above this cut off frequency.
  - Insertion loss is more critical when imaging at 60MHz because of increased tissue attenuation at the higher operating frequency. Assuming a 1dB/cm/MHz slope, the attenuation across an 8mm field of view is 42dB at 60MHz, an increase of 14dB, compared to the 28dB of tissue attenuation at 40MHz.

The above limitations are extremely relevant to the ACIST HD-IVUS system due to system operation at both the 40MHz and the 60MHz bands, necessary to provide higher resolution IVUS imaging. In order to pass both frequency spectrums, the minimum bandwidth requirement for the system's rotating coupler is 30-74 MHz, assuming a 60% fractional bandwidth. The unique design advantages provided by the mercury wetted slip ring of high bandwidth (DC-200MHz), high power handing ability (3.0A), low noise, and low insertion loss (<-1dB) are critical to the ACIST imaging system design.

While the mercury wetted slip ring is not used in other IVUS systems, it is being used in hundreds of different industrial and consumer applications such as automotive, defence, test equipment, semiconductor manufacturing, textile production, and other markets.

b) Please detail if the devices mentioned fall under the general category 8 scope (as defined in Article 43(21) of Directive 2011/65/EU) or if they are fall under the scope of sub-category 8 in vitro diagnostic medical devices (as defined in Article 43(22) of Directive 2011/65/EU).

This device falls under the general category 8 scope as defined in Directive 2011/65/EU. It is a medical device as defined in Article 3(21) of Directive 2011/65/EU and Article 1(2a) of Directive 93/42/EEC.

c) Are the mercury based slip-rings in use solely in intravascular ultrasound imaging or in other applications as well (i.e., other ultrasound devices falling under Cat. 8 or falling in other RoHS 2 Annex 1 categories)?

Because of the unique requirements presented by high frequency intravascular ultrasound imaging, it is unlikely that mercury based slip-rings are utilized in other ultrasound devices. ACIST Medical Systems is not presently aware of the use of this component in other applications related to category 8 or other RoHS 2 Annex 1.

d) Are such products already marketed on the EU market? How many components are placed on the EU market per year (or are estimated to be placed on the market in the future) – please estimate and quantify the amount of mercury placed on the EU market through this application on an annual basis.

The ACIST HD IVUS system is not currently marketed in Europe. The company estimates that less than an average of 75 components would be placed on the EU market through this application per year for the next 5 years, with each component containing 450 mg of mercury. Therefore, on an annual basis, the total amount of mercury placed on the EU market will not exceed 34 grams. All of this mercury is contained within the system, fully retrievable, and not emitted from the system.

e) Do further application areas fall under the scope of applications to which the substance restrictions of the RoHS 2 Directive apply, i.e., besides intravascular ultrasound imaging applications?

ACIST Medical Systems is not aware of any further application areas to which the substance restriction of the RoHS 2 Directive apply.

2. Please explain in more detail the general operation of intravascular ultrasound imaging and how the mercury containing slip ring functions within such devices;

a) Does the mercury containing slip-ring prevent friction that would otherwise be caused by the rotation of the transducer?

The primary function of this electro-mechanical component is to provide transmission of radio-frequency energy through a mechanically rotating shaft to a non-rotating connector within the system. The slip ring is primarily designed to maintain signal integrity across the rotating boundary. The use of mercury within the slip ring increases the components current handling ability while reducing the contact noise that is normally present on non-mercury wetted sip rings.

Non-mercury wetted slip rings rely on precious metal on metal fingers on precious metal rotor contacts. These solid to solid contacts have small surface area contact area and metal migration occurs under the high peak transmit power of the HD-IVUS system. The metal migration quickly destroys the component. Furthermore, non-mercury wetted slip rings generate in-band radio frequency noise as the precious metal fingers vibrate against the drum during rotation.

Prevention of friction is therefore an important attribute of the mercury slip ring, because friction leads to wear and electrical noise which degrades the signal transmission properties of the component. The conductive liquid Mercury within the slip ring provides for lower friction than any solid-to-solid contact.

b) What are the unique qualities that the use of mercury enables and why couldn't these be fulfilled with other substances?

Compared to any solid conductive material, mercury allows for transmission of electrical signals between moving components with high power and low noise. The ACIST HD-IVUS system is a high gain (+60dB) wide band (60% fractional bandwidth) system that is extremely susceptible to noise sources. The use of mercury in the slip rings virtually eliminates the RF noise generated by typical metal on metal slip rings as the metal contacts vibrate under rotation. The use of mercury in the slip ring also increases the contact area of the liquid metal on solid metal contacts thereby supporting the high peak power requirements of the ACIST HD-IVUS system.

c) Is the slip-ring replaced in the device from time to time or is the component life time (stated as 828 days on average) compatible with device lifetime?

The component lifetime is compatible with the device lifetime. The slip ring is provided in a completely sealed housing and requires no maintenance. This component is designed to last well beyond the expected lifetime of the overall system and is therefore not designed to be replaced.

The stated average lifetime of 828 days reflects continuous operation. In the ACIST system, the component only rotates when the intravascular catheter is attached and the system is actively imaging. Therefore, the relevant lifetime parameter is the rated number of revolutions. Requirements for the component are based upon procedure time and number of procedures:

Table 1
Component life requirements

Procedures per week	5
Years of use	7
Average procedure time (hours)	0.3
Hours of use over life	546
Minutes of use over life	32760
Average rpm (system operates at 1800 RPM for ¾ of operation, and 3600 RPM for ¼ of operation)	2175
Revolutions over life	71253000
Millions of revolutions over life	71.253

Note that, in the original application the average lifetime was incorrectly stated to be "over 2 million cycles before failure". The correct average lifetime, based on information provided by the manufacturer, is over 2 **billion** cycles (828 days of operation = 1,192,320 minutes of operation, which is 2.3 billion revolutions at the average revolution rate of 1920 RPM utilized by the manufacturer for cycle testing). Therefore, the demonstrated average component lifetime is 32x the anticipated required lifetime, and so the likelihood of component failure is very small.

d) Technical diagrams demonstrating the operation of the slip ring and not just its alignment within the system may be of assistance.

Detailed technical diagrams of the slip ring operation are proprietary to the manufacturer and not able to be provided.

3. You state that the mercury within the component is enclosed and substance is accumulated at the end of life within the device (or component) body. Please state what risks of mercury emissions apply to the component during the various life cycle phases (especially end-of-life) and how these risks are avoided or reduced.

There is negligible risk of mercury emissions that apply to the component at end of life. End of life for the component is defined as either when the component or the sub-system which contains the component fails, or when the system is taken out of use by the customer. The risk of any emissions is mitigated through ACIST Medical System's policy for disposal of the component which conforms to the WEEE Directive 2012/19/EU. ACIST's policy is to retrieve the entire sub-component from the customer and recycle and/or properly dispose of the system per applicable laws and regulations. The Mercury containing component will be recycled through the original manufacturer (Mercotac), who is committed to a long term recycling program.

Since the component life exceeds the anticipated usage of the component throughout the system life, the most likely scenario is that the system will be retrieved by ACIST with a fully functional slip ring component. Even in the event of a component failure, the mercury within the component is enclosed, thereby providing a high degree of assurance that no mercury emission will occur.

4. Please provide information to allow a technical comparison between slip rings containing mercury, for which this request for exemption has been made, and mercury free slip rings.
   a) In your response please refer to qualities that are enhanced or enabled through the use of mercury, and how the operation of the various components compares – please express such information on a quantitative basis.

Non-mercury slip rings do not present a viable alternative to the stated mercury slip rings for the reasons stated in 2.b. above. Electrical noise introduced into the system from non-mercury slip rings adversely impacts the systems signal to noise ratio and results in visible electrical noise transients in the IVUS images. Furthermore, non-mercury wetted slip rings are not rated to the high peak power of the ACIST HD-IVUS system and fail within minutes.

   b) Please refer in your response to the various alternatives that exist on the market for mercury containing slip rings, and why their area of application is not compatible with the requirements or operation conditions typical of intravascular ultrasound imaging devices.

As previously discussed, Mercury wetted slip rings have very low contact impedance, relatively high power handling capabilities, low noise and broad bandwidth. Non-mercury wetted slip rings typically rely on rotating precious metals fingers in direct contact with a non-rotating precious metal drum. The contact is maintained by constant frictional force applied by the fingers as they “press” against the drum.

There are inherent problems with this design, some of which are identified below:

- As the precious metal wears the contact impedance and insertion loss increases.
- The relatively low contact surface area of the wires on the drum limits the power handling ability of the connection.

- The mechanical nature of the connection generates electrical “noise” as the contact impedance changes slightly as the fingers move across the drum.

Those experienced in the industry are aware that non-mercury slip rings show rapid contact failure when exposed to the high currents necessary for invasive IVUS imaging. Non-mercury slip rings cannot simultaneously handle high currents (which require high metal-to-metal contact area) without introducing unacceptable electrical noise. Given that the ACIST HD-IVUS system operates at substantially higher average power then existing IVUS systems, non-mercury wetted mechanical slip rings suitable for use have not been identified and likely do not exist.

c) What would be the consequence of substituting mercury containing slip-rings with possible mercury-free components in terms of costs of device operation, possible risks to patients?

To the best of ACIST knowledge, non-mercury wetted slip rings that meet the power and low noise requirements of the ACIST HD-IVUS system do not exist. A custom design effort may be able to address the power requirement but it is likely that the low noise requirement cannot be met using a solid metal on metal rotating contact.

The key clinical advantages that are enabled by the use of the mercury wetted slip rings within the ACIST HD-IVUS system are:

- The wide band width of the mercury wetted slip rings enables the ACIST HD-IVUS system to operate at both 40 MHz (which is used by current IVUS systems) and 60MHz on the same catheter.
- The 3600 rpm rotational speed of the mercury wetted slip rings enables high rotational speeds (60 frames per second), which enables high speed pullback (see response to question 5b below), which reduces the risk to the patient of catheter induced ischemia and extends procedure times.
- The low noise and low insertion loss of the mercury wetted slip rings enables 60MHz imaging.
- The high power handling capabilities of the mercury wetted slip ring enables 8X oversampling and averaging to improve the overall system’s signal to noise ratio by 9dB.

Operation at higher imaging frequency allows higher spatial resolution with good signal-to-noise ratio. Better resolution images support better assessments of the vessel structure, thus potentially improving the treatment of the patient. Clinically, an incorrect assessment of the vessel structure could result in incorrect placement of the stent, vessel dissection, perforation or stent stenosis. The potential resulting harm of these hazards is surgery, impairment of activity or death.

5. You state that the mercury containing slip-ring is used to maintain a connection as the transducer is rotated at varying rotational speeds (0 – 3600 RPM).
   a) Why is the rotation of the transducer required?

The ACIST HD-IVUS system is a single element mechanically rotating IVUS system (console and catheter), similar in architecture to the Boston Scientific iLab / Atlantis catheter and Volcano s5 and s5i / Revolution catheter systems. An IVUS catheter is inserted into a patient's coronary artery via the circulatory system during percutaneous coronary interventions. From within the coronary artery, the transducer within the catheter must be rotated 360 degrees in order to scan around the entire artery.

Alternatively, Volcano Corporation markets a synthetic aperture array catheter that does not require rotation of the transducer element. The synthetic aperture transducer contains 64 elements that are electronically scanned through 360 degrees to cover the artery. The disadvantage of this approach is the relatively high cost of the synthetic aperture transducer and the low (20 MHz) frequency of operation of the device. The frequency of operation of synthetic aperture array catheters is limited to 20MHz because of the cross talk between the 64 elements within the device. Therefore, synthetic aperture (non-rotating) devices are possible, but the resolution of these devices compared to mechanically scanning IVUS catheter is limited.

The advantage of the mechanically rotating IVUS catheter systems is the high operating frequency (40 and 60 MHz) of the transducer within the catheter. The frequency of the transducer establishes the resolution of the entire system. Therefore, a higher frequency transducer produces higher resolution images.

   b) Please explain what parameters determine the transducer rotation speed – area of application, phase of operation, device type etc.

In addition to imaging the interior of the artery at a single point, it is desirable to scan the entire length of the artery. This is accomplished by using a motorized system that mechanically pulls back the transducer inside the catheter at a controlled speed. As the speed of the pullback is increased, the rotational speed is also increased to maintain acceptable spacing between the acquired image frames in order to adequately "cover" the artery under interrogation.

It is important to note that higher pull back speeds reduce catheter in-situ dwell times, which reduces the risk of catheter induced ischemia. Catheter induced ischemia occurs when the presence of the catheter within a diseased artery reduces the blood flow sufficiently to the heart tissues that the patient experiences ischemia which is generally associated with chest pain.

Therefore, the HD-IVUS system has been designed to acquire images at a high frame rate (60 frames per second), which requires a rotation speed of 3600 RPM. This frame rate allows pullback rates of up to 10 mm/sec. At lower pullback rates, a lower frame rate of 30 frames per second is adequate, corresponding to 1800 RPM.

c) Do all applications operate in the full range of rotation speeds or can devices be categorised?

The rotation speed required in the HD-IVUS product is either 1800 RPM or 3600 RPM, as described above.

6. The information submitted states that the use of mercury enables a virtually noise free connection.

a) How is the degree of noise measured and what noise degree comprises a threshold above which the ultrasound produced images are impaired?

The RF signal received from the transducer ranges from a maximum of 7 millivolts peak to peak (-40dBm) to about 0.20 millivolts peak to peak (-90dBm). The high end of this range (7 mV) is the bright reflection represented by metal such as stents deployed to provide support struts to prop open a diseased section of a blood vessel. The low end of this range (0.20 mV) represents the ultrasound reflection from soft tissue through the blood within vessel, and therefore, represents the typical reading for an intravascular ultrasound imaging system.

Impairment of ultrasound images begins when the noise source exceeds the noise floor of the system. The noise floor of the system, prior to signal averaging, is 0.20 millivolts peak to peak or about -90dBm. The noise from the mercury wetted slip ring contributes to the overall noise source of the system and is therefore less than 0.20 millivolts peak to peak. Noise from a non-mercury wetted slip ring is reasonably anticipated to be in the range of tens to hundreds of millivolts.

b) Does the degree of noise depend on the rotation speed?

In mercury slip rings, the degree of noise does not strongly depend on the rotation speed. Mercotac's 205-H slip ring typically contributes noise at a consistently low level of noise at both 1800 and 3600 rpm HD-IVUS System's operating modes.

c) If so, please provide information to specify what degree of noise is tied with what rotation speed?

The noise performance required at higher rotation speed is higher since less signal averaging can be performed to produce the same spatial resolution. The degree of noise resulting from the mercury slip ring is acceptable at both modes of HD-IVUS operation. In non-mercury slip rings, noise performance is presumably more degraded at high rotation speeds because friction effects leading to noise are worsened at high rotation speeds.

d) How much does the noise level depend on the concentricity of the transducer?

Concentricity of the mercury slip ring assembly or transducer will not have a significant impact on the noise level. In non-mercury slip rings lack of concentricity will have a major impact because variable friction and electrical resistance will introduce electrical noise.

e) Why wouldn't it be possible to eliminate the need for the mercury based slip-ring through a more precise fabrication of the transducer connector?

Based on conversations with the slip ring manufacturer, higher precision fabrication of the slip ring assembly would not allow elimination of the mercury. Because of the power, lifetime and speed requirements of the application, any technical solution relying on solid metal-to-metal contact, even if manufactured more precisely, would not meet the performance required of the ACIST HD-IVUS system.

f) Could alternator brushes be considered a possible alternative, assuming the transducer connector is fabricated with more precision?

Alternator brushes are not a viable alternative for the stated system requirements for high power and low noise at high rotational operating speed application like HD-IVUS imaging system. This technology does not meet the high power, low noise and long life requirements.

7. It is assumed that conductivity also plays a role in the functionality of the mercury based slip-ring. Concerning the conductivity performance please state the:
   a) Maximum resistance; or
   b) The minimum conductance; or
   c) The intensity of the current;

   And how the mercury slip-ring performs in respect of these aspects in comparison with possible alternatives.

The specification for Mercotac 205-H is as follows:

- Contact resistance: < 1 milliohm
- Voltage AC/DC: 0 – 250 V
- Amp rating at 240VAC: 4 Amps
- Maximum Frequency: 200 MHz

There is no viable alternative. Rotary capacitive couplers are not practical because of the high capacitive coupling required. Rotary inductive couplers are not practical, because they do not provide adequate bandwidth, power handling capability, low insertion loss and frequency response. Non-mercury wetted slip rings are not practical because they cannot handle the high peak current and they generate electrical noise that impacts the performance of the system.

8. Please provide a detailed roadmap towards RoHS compliance for the mercury containing slip-rings (i.e., for the possible substitution of mercury in these devices, or for their elimination through the use of other technologies) including timelines for the various tasks and results to be accomplished.

Based on current technology, substitution of any other material for Mercury within the slip ring is not possible because Mercury is the only conductive metal which is a liquid at room temperature. Use of any type of solid contact increases electrical resistance, decreases life through temperature build up and wear, introduces electrical noise through variation in resistance via mechanical non-uniformities, decreased bandwidth though introduction of resistance, and limits power handling through the need to reduce surface area of the contact. ACIST Medical Systems will continue to monitor and evaluate any advancements of technology as it becomes available. As detailed within this response, there is no substitution at this time for the mercury slip ring because there is no equivalent technology available.

9. Please provide a proposal for the wording formulation of a possible exemption.

Mercury components used in high operating frequency (>50MHz) Intravascular Ultrasound Imaging Systems.