



COCIR response to the European Commission request regarding the banning of mercury-containing sphygmomanometers¹

Introduction

The European Commission is investigating a possible ban of sphygmomanometers containing mercury (Hg) and is requesting responses from European stakeholders.

COCIR is the European trade association representing the imaging, electromedical and healthcare IT industry. COCIR has a substantial interest in the topic of Hg-sphygmomanometers because of the close relationship with many applications of sphygmomanometers in the area of patient care and monitoring. Blood pressure is one of the key diagnostic parameters used from basic healthcare at one extreme to critical care situations at the other extreme.

COCIR is happy to contribute to the impact analysis being initiated by the European Commission.

COCIR Recommendation:

COCIR is of the opinion that Hg-sphygmomanometers **must not be banned** from either practical use or from calibration purposes because they provide the most accurate readings possible today.

Banning Hg-sphygmomanometers from all practical use will lead to a substantial negative impact on public health. Any potential benefit to the environment is very small compared to other sources of environmental mercury and is by far outweighed by the positive impact on public health of these devices, for which at this moment there is no equivalent alternative.

General information about COCIR:

Founded as a non-profit trade association in 1959, COCIR represents the Radiological, Electromedical and Healthcare IT industry in Europe. As such, our members play a driving role in developing the future of healthcare both in Europe and worldwide. COCIR is committed to supporting its members and communicating with its partners in Europe and beyond on issues which affect the medical technology sector and the health of EU citizens. COCIR also works with various organisations promoting harmonised international standards and fair regulatory control that respects the quality and effectiveness of medical devices and healthcare IT systems without compromising the safety of patients and users. We encourage the use of advanced technology to support healthcare delivery worldwide. COCIR's key objectives include promoting free worldwide trade of medical devices and maintaining the competitiveness of the European health sector.

COCIR Company Members: Agfa-Healthcare, Aloka, Bosch, Canon Europe, Carestream Health, Dräger Medical, Elekta, Fujifilm, GE Healthcare, Hitachi Medical Systems Europe, IBA Ion Beam Applications, IBM, ICW, Intel, iSoft, Medison, Philips Healthcare, Healthvision, Siemens Healthcare, Toshiba Medical Systems Europe.

COCIR National Associations Members: AGORIA (Belgium), Assobiomedica (Italy), AxREM (UK), FENIN (Spain), FIHTA (Finland), HHT (Netherlands), SPECTARIS (Germany), SNITEM (France), Swedish MedTech (Sweden), TipGorDer (Turkey), ZVEI (Germany)

¹ "Mercury" sphygmomanometers for use in healthcare are temporarily exempted from the marketing restrictions affecting other measuring instruments containing mercury pursuant to Directive 2007/51/EC relating to restrictions on the marketing of certain measuring devices containing mercury. According to the annex of the Directive, the European Commission shall carry out a review of reliable safer alternatives by October 2009, hence this request.

DETAILED BRIEFING

Most of the rationale given below has been obtained from actual clinical users of various types of blood pressure instruments. Many of these experts are members of the USA-based AAMI Sphygmomanometer Committee² and/or the American Heart Association (1). COCIR fully supports the arguments presented.

Mercury sphygmomanometers have been the gold standard for the auscultatory estimation of blood pressure for over a century (1, 2). In addition to their use in clinical practice and in large numbers of clinical studies, they remain a primary standard used in the validation of automated sphygmomanometers. While there are alternatives to the use of these devices (3), there is a place for mercury sphygmomanometers in professional use with appropriate precautions for use. Furthermore, all of the long-term longitudinal studies, e.g. Framingham Heart, that are used as the basis for determining when/how to treat patients with hypertension are based on mercury sphygmomanometers. The historical gold standard for non-invasive blood pressure estimation, most recently detailed by the American Heart Association (4), is based on a column of mercury and the sounds that the clinician hears as a cuff on the arm is deflated.

While there are reports of spills from mercury sphygmomanometers (5, 6), to our knowledge, there is no data on the amounts of mercury released from these devices compared to other sources. In the US, the major source of mercury in the environment is industrial. One study indicates that 85% of all mercury in the environment is released from coal-fired power plants (7). A similar situation exists worldwide as described in a report by the Zero Mercury Working Group (8).

The manufacturers of mercury sphygmomanometers have implemented numerous safety features to reduce the risk of a mercury spill even when devices are dropped or damaged. It is recommended that the use of these devices by qualified professionals still be allowed with appropriate safety precautions. Users should be encouraged to contact the manufacturer of the device to ensure that it contains the most current safety precautions.

Information provided by the US-FDA indicates that FDA has no plan to ban mercury in cardiovascular medical devices.

Users indicate that "there is no single measurement issue ... as important to the world's health as the accurate measurement of blood pressure in the physician's office and in the patient's home" and "we have the moral imperative and responsibility to do all we can to assure that blood pressure is measured accurately by setting the standards to protect public health".

Calculations indicate that with an under- or overestimate of actual blood pressure of only 5 mm of mercury will result in missing up to 40 % of hypertension or to a similar number of patients unnecessarily treated with medications for high blood pressure.

² <http://www.aami.org/committeecentral/Committee/ShowCommitteeDetail.cfm?ComID=0SP0000>

References

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