Assistance to the Commission on Technological Socio-Economic and Cost-Benefit Assessment Related to Exemptions from the Substance Restrictions in Electrical and Electronic Equipment (RoHS Directive)

Final Report – Pack 4

Report for the European Commission DG Environment under Framework Contract No ENV.C.2/FRA/2011/0020

Authors:

Carl-Otto Gensch, Oeko-Institut

Yifaat Baron, Oeko-Institut

Markus Blepp, Oeko-Institut

Otmar Deubzer, Fraunhofer Institut IZM

22/04/2014

9.0 Exemption Request No. 2013-4 “Mercury components used in high operating frequency (>50MHz) Intravascular Ultrasound Imaging Systems”

Abbreviations

ACIST	ACIST Medical Systems - Manufacturer of advanced contrast injection technologies for the cardiac cath-lab, hybrid operating room and radiology suite
ERC	Electric Rotating Connector
Hg	Mercury
IVUS	Intravascular ultrasound imaging system

9.1 Description of Requested Exemption

Sections 9.1 through 9.3 are heavily based on information provided by the applicant and other stakeholders and do not necessarily reflect the view of the consultants.

ACIST[138] has applied for an exemption for:

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

The applicant has explained that mercury is applied in an electro-mechanical component – electric rotating connectors (ERC) - used in medical device applications for intravascular ultrasound imaging[139]. In such systems, an intravascular ultrasound imaging system (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. [140]

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

[138] ACIST (2013a), Original Request for Exemption from the RoHS 2 Directive, submitted by the applicant 26.04.13, available under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_IX/Request_2013-4/ACIST_Medical_Systems_Exemption_Application__Directive_2011-65-EU__4-26-13.pdf

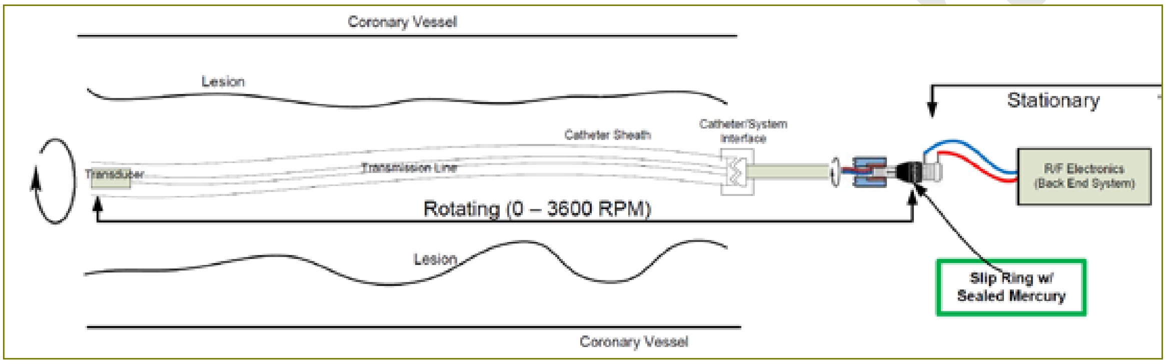
[139] Op. cit. ACIST (2013a)

[140] ACIST (2013b), Answers to First Clarification Questions , submitted by the applicant 31.07.2013, available under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_IX/Request_2013-4/20130731_ACIST_Medical_Systems_Response.pdf

in the slip rings[141] (i.e., the ERC) 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. [142]

The use of the mercury for the conduction path provides a virtually noise free signal between a mechanically rotating ultrasound element (transducer) and stationary electronics. This connection transmits both a high voltage RF signal at specific frequencies and a low voltage RF reflected ultrasound signal at specific frequencies. This connection is maintained as the transducer is rotated at varying rotational speeds (0 – 3600 RPM). See Figure 9-1 below for illustration.[143]

Figure 9-1: System block diagram, indicating critical function performed by mercury based electric rotating connector



Source: ACIST (2013a)

ACIST further, state that devices using the mercury based slip rings, prevent significant electrical noise which would impact the image quality, possibly having consequences for patients. It is elaborated that they operate with higher pull back speeds, reducing catheter in-situ dwell times, which in turn reduce the risk of catheter induced ischemia.[144]

In a later communication, ACIST[145] explains that at present the ACIST IVUS HDi/Kodama is the only IVUS system that can operate at both the 40 and the 60 MHz frequencies. ACIST provides a comparison of system properties with IVUS models of other manufacturers (see Table 9-1 below). The higher frequency operation is

---

[141] ACIST (2013b) stated that to their knowledge, “the mercury slip ring component is not currently used with any other intravascular ultrasound imaging system (IVUS). All currently marketed IVUS systems utilize rotary inductive couplers (rotating transformers)”

[142] Op. cit. ACIST (2013b)

[143] Op. cit. ACIST (2013a)

[144] Op. cit. ACIST (2013b)

[145] ACIST (2014), ACIST Response to 2nd Round of Clarification Questions, submitted per email on 01.02.2014.

understood to allow obtaining higher resolution imaging beneficial for patients. Furthermore, system pullback speeds for the ACIST IVUS HDi, specified at 0.5, 1.0, 2.5, 5.0 or 10.0 mm/s. are explained to allow a range of dwell times between 130 to 16 seconds whereas other IVUS devices will have dwell times in the range of 130-70 seconds, depending on the applied pullback speed. ACIST reference two angioplasty studies indicating that ischemia generally occurs in patients undergoing balloon inflations in 30 to 60 seconds. This is to show that the possible reduced dwell times can assist in reducing the risk of catheter induced ischemia.

Table 9-1: Comparison of IVUS Manufacturers, Source: ACIST (2014)

Feature	ACIST HDi/Kodama	ACIST HDi/Kodama	BSC iLab /SR Pro	Volcano s5 / Revolution	SJM Ilumien / Dragonfly
Frequency / Wavelength	60 MHz	40 MHz	40 MHz	45 MHz	1300 nm
Energy Source	Ultrasound	Ultrasound	Ultrasound	Ultrasound	NIR Light
Axial Resolution	0.04 mm	0.06 mm	0.09 mm	0.100 mm	0.015 mm
Lateral Resolution	0.09 mm	0.14 mm	0.48 mm	0.620 mm	0.04 mm
Soft Tissue Penetration	> 2.5 mm	> 3.0 mm	> 3.0 mm	> 3.0 mm	> 0.8 mm *
Blood Penetration	> 3.4 mm	> 4.0 mm	> 4.0 mm	> 4.0 mm	< 1.2 mm
Frame Rate(s)	30 or 60 fps	30 or 60 fps	30 fps	30 fps	100 fps
Pullback Speed(s)	0.5, 1.0, 2.5, 5.0 or 10.0 mm/s	0.5, 1.0, 2.5, 5.0 or 10.0 mm/s	0.5 & 1.0 mm/s	0.5 & 1.0 mm/s	10 or 20 mm/s
Calibrated Frame Spacing(s) Available	0.02, 0.03, 0.04, 0.09, or 0.017 mm	0.02, 0.03, 0.04, 0.09, or 0.017 mm	0.02 or 0.03 mm	0.02 or 0.03 mm	0.1 or 0.2 mm
Calibrated Pullback Length	120 mm	120 mm	100 mm	100 mm	75 mm

· Soft Tissue Penetration with contrast injection (blood clearing)

9.2 Applicant's Justification for Exemption

The applicant refers to www.mercotac.com, for further detail as to the properties of these components. In short the following points are explained:

The Mercotac[146] ERC uses *"a unique design principle unlike the sliding, brush contact of a slip ring. The connection is made through a pool of liquid metal molecularly bonded to the contact, which provides a low-resistance, stable connection. During rotation, the fluid maintains the electrical connection between the contacts without any wear."* The Mercotac connector is said to have the following benefits:

- Unlike a slip ring, Mercotac connectors produce near zero electrical noise due to their unique design. The connectors do not degrade the signal over time;
- Resistance through the rotating contact is less than one milliohm;
- The connectors are maintenance free;
- The connectors are more compact and cost far less than slip rings of equal capacity; and
- Both current power and instrumentation signals can be sent through a single, compact connector.

ACIST[147] states that the manufacturer of the slip ring has completed reliability testing and recorded an average life of 828 days and over 2 million cycles before failure. For safety the device is designed to accumulate the mercury at the end of life in a containment area inside the body. In addition there are redundant sealing mechanisms to prevent external mercury leakage.

According to the applicant[148], 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. 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.

ACIST[149] details "the key clinical advantages that are enabled by the use of the mercury wetted slip rings within the ACIST HD-IVUS system are:

[146] See www.mercotac.com; last accessed 14.01.14

[147] Op. cit. ACIST (2013a)

[148] Op. cit. ACIST (2013b)

[149] Op. cit. ACIST (2013b)

- *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, which reduces the risk to the patient of catheter induced ischemia and extends[150] 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…* [and preventing] *incorrect placement of the stent, vessel dissection, perforation or stent stenosis…*
- *In addition… 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* [respectively]*…*
- *… 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…*

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…

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

[150] In light of the duration quantifications later provided, the consultant assumes this mean that an extended procedure (imaged length) can be performed at a duration, in which similar devices would only be able to scan a shorter section of the artery.

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."

ACIST[151] explains that 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.

According to the applicant[152], 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.

9.2.1 Possible Substitute Alternatives

The applicant[153] claims that *"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, decreases bandwidth through introduction of resistance and limits power handling through the need to reduce surface area of the contact..."*

9.2.2 Possible Design Alternatives

In the information submitted by ACIST, a few design alternatives are mentioned, that could be relevant for eliminating the need for mercury in such applications:

- The use of silver graphite brush slip-rings
- The use of rotary inductive couplers (rotating transformers), which is practiced in other IVUS.

In short, the applicant[154] states that *"There is no viable alternative. Rotary capacitive couplers are not practical because of the high capacitive coupling required... 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."*

---

[151] Op. cit. ACIST (2013b)

[152] Op. cit. ACIST (2013b)

[153] Op. cit. ACIST (2013b)

[154] Op. cit. ACIST (2013b)

The applicant[155] provides information concerning silver-graphite brush slip-rings, a possible design alternative to the mercury based electric rotating connectors. ACIST explains that:

> *"Typical silver-graphite brush slip rings exist in industrial and commercial use. They are used to transfer power, control circuits, analog or digital signals including data and electrical signals from a stationary to a rotating structure. Examples include generators, motors, alternators, wind turbines, and radio telescopes.*
>
> *A silver graphite brush slip ring introduces noise to the signal being transmitted for processing. In the application in question the signal generated must be virtually noise free to insure the equipment operates properly and provides an accurate picture of the area being imaged… Alternative design is not feasible that supports current system performance requirements for a low-noise, high-voltage transmit, and a low-voltage receive transmission at high rotational speed… Resistance through a typical slip ring is 10 - 20 milliohms. This design is incapable of providing a noise free signal that is required for the system to perform properly. Noise introduced into the system in this matter would be indistinguishable from actual reflected ultrasound signal, rendering the image produced unusable for medical imaging".*

As for rotary inductive couplers (rotating transformers), used in other IVUS, ACIST[156] asserts that compared to mercury based ERC, couplers have the following limitations (see source for further detail):

- "*Reduced bandwidth;*
- *Reduced peak power handling due to magnetic core saturation;*
- *Reduced high frequency performance due to available ferrite materials; and*
- *Higher insertion losses (-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).*

> *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 handling ability (3.0A), low noise, and low insertion loss (<-1dB) are critical to the ACIST imaging system design."*

[155] Op. cit. ACIST (2013a)

[156] Op. cit. ACIST (2013b)

Further alternatives have been named in a contribution made by Moog Components Group[157] (hereafter MOOG), including:

- Fibre brush technology;
- Composite brush technology (including but not limited to silver-graphite slip rings mentioned above); and
- Nobel metal monofilament brushes (gold / silver / palladium alloy based brushes).

From an application note[158] made by MOOG, it can be understood that besides the fibre brush technology, the various alternatives all have various limitations that would not allow them to be practical for use in the ACIST IVUS HDi. Fibre Brush technology is explained to "*feature a brush design composed of multiple small "fibres", or wires, culminated into a bundle that provide intimate ring contact, low brush force, low torque, and excellent conductive properties. The multiple fingers allow low contact force and subsequently low friction and very low wear rate. The multiple contacts also provide good current density properties for high current. These contacts are well suited for low noise and high current hybrid applications. Evaluation of this technology is certainly warranted in intravascular ultrasound imaging and fibre brushes are actually being used in similar applications… Advantageous features of this technology are very low electrical noise, excellent conductivity, and very long life*." Further details are available in the submitted documents.

ACIST[159] was thus asked to explain if this technology could provide a practical alternative for the ERC, eliminating the need for Hg in this application. They stated that:

"An analysis was performed on the Moog Product Catalogue for Slip Rings. All products were filtered for acceptability based on the following minimum performance requirements.

- *3A current rating;*
- *80V voltage rating;*
- *3600 rpm speed rating.*

Only the EC3848-6 meets the voltage and speed requirements and may be configured using multiple contacts to meet the current requirement, but the following specific concerns with the EC3848-6 arose during the assessment:

[157] Moog (2013a), Contribution to RoHS Stakeholder 2013 Consultation 1 – Answers to Questionnaire, submitted 02.10.2013, available under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_IX/Request_2013-4/20131002_Moog_Contribution_RoHS_Ex_Re2013-4_mercury_slip_ring_response.pdf

[158] MOOG (2013b), Application note sumitted by MOOG during the 2013 Stakeholder Consultation 1: Fibre Brushes – The Low Maintenance, Long Life, High Power Contact Slip Ring Material ", available under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_IX/Request_2013-4/20131003_Moog_App_note_207_long_life_contacts.pdf

[159] ACIST (2014)

- *The published EC3848-6 spec sheets provide little data regarding RF performance. Only one parameter is listed that is of interest to an RF application. The 20 milliohms specification does not provide a complete picture due to being limited to the 5 rpm speed. This would have to be measured at operating speed, then the results would have to be shown in relation to frequency.*
- *Other missing information that would be required to characterize an inline RF device includes: Return loss vs frequency; Loss vs frequency; and Noise vs frequency.*
- *The EC3848-6 does not have a 3 amp per channel capability (rated at 1 amp per channel). It would require three contacts for each leg of our signal path to handle our 3 amp signal. This would impact noise susceptibility due to the transmission line differences between the Mercotac coax transmission line and the Moog solid wire flying lead and solder terminal design. To accommodate this difference, a complete redesign of the electronics would be required, and the make-and-break electrical contacts would still be subject to pitting and the reliability issues mentioned above.*
- *Routing the signal path through 6 individual slip rings will not only upset the critical balance of the catheter connection, but also expose the signal path to interference from the motor driver circuitry as well as the digital circuit boards inside the PIM. The motor and digital circuit boards are located within millimetres of the slip ring.*

Due to the above concerns and analysis, ACIST Medical Systems, Inc. does not find any Moog slip ring to be a candidate to replace the Mercotac slip ring."

9.2.3 Environmental Arguments

ACIST[160] claim 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.

[160] Op. cit. ACIST (2013b)

9.3 Stakeholders' Contributions

Two contributions were made during the stakeholder consultation.

The Swedish Ministry[161] of environment has expressed concern as to the proposed formulation of the requested exemption. They recommend the exemption be specified more clearly, to avoid its application by uses other than intended. It is suggested that the specification be available only to medical device applications for intravascular ultrasound imaging.

Moog Components Group[162], [163] (MOOG) provided a contribution opposing the requested exemption. The key issues addressed in the submitted information is detailed in Section 9.2.2 above and therefore not repeated in this section.

MOOG do not support the request for exemption and criticize the *"lack of rigor in evaluation of alternatives"* apparent in the exemption request. They further state that the negligible risk associated by the applicant regarding mercury emissions should be quantified and supported with *"a more rigorous analysis"*.

9.4 Critical Review

9.4.1 REACH Compliance - Relation to the REACH Regulation

Section 5.0 of this report lists entries 18 and 18a of Annex XVII of the REACH regulation, restricting the use of Hg compounds in anti-fouling or impregnation substances and in thermometers and other measuring devices intended for sale to the general public.

In the consultants' understanding, these entries do not apply to the use of Hg in IVUS devices, for which an exemption is requested. In other words, the use of Hg in question is not subject to any restrictions by REACH.

The consultants conclude that the use of Hg in IVUS devices for which an exemption has been requested does not weaken the environmental and health protection afforded by the REACH Regulation. An exemption could therefore be granted if other criteria of Art. 5(1)(a) apply.

9.4.2 Scientific and Technical Practicability of Hg Substitution

From the information submitted by the applicant and the various stakeholders, two issues appear to be paramount in the review of this request.

[161] Swedish Ministry of Environment, Contribution to RoHS Stakeholder 2013 Consultation 1, submitted 11.11.2013, available under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_IX/SE_Comments_on_stakeholder_consultation_RoHS_Aug_Nov_2013.pdf

[162] Op. cit. Moog (2013a)

[163] Op. cit. Moog (2013b)

The first regards the possibility of replacing the mercury containing components in the IVUS device. In this respect, the main question concerns the practicability of substituting the mercury based electric rotating connectors with mercury free alternatives.

The second aspect is connected to the applicant's indication that this type of IVUS device is not yet marketed on the EU market. ACIST[164] states that approval of the requested exemption will allow it to immediately begin European regulatory submissions for full product commercialization. It is thus important to verify that other devices already available on the EU market do not provide the same function, or that the non-compliant device has a significant benefit over existing alternatives.

9.4.2.1 Substance Alternatives

The applicant's main explanation, concerning substance alternatives, identifies the qualities of Hg in comparison with other substances. The conductive properties of Hg and its liquid consistency at room temperature provide a plausible explanation why mercury cannot be substituted at present within this application.

9.4.2.2 Design Alternatives

A number of possible alternatives are raised by both the applicant and by MOOG, one of the contributing stakeholders. Most of these alternatives are explained to be impractical for the IVUS application for technical reasons:

- Ø Elements used in current IVUS devices would not be compatible with the 60 MHz performance, resulting in a loss of analysis capabilities.
- Ø Alternative slip ring technologies usually have higher maintenance requirements, cannot operate at the high rotational speeds required and produce significant electric-noise impairing imaging capabilities.

The only exception to this rule concerns fibre brush technology, which according to MOOG has a number of qualities that suggest it to be a possible design alternative. This includes a low wear rate (low maintenance requirements); high conductivity; suitability with low noise and high current hybrid applications; and acceptable high operating frequency in the operational range of 40 – 60 MHz

The applicant was thus asked to clarify if this specific kind of fibre brush technology could be a possible alternative. ACIST made a first screening of possible elements specified in a MOOG product catalogue to identify elements that would operate with three initial requirements: the current rating; the voltage rating and the speed rating.

A single component was identified and a first compatibility evaluation was performed by ACIST. The explanations provided as to the limitations of its applicability in the current device are detailed in Section 9.2.2 above and are viewed by the consultant as plausible. The main aspect is understood to be a technical non-compatibility, as the identified element lacks a 3 amp per channel capability and would require three

---

[164] Op. cit. ACIST (2014)

contacts for each leg of the signal path to handle the 3 amp signal. Though it could be argued that other described performance limitations would need to be observed in practice, it can be followed that a redesign of the electronics of the device would indeed be required, meaning that the element could not provide a practical substitute in the short term. It should however be noted that cooperation with a fibre brush technology supplier for the development of an element for use in the ACIST IVUS device, may allow for eliminating the use of the Hg based element in the future.

9.4.2.3 Comparability with Alternative Devices

The applicant provides a comparison of the ACIST IVUS device with other IVUS devices currently on the market. This comparison allows a better understanding of the unique capabilities that the ACIST IVUS device provides, including higher resolution (both axial and lateral), higher frame rates and faster pull-back speeds. Although the soft tissue and blood penetration are somewhat reduced when the device operates in the 60 MHz frequency, the standard 40 MHz operation is comparable in this regard, still offering the detailed benefits which are also provided in the 60 MHz mode.

Higher resolution is understood to increase the diagnostic abilities. To further address this benefit, ACIST references a number of studies[165] comparing between the diagnostic abilities of the 60 MHz device and other devices. To summarize the studies ACIST[166] states: "*Human clinical data is limited to one study (23 patients). This study achieved its end point of no device related adverse events and image non-inferiority to conventional 40MHz IVUS. Additional pre-clinical in-vitro and cadaver studies have been conducted at Stanford Hospital. Several abstracts and posters have been presented at the American Heart Association (AHA) and Transcatheter Cardiovascular Therapeutics (TCT) medical conferences. These presentations reported on superiority of 60MHz IVUS over conventional 40MHz IVUS for microscopic atherosclerotic plaque evaluation and thrombus detection*".

Furthermore, higher pull-back speeds are understood to allow shortening of the procedure duration, resulting in a lower risk of developing catheter induced ischemia. Though it is difficult to quantify the degree of benefit that the ACIST device provides in relation to other devices currently on the market, ACIST provided a comparison with the dwell times of other devices. This comparison shows that though the ACIST device

---

[165] Cited in ACIST (2014) as:

1) Tanaka S, Sakamoto K, Yamada R, et al. PLAQUE ASSESSMENT WITH A NOVEL HIGH–DEFINITION 60–MHZ IVUS IMAGING SYSTEM: COMPARISON WITH CONVENTIONAL 40 MHZ IVUS AND OPTICAL COHERENCE TOMOGRAPHY. *J Am Coll Cardiol.* 2013;61(10_S): doi:10.1016/S0735-1097(13)61878-1 (Link: http://content.onlinejacc.org/article.aspx?articleid=1666095)
2) Tanaka S, Sakamoto K, Kitahara H, et al. TCT-661 Assessments of Lipid Plaque and Thrombus With a Novel High-Definition 60-MHz IVUS Imaging System: Comparison with Conventional 40-MHz IVUS and Optical Coherence Tomography. *J Am Coll Cardiol.* 2013;62(18_S1):B201-B202. doi:10.1016/j.jacc.2013.08.1410. (Link: http://content.onlinejacc.org/article.aspx?articleid=1759976)

[166] Op. cit. ACIST (2014)

can perform with comparable dwell times (130 / 70 seconds), it can also perform with significantly shorter dwell times (34 / 22 / 16 seconds), depending on the pullback speed applied. ACIST further quote a number of studies[167] to show that ischemia can develop in as little as 30 to 60 seconds, supporting that any reductions would allow reducing the risk of developing ischemia to some degree.

In light of the mentioned advantages of the ACIST device, the consultant can follow that the new application would have benefits over the current devices on the market that would contribute to the health of patients.

9.4.3 Environmental Arguments

As in the consultants understanding, the main justification for the request regards the impracticability of substitution, these arguments were not reviewed. The consultants would like to point out, however, that this neither indicates agreement nor disagreement with the applicant's environmental arguments.

9.4.4 Review of Stakeholder Contributions

The Swedish Ministry[168] of environment has expressed concern as to the proposed formulation of the requested exemption. The applicant was asked prior to the consultation as to further applications in which mercury based electric rotating connecters are in use. Further uses which would need to be RoHS compliant were not identified in the applicant's response, which was included in the documents made available for the stakeholder consultation. As stakeholders did not provide further information in this regard, it is concluded that the exemption is only required for IVUS applications. Thus the Swedish Ministry's recommendations are to be taken into consideration, should an exemption be recommended.

MOOG has contributed information regarding various slip-ring applications that are considered as possible design alternatives. From the contributed information, explained in Section 9.4.2.2, it is understood that only fibre brush technology may be a practical alternative. In light of the applicant's evaluation of possible fibre brush elements, it can be followed that at present this alternative could not replace the Hg based ERC.

---

[167] Quoted in ACIST (2014) as:

1) Catheter Cardiovasc Interv. 2013 Feb; 81(3):446-53. doi: 10.1002/ccd.23343. Epub 2012 Jan 10
2) EUR Heart J. 1987, Apr; 8(4):347-53: The evolution of mycordial ischemia during percutaneous transluminal coronary angioplasty
3) J Am Coll Cariol 1986 Jun;7(6):1245-54 Regional myocardial dysfunction during coronary angioplasty: evaluation by two-dimensional echocardiography and 12 lead electrocardiography

[168] Op. cit. Swedish Ministry of Environment (2013)

9.4.5 Conclusions

Article 5(1)(a) provides that an exemption can be justified if at least one of the following criteria is fulfilled:

- their **elimination or substitution** via design changes or materials and components which do not require any of the materials or substances listed in Annex II is scientifically or technically impracticable;
- the **reliability** of substitutes is not ensured;
- the total negative **environmental, health and consumer safety impacts** caused by substitution are likely to outweigh the total environmental, health and consumer safety benefits thereof.

From the information provided by the applicant, it is understood that at present, elimination or substitution of mercury in the ACIST IVUS device is impractical. As the device is currently not available on the EU market, in the consultants' view, it is further necessary to establish that it has advantages over similar devices that are already available on the EU market. Though this device is understood to be the only IVUS device that uses the mercury based ERC, it is also understood to have a number of advantages over other IVUS devices available on the market, from which treated patients could benefit. It is thus concluded that:

- The ACIST IVUS has unique capabilities that could have a positive impact on patients health; and
- The Hg based ERC component within it could not be replaced with a RoHS compliant component at present.

Assuming that the EU COM recognizes the health advantages of the ACIST IVUS as significant in comparison with other IVUS devices currently on the market, an exemption from the RoHS substance restrictions would be justified, as one of the main criteria is fulfilled.

As for the duration of a possible exemption, the applicant has not provided any quantitative information as to the time needed before a RoHS compliant IVUS device, performing at both 40 and 60 MHz, could become available on the market. This was explained in light of the lack of an alternative that could replace the Hg based ERC component. It can be understood that in any case, developing an alternative shall require time, as shall the reworking of a possible alternative into the design of the device. However, as it cannot yet be ruled out that fibre brush technology could provide a basis for developing a RoHS compliant replacement for the Hg based ERC, the consultants understand this technology to be a candidate for further research. The consultants would thus propose that the EU COM consider granting an exemption for a shorter duration, allowing the applicant time to perform further research concerning the candidate technology and the time needed before a RoHS compliant device could come on the market.

As for the exemption wording, the applicant[169] submitted a reformulation of the proposed wording:

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

The consultants agree with the Swedish Ministry of Environment, that the formulation should be more precise, to limit its application to the use for which it was intended. In this regard, the consultant proposes a few changes:

- Ø To limit the exemption to category 8, as stakeholders have supplied no indication that mercury based ERCs are in use in other devices regulated by the RoHS Directive;
- Ø To further limit the exemption scope by stating the component of relevance, as the proposed formulation would allow the use of Hg in all components used in IVUS devices;

The following wording is thus proposed should an exemption be granted:

> *"Mercury electric-rotating connectors used in intravascular ultrasound imaging systems capable of high operating frequency (>50MHz) modes of operation."*

9.5 Recommendation

Assuming that the EU COM recognizes the health advantages of the ACIST IVUS as significant, in comparison with other IVUS devices currently on the market, an exemption from the RoHS substance restrictions would be justified, as one of the main criteria is fulfilled. Under these conditions the consultants recommend granting an exemption with the following wording:

> *"Mercury electric-rotating connectors used in intravascular ultrasound imaging systems capable of high operating frequency (>50MHz) modes of operation."* *22 July 2019*

Should an exemption be granted, it should be added to Annex IV of the RoHS Directive.

9.6 References Exemption Request 2013-4

ACIST (2013a), Original Request for Exemption from the RoHS 2 Directive, submitted by the applicant 26.04.13, available under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_IX/Request_2013-4/ACIST_Medical_Systems_Exemption_Application__Directive_2011-65-EU__4-26-13.pdf

ACIST (2013b), Answers to First Clarification Questions , submitted by the applicant 31.07.2013, available under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_IX/Request_2013-4/20130731_ACIST_Medical_Systems_Response.pdf

[169] Op. cit. ACIST (2013b)

ACIST (2014), ACIST Response to 2nd Round of Clarification Questions, submitted per email on 01.02.2014.

Moog (2013a), Contribution to RoHS Stakeholder 2013 Consultation 1 – Answers to Questionnaire, submitted 02.10.2013, available under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_IX/Request_2013-4/20131002_Moog_Contribution_RoHS_Ex_Re2013-4_mercury_slip_ring_response.pdf

MOOG (2013b), Application note submitted by MOOG during the 2013 Stakeholder Consultation 1: Fibre Brushes – The Low Maintenance, Long Life, High Power Contact Slip Ring Material ", available under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_IX/Request_2013-4/20131003_Moog_App_note_207_long_life_contacts.pdf

Swedish Ministry of Environment (2013), Contribution to RoHS Stakeholder 2013 Consultation 1, submitted 11.11.2013, available under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_IX/SE_Comments_on_stakeholder_consultation_RoHS_Aug_Nov_2013.pdf