



# OIML BULLETIN

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Legal metrology for health



## BULLETIN

VOLUME LXII • NUMBER 4

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IAN DUNMILL

BIML Assistant Director

## Legal metrology for health

Although the COVID-19 pandemic was already with us and having a significant and unprecedented effect on all our lives when theme for World Metrology Day 2021 *Measurement for Health* was decided in late summer last year, none of us would have thought that we would still be suffering from its disruption over a year later!

Two already running projects on sphygmomanometers were successfully concluded in 2020 with the approval of two revised Recommendations (R 148 and R 149) at the 55th meeting of the International Committee of Legal Metrology (CIML) in October that year. Discussions on the theme of health at that meeting, and at the CEEMS Advisory Group, raised awareness of the concerns from many within the legal metrology community about widespread problems with the regulation and traceability of measuring instruments used in the field of health. These problems were being brought to the fore by the publicity and controversies surrounding the exceptional circumstances of the pandemic. In many countries, medical measuring instruments do not fall within the traditional scope of legal metrology, and so the problems were new to those in legal metrology institutions.

As a result, the OIML established a *Task Force on medical devices used in legal metrology*, which first met in April 2021, and which proposed several areas of work which should be undertaken within the OIML. I am pleased to say that five new project proposals have been put forward for approval at this year's meeting of the CIML. If these are approved, their work will result in updated Recom-

mendations and guidance in the fields of blood pressure measurement and clinical thermometry, both of which have proved crucial in the fight against COVID-19.

On a positive note, the increasing interest in the digitalisation of legal metrology overlaps with these concerns, and helps in providing solutions to some of them. The increased use of online technology, to which we have all been forced to adapt since the beginning of 2020, should also improve the speed at which the OIML can respond to problems such as these in the future. Although the pandemic has highlighted problems with the suitability, accuracy, reliability and use of certain instruments, it has also increased the demand for standards and better regulation, especially in countries with developing metrology systems, and has increased cooperation and information exchange at international and regional levels, which can only benefit legal metrology in the longer term.

This special edition of the OIML Bulletin on the theme of Measurement in Health was planned to illustrate the breadth of legal metrology in this area, and to stimulate interest in it. We hope you find this issue interesting, as we believe that the extremely varied contents of its articles clearly indicates the wide range of instruments used in the medical field where metrology is absolutely essential in ensuring our health. The pandemic has made everyone focus on what is really important – our health, where measurement plays an important role, as it does in almost all aspects of our lives. ■



## HEALTH

## Influential factors on the calibration accuracy of ventilators

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### Abstract

Ventilators are important life supporting machines and they are widely used in the treatment of COVID-19. Inaccurate output of ventilators may be fatal to patients. It is necessary and useful to periodically calibrate ventilators to ensure their accuracy and reduce the medical risk. The principle of the flow sensor and the oxygen sensor is introduced, and the influential factors on the calibration accuracy are analyzed. Experimental results show that the correction mode and the gas type should be strictly set when calibrating the tidal volume of a ventilator. It is also important to select a test lung with the appropriate compliance parameter and a filter with adequate ventilation performance. It is necessary to pay close attention to a possible performance change of the oxygen sensor and calibrate it with standard gases if necessary.

**Key words:** ventilator; ventilator tester; tidal volume; oxygen concentration

### 1 Introduction

A ventilator is a mechanical ventilation machine used to treat respiratory insufficiency or failure in emergency treatment, surgery and rehabilitation [1]. Since the COVID-19 pandemic broke out, ventilators have been widely used in the treatment of severely ill patients. The clinical risk of ventilators is determined by the application scenario, the disease type, the severity level (whether there is autonomous respiration), the ventilation modes (invasive or non-invasive), etc. According to the international standard ISO 14971:2007 *Medical devices - Application of risk management to medical devices* [2], the risk index of the ventilator can reach 12, indicating a high medical risk. The accuracy of many

parameters such as the tidal volume and the oxygen concentration has a strong impact on the therapeutic effect and even life safety [3,4]. Due to the diversity of ventilators and their different application scenario, it is not possible to use the same criterion to evaluate each type. In China, there are calibration guidelines for different types of ventilators. They are calibrated according to guidelines and users' requirements rather than verified compulsively. It has been a consensus that periodical calibration is necessary to ensure the accuracy of ventilators and reduce the medical risk, especially when they are massively used in the global COVID-19 pandemic.

Many factors influence the calibration accuracy of ventilators: the ventilator tester, the test lung, and the filter are all possible error sources. Their influences on the tidal volume and the oxygen concentration are investigated by experiments. Conclusions and suggestions are given to guide the calibration practice of ventilators.

## 2 Influence of the ventilator tester

### 2.1 Principle of ventilator testers

Ventilator testers are used to test the metrological performance of ventilators by manufacturers, hospitals and metrological laboratories. There are a number of commercial options, such as the Fluke VT-PLUS, or the Imtmedical PF-300. The National Institute of Metrology of China has also developed a ventilator tester (NIM-HC-03), which is intended for the calibration of critical care ventilators, emergency and transport ventilators, and non-invasive ventilators, which are traceable to national measurement standards, shown in Figure 1.

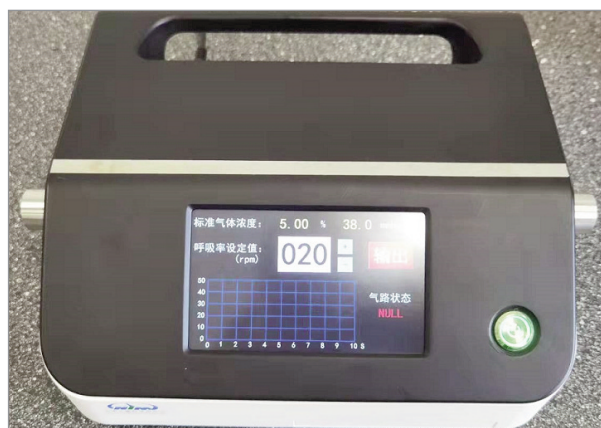


Figure 1: NIM-HC-03 ventilator tester

A differential pressure sensor is usually used to measure the gas flow rate, which is used by the VT PLUS and PF-300 ventilator testers. The gas flow rate is approximately proportional to the pressure difference between the two sides of the restrictor (pore plate) of the sensor over a certain range of flow rate. The gas flow rate value is obtained by measuring the pressure difference at points upstream and downstream of the restrictor while the gas is flowing [5]. The principle is shown in Figure 2.

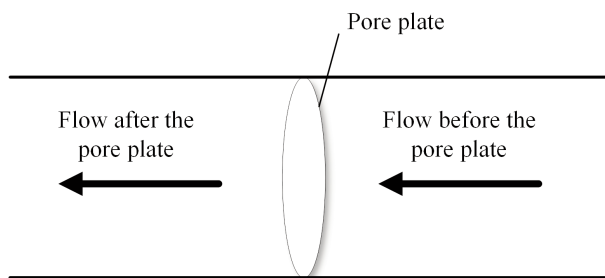


Figure 2: Principle of the differential pressure sensor

Theoretically, the pressure difference  $\Delta p$  can be calculated as:

$$\Delta p = c_1 \eta Q + c_2 \rho Q^2 \quad (1)$$

where  $c_1$  and  $c_2$  are constants determined by the geometric structure of the restrictor,  $\eta$  is the gas dynamic viscosity,  $Q$  is the gas flow rate, and  $\rho$  is the gas density.

The pressure difference depends on the geometric structure of the restrictor, the value of the gas viscosity, the gas flow rate, and the gas density, while the gas viscosity coefficient and the gas density are determined by the gas type, the environmental temperature, and humidity. Thus, the gas type and the environmental parameters should be set and measured accurately to reduce the error while using a ventilator tester to calibrate the gas flow rate.

## 2.2 Influence on the tidal volume

The settings of the gas type and the correction mode have an obvious influence on the measurement result of the flow rate. The tidal volume is derived by integrating or accumulating the flow rate over time. Thus, the result of the tidal volume is also influenced by the gas type and the correction mode.

### 2.2.1 Correction mode

According to the equation of state for an ideal gas, the volume of a fixed mass of gas is related to its pressure and temperature. The environmental temperature, humidity, and atmospheric pressure all influence the measurement result of the tidal volume. Usually, there are different options of correction modes in ventilator testers which can be used to minimize the error caused by environmental factors:

**ATP:** Automatic temperature and pressure correction mode. The measurement result of the tidal volume is corrected in line with the conditions of environmental temperature and atmospheric pressure. There are also ATPD mode (dry air) and ATPS mode (saturated moist air).

**BTPS:** The result is corrected in line with the conditions of environmental atmospheric pressure, standard human body temperature 37 °C and saturated moist air.

**STPD<sub>0</sub>:** The result is corrected to 0 °C, standard atmospheric pressure and dry air, also referred to as the "0/1013" mode in some testers, such as the PF-300.

The results at different modes can be derived from each other:

$$Q_{BTPS} = Q_{ATPS} \times \left( \frac{p - p_{H_2O}}{p - 47} \right) \left( \frac{310.15}{273.15 + t} \right) \quad (2)$$

$$Q_{STPD0} = Q_{ATPS} \times \left( \frac{p - p_{H_2O}}{760} \right) \left( \frac{273.15}{273.15 + t} \right) \quad (3)$$

$$Q_{STPD0} = Q_{ATPD} \times \left( \frac{p}{760} \right) \left( \frac{273.15}{273.15 + t} \right) \quad (4)$$

where  $Q_{BTPS}$ ,  $Q_{ATPS}$ ,  $Q_{STPD0}$  and  $Q_{ATPD}$  are the tidal volumes at the BTPS mode, ATPS mode, STPD<sub>0</sub> mode and ATPD mode respectively,

$p$  is the atmospheric pressure,

$p_{H_2O}$  is the saturated vapor pressure,

$t$  is the environmental temperature,

310.15 is the normal body temperature in K,

273.15 is the conversion from C to K,

760 standard atmospheric pressure in mmHg, and

47 is the partial pressure of water in mmHg in saturated air at 37 °C.

In order to investigate the influence of different correction modes on the result of the tidal volume, four ventilator testers were used to measure the tidal volume of the same active servo lung (ASL5000) under

Table 1: Results of tidal volume at different correction modes (Unit: mL)

Nominal tidal volume	Model of ventilator tester	Results of ASL5000	Results of ventilator testers		
		ATP	ATP	BTPS	STPD <sub>0</sub> /1013
200	VT PLUS	199.83	196	218	179
	VT 650	199.54	206	233	183
	PF-300	199.22	205	223	181
	NIM-HC-03	199.96	201	227	181
400	VT PLUS	399.53	389	433	358
	VT 650	399.55	412	452	365
	PF-300	399.84	404	442	355
	NIM-HC-03	399.87	405	449	362
500	VT PLUS	499.61	493	547	444
	VT 650	500.23	515	560	453
	PF-300	499.63	502	549	448
	NIM-HC-03	500.78	514	554	443
600	VT PLUS	600.28	596	657	538
	VT 650	600.33	611	666	539
	PF-300	599.53	611	666	542
	NIM-HC-03	601.36	616	671	543
800	VT PLUS	800.16	801	886	716
	VT 650	800.89	810	882	714
	PF-300	799.45	811	881	729
	NIM-HC-03	799.16	796	865	695
1000	VT PLUS	1000.19	1003	1104	894
	VT 650	1000.61	1012	1103	892
	PF-300	1000.02	1011	1084	919
	NIM-HC-03	998.28	982	1051	903

conditions of room temperature, standard atmospheric pressure, and dry air. The results are shown in Table 1. The software interface of the ASL5000 is shown in Figure 3 and the device was operated in ATP mode.

It can be observed from Table 1 that the results of the tidal volume obtained by four ventilator testers are strongly dependent on the correction mode. If the

ventilator testers are set to the same mode as the ASL5000, the testers give similar results to the test lung. Otherwise, there is a large error in the measurement of tidal volume and it increases as the tidal volume increases. It is indicated that the correction mode of the ventilator testers should be set to be the same mode as the ventilator under calibration.

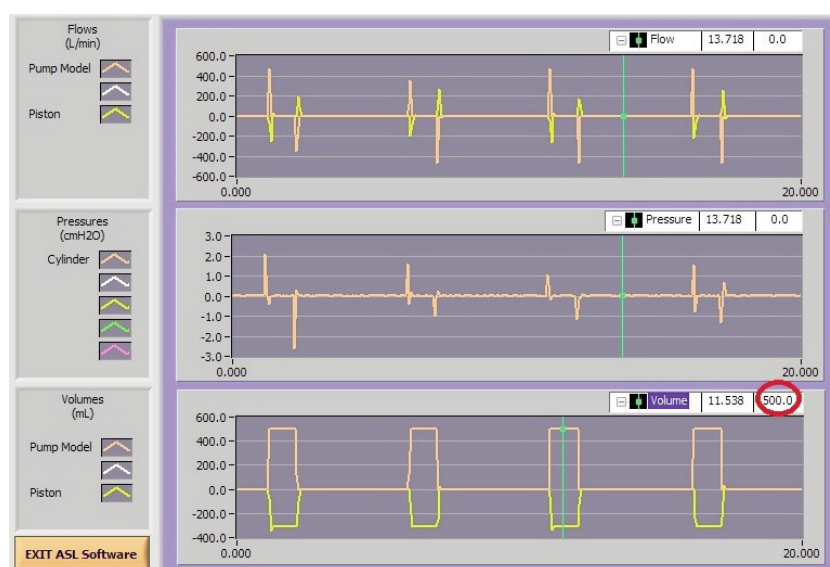


Figure 3: Software interface of the ASL5000 at a tidal volume of 500 mL



Table 2: Results of tidal volume vs. different gas type (Unit: mL)

Nominal tidal volume	Model of ventilator tester	Results of ASL5000	Results of ventilator testers			
		AIR	AIR	N <sub>2</sub>	O <sub>2</sub>	CO <sub>2</sub>
200	VT PLUS	199.83	196	200	172	237
	PF-300	199.24	202	210	177	251
400	VT PLUS	399.49	391	400	349	475
	PF-300	399.77	406	418	358	491
500	VT PLUS	499.38	493	505	440	595
	PF-300	498.88	501	515	445	605
600	VT PLUS	600.08	595	609	531	716
	PF-300	599.56	602	618	534	719
800	VT PLUS	800.12	796	814	717	954
	PF-300	800.25	807	831	720	954
1000	VT PLUS	1000.8	994	1018	900	1187
	PF-300	1000.42	1009	1038	901	1174

### 2.2.2 The gas type

Equation (1) shows that the measurement result of the flow rate is also influenced by the gas viscosity and the gas density, which are determined by the gas type [6]. Commercial ventilator testers have options for gas type settings, including nitrogen, oxygen, air, carbon dioxide, etc.

In order to investigate the influence of the gas type on the result of the tidal volume, a VT PLUS ventilator tester and a PF-300 ventilator tester were used to measure the tidal volume of the ASL5000 at room temperature, standard atmospheric pressure, and dry air. The results are shown in Table 2. The oxygen concentration in the air is 21 % (volume by volume concentration).

It can be observed from Table 2 that the gas type has a strong impact on the measurement results. If the gas type is not correctly set in the ventilator testers, there will be a significant error in the result of the tidal volume. The measurement error is related to the density and the viscosity coefficient. It is required that the gas type of ventilator testers should be set according to the real gas type used for the calibration.

### 2.3 The influence on the oxygen concentration

Electrochemical sensors (oxygen batteries) are used to measure the oxygen concentration in ventilator testers. The concentration value is obtained by measuring the electric current generated by the chemical reaction between the electrochemical material in the sensor and the oxygen molecule in the air. Since the reaction is irreversible, the sensitivity of the sensor will continue to decrease as the electrochemical material is consumed in daily use, leading to a larger and larger measurement error in the oxygen concentration. Usually, the life span of the sensors in ventilator testers is 1 year.

A PF-300 ventilator tester was used to measure the standard gases whose oxygen concentration is 21 % and 99 % (volume by volume concentration) in 6 successive months. The results are shown in Table 3.

It can be observed from Table 3 that the measured result of the oxygen concentration obviously decreases with time. It suggests that the sensors should be calibrated with standard gases before they are used to calibrate a ventilator, even within their lifetime. Expired sensors should be replaced with new ones and also calibrated with standard gases before use.

Table 3: Measurement results of oxygen concentration

Standard values of oxygen concentration	Measurement results of oxygen concentration					
	1st month	2nd month	3rd month	4th month	5th month	6th month
21.25 %	21.2 %	20.8 %	20.2 %	19.6 %	19.0 %	18.4 %
99.30 %	100.0 %	98.1 %	93.6 %	91.4 %	88.7 %	86.6 %

### 3 Influence of the test lung

#### 3.1 Principle of test lungs

Test lungs are designed to simulate the breathing of human lungs, used as auxiliary equipment in the calibration of ventilators. Test lungs can be classified as being either passive test lungs or active test lungs. The former can only work with ventilators or external dynamic sources and simulate certain types of respiration, while the latter can actively simulate more types of respiration.

Passive test lungs (shown in Fig 4) are frequently used in the calibration of ventilators. They usually adopt the structure of a clamp and an air bag. The air bag is replaceable to simulate different tidal volumes. The flexibility of the clamp is adjustable to simulate different compliance conditions. Passive test lungs are cheaper and simpler in structure than active test lungs, but they cannot simulate autonomous respiration of patients and cannot be used to evaluate the synchronization performance of ventilators.

Compliance and airway resistance are two major parameters of test lungs.

The lung and the thoracic cage are elastic. The compliance is used to characterize the elastic resistance [7], defined as the gas volume contained in per unit pressure:

$$C = \Delta V / \Delta P \quad (5)$$

where  $C$  is the compliance,  $V$  is the volume change caused by pressure change, and  $P$  is the pressure change.

The gas has to overcome the ventilation resistance to enter or exit the pulmonary alveolus. Pulmonary ventilation resistance can be divided into elastic resistance and non-elastic resistance. The former includes the elastic resistance of the lung and the thorax, and the latter includes the airway resistance, the inertial resistance, and the viscous resistance of tissue. The



Figure 4: Typical passive test lungs

airway resistance  $R$  is defined as the pressure generated in per unit flow rate.

The compliance and the elastic resistance are reciprocal. A larger elastic resistance means that the elastic tissue is harder to expand and corresponds to lower compliance, and vice versa.

#### 3.2 Influence of the compliance on the tidal volume

##### 3.2.1 Testing conditions

The testing conditions for calibrating the tidal volume of ventilators are recommended in IEC 60601.2.12:2009 *Medical Electrical Equipment - Part 2-12: Particular Requirements for the Safety of Lung Ventilators - Critical Care Ventilators* [8]. The compliance and the airway resistance should be adjusted according to the requirements listed in Table 4.  $V_t$  denotes the tidal volume.

It should be noted that some test lungs do not allow the airway resistance to be adjusted and the compliance, or their specifications cannot meet the requirement for the testing conditions recommended in IEC 60601.2.12:2009.

Table 4: Testing conditions recommended in IEC 60601.2.12:2009

Parameters	Testing conditions		
	$V_t > 300 \text{ mL}$	$30 \text{ mL} \leq V_t \leq 300 \text{ mL}$	$V_t < 30 \text{ mL}$
Respiratory frequency	$10 \text{ min}^{-1}$	$20 \text{ min}^{-1}$	$30 \text{ min}^{-1}$
I:E	1:2	1:2	1:2
Airway resistance	$0.5 \text{ kPa}/(\text{L} \cdot \text{s}^{-1}) \pm 10 \%$	$2 \text{ kPa}/(\text{L} \cdot \text{s}^{-1}) \pm 10 \%$	$5 \text{ kPa}/(\text{L} \cdot \text{s}^{-1}) \pm 10 \%$
Compliance	$500 \text{ mL}/\text{kPa} \pm 5 \%$	$200 \text{ mL}/\text{kPa} \pm 5 \%$	$10 \text{ mL}/\text{kPa} \pm 5 \%$

Note: The accuracy of the airway resistance and compliance applies to the full measurement range.

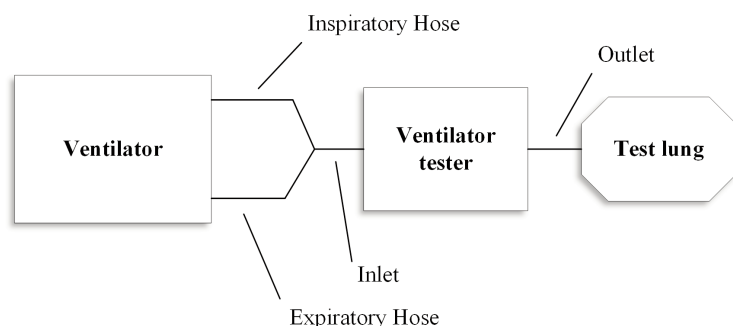


Figure 5: Connection of the ventilator calibration system

### 3.2.2 Calibration results of the same ventilator at different compliances

A PF-300 ventilator tester was used to calibrate a Fabius plus XL ventilator. A QuickLung was used as the load with adjustable compliance. The ventilator tester, the ventilator, and the test lung were connected in the way shown in Figure 5.

The ventilator was set to work in the VCV (volume-controlled ventilation) mode. The respiratory frequency is 20 per minute. I:E = 1:2; PEEP = 0.2 kPa;  $\text{FiO}_2 = 40\%$ . The ventilator tester was set to work in the BTPS mode, and the gas type was set as Ari/ $\text{O}_2$ -Auto mode. The airway resistance of the test lung was 2 kPa/(L·s<sup>-1</sup>). The compliance was set to 100 mL/kPa, 200 mL/kPa, and 500 mL/kPa. The tidal volumes of 400 mL, 500 mL, and 600 mL were calibrated. The results are shown in Table 5.

In order to investigate the stability of the measurement results, the measurement was repeated over 4 successive weeks using the same instruments, methods, and conditions. The calibration point of the tidal volume was fixed at 500 mL. The results are shown in Table 6. It can be observed from Table 5 and Table 6 that the measured values of the tidal volume increase with the

compliance at each calibration point. The larger the tidal volume is, the greater is the impact of the compliance on the result.

### 3.2.2 Calibration results of different ventilators at different compliances

A PF-300 ventilator tester was used to calibrate three ventilators, with a QuickLung used as the load. The ventilator was set to work in the VCV mode. The respiratory frequency was 20 per minute. I:E = 1:2; PEEP = 0.2 kPa;  $\text{FiO}_2 = 40\%$ . The ventilator tester was set to work in the BTPS mode, and the gas type was set as Ari/ $\text{O}_2$ -Auto mode. The airway resistance of the test lung was 2 kPa/(L·s<sup>-1</sup>). The compliance was set to be 100 mL/kPa, 200 mL/kPa, and 500 mL/kPa. The tidal volume of 500 mL was calibrated and the results are shown in Table 7, from which it can be observed that the measurement result of the tidal volume increases with the compliance at the calibration point of 500 mL for all ventilators.

## 4 Filter

The filter is used to reduce particles and condensed water. The filter is usually required to be installed between the ventilator and the inlet of the ventilator tester in order to protect internal sensors. As a consumable device, its ventilation performance varies with time and the purity of passing gas flow. Thus, the calibration result of the tidal volume is also influenced by the filter. It is recommended that filters with adequate ventilation performance should be installed in the airway when calibrating ventilators.

Table 5: Results of tidal volume of the same ventilator

Nominal tidal volume (mL)	Compliance (mL/kPa)	Tidal volume (mL)			
		1	2	3	Averaged value
400	100	371	371	372	371
	200	401	400	401	401
	500	410	410	410	410
500	100	401	400	401	401
	200	517	515	516	516
	500	531	530	531	531
600	100	422	423	424	423
	200	595	595	595	595
	500	643	644	643	643



Table 6: Calibration results of three ventilators at a calibration point of 500 mL

Time	Compliance (mL/kPa)	Tidal volume (mL)			Averaged value
		1	2	3	
1st week	100	401	400	401	401
	200	517	515	516	516
	500	531	530	531	531
2nd week	100	394	393	394	394
	200	505	506	506	506
	500	538	539	538	538
3rd week	100	399	398	399	399
	200	510	510	511	510
	500	540	540	540	540
4th week	100	403	404	405	404
	200	511	510	509	510
	500	535	536	535	535

Table 7: Results of tidal volume of different ventilators

Model of ventilator	Compliance (mL/kPa)	Tidal volume (mL)			Averaged value
		1	2	3	
Fabius plus XL	100	401	400	401	401
	200	517	515	516	516
	500	531	530	531	531
Servo-s	100	444	444	444	444
	200	518	518	518	518
	500	545	545	545	545
840	100	370	370	371	370
	200	521	520	522	522
	500	540	540	540	540

## 5 Conclusions

It is necessary to calibrate ventilators periodically to ensure the accuracy of their output parameters such as the tidal volume and the oxygen concentration. The influence of ventilator testers and test lungs on the calibration results of the tidal volume and the oxygen concentration were investigated by experiments. In order to reduce the measurement error, it is recommended that:

- 1) The correction mode should be set to be the same as the ventilator. The gas type should also be set correctly;
- 2) The compliance of the test lung should be set according to the recommendation in IEC 60601.2.12:2009;
- 3) The oxygen sensor should be within its life span and calibrated with standard gases before use;
- 4) The filter should be in good condition and have adequate ventilation performance.

Ventilators are high risk medical devices and the accuracy of the output parameters is crucial to patients' life safety. Periodical calibration is a necessary and useful method to ensure their quality within the life span. Considering the high risk level, it is suggested that the OIML may consider drafting a Recommendation or Document to serve as a guideline for quality management of ventilators. ■

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## HEALTH

## Pandemic response in Austria: establishing a full testing and certification infrastructure for particle filtering half masks

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### Abstract

During the COVID-19 global pandemic, wearing masks is one of several strategies employed to reduce disease transmission. Particle filtering half masks can reduce concentrations of aerosol particles breathed in by the wearer by 90 % or more. However, proper product testing, certification and designation are crucial to ensure that users can recognize and trust a mask that will offer this level of protection. As part of Austria's response to the pandemic, the Federal Office of Metrology and Surveying ("Bundesamt für Eich- und Vermessungswesen", BEV) established both a new testing laboratory and a notified body for certification of particle filtering half masks within a remarkably short time. This article gives a short introduction on selected physical concepts underlying the functionality of particle filtering half masks, as well as a brief outline of how they are tested and certified in the European Union. Finally, the article presents the path taken by BEV, from the first mask testing setup to the fully operational testing and certification infrastructure in place today.

## 1 Introduction

### 1.1 Particle filtering half masks – an important part of pandemic response strategies

Face masks have been used as part of the COVID-19 pandemic response strategy in many countries, following recommendations of the World Health Organization

or other authorities. Masks can be beneficial in two ways: first, they can protect the wearer from inhaling droplets and aerosol particles containing the SARS-CoV-2 virus; second, they can prevent droplets ejected by the wearer from entering the surrounding air, thus protecting others. Such droplets are known agents of disease transmission, however, viruses, including the SARS-CoV-2 virus, are found in the much smaller aerosol particles as well [1,2,3].

Three general kinds of masks have been most commonly in use during the pandemic: medical masks, cloth/fabric masks, and particle-filtering half masks. Medical (surgical) masks are standardized and protect the wearer from droplets, sprays, and splatters, as well as protecting others from droplets emitted from the wearer's mouth. Reusable cloth masks are often not produced to specific standards (efforts towards standardization have been made [4]), sport a large variety of designs and materials, and attempt to serve roughly the same purpose as a medical mask (with mixed success). Both medical and cloth masks do not protect very well against aerosol particles, for reasons outlined in *Section 1.2*. Particle-filtering half masks (also called "particle filtering respirators", "filtering face piece respirators (FFR)", or, depending on the regulating standard, "FFP2 masks" and "FFP3 masks", or "N95 respirators") are standardized and regulated. They filter the air breathed by the wearer, reducing the exposure to ambient aerosol particles. Provided they do not have an exhalation valve (through which the exhaled air escapes without any filtering), they also protect others from exhaled droplets and aerosol particles. The three types of masks and their use in protecting against aerosol particles are summarized in *Table 1*.

In the ongoing pandemic, official recommendations have often reserved particle filtering half masks for special procedures in health care [5]. In practice, they have been used far more widely. Depending on the time, pandemic situation and country, rules and recommendations on wearing face masks in different settings have ranged from recommendations to cover mouth and nose with any cloth mask (or even just a scarf), to medical mask requirements, to mandatory use of particle filtering half masks. For example, in Austria, in the period between 25 January and 1 July 2021, particle filtering half masks have been mandatory for the general public in businesses, public transport, and other public locations.

A particle filtering half mask covers the nose, mouth, and chin. The face piece is typically made entirely (or substantially) of filter material; it could also be a face piece with main filter(s) as an integral part of the device that cannot be removed or exchanged. Often, an easily bendable metal piece is worked into the mask, to be molded by the wearer to fit snugly across the bridge of their nose. The face piece may also have an exhalation

Table 1: Types of masks and their suitability for reliable protection from aerosol particles

Protection from aerosol particles	Protects wearer	Protects others
Particle filtering half mask without exhalation valve	Yes	Yes
Particle filtering half mask with exhalation valve	Yes	No
Medical (surgical) masks	No	No
Cloth mask	No	No

valve. The mask is kept in place with a head harness consisting of ear loops or straps connecting on the back of the head. Masks may be packaged with additional devices, such as plastic hooks or other connection pieces, to allow adjustments for a snug fit. The filter material typically consists of three stacked materials, with the outer layers offering protection for the filtering inner layer. At first glance the design appears to be simple, an effective particle filtering half mask is actually a highly specialized product that cannot easily be replaced by other mask types or materials without compromising on the level of protection [6,7].

From visual inspection of the product alone, it is not possible to reliably distinguish a defective or ineffective mask from an effective one, and a certified product from a counterfeit. A reliable testing and certification process, including a specific designation of the masks, is therefore very important. *Section 1.3* describes how this is implemented in the European Union.

## 1.2 Particle-filtering half masks - basic physical principles

When speaking, singing, coughing, or sneezing, or even just breathing, humans produce droplets and aerosol particles [8,9,10]. Aerosol particles are defined as liquid or solid particles suspended in air. This definition includes droplets, as it makes no statement about how large a liquid particle must be to be considered a droplet. However, different scientific fields have sought to differentiate aerosol particles (remaining suspended) and droplets (thought of as falling down fast) using different size boundaries [9]. The pandemic has sparked a debate about these (sometimes rather arbitrary) size boundaries, as the scientific fields have come together to address the issue of possible transmission paths (which incidentally can defy size boundaries) [9,10,11]. A thorough discussion is beyond the scope of this article; for now, aerosol particles can be thought of as particles or small droplets that remain suspended in air for several minutes to many hours, with typical sizes ranging from just a few nanometers to several hundred micrometers.

A large fraction of aerosol particles is too small to be seen. There are many thousands, sometimes even tens or

hundreds of thousands of particles in every milliliter of air we breathe, many of them not causing (immediate) harm. They come from a variety of natural sources and human activities, such as fine windblown dust, sea spray, or engine exhaust. Aerosol particles exiting human mouths and respiratory tracts are but a tiny fraction of the total aerosol in most outdoor settings, but can accumulate indoors, especially in crowded spaces with poor ventilation [10]. Aerosol particles can contribute to the spreading of viruses [12]. Understanding how particle-filtering half masks protect against harmful (and, incidentally, also harmless) aerosol particles requires knowledge of their physical properties, which are sometimes a little counter-intuitive.

First, aerosol particles do not move through air like macroscopic objects. While large drops ejected in a cough or a sneeze can be imagined as moving like a tennis ball or a projectile, this visualization does not hold for aerosol particles. To them, air is viscous; first and foremost, the particles move with the airflow. There are some processes by which particles move relative to the air: larger particles (several hundred nanometers and above) may be removed from an accelerating or curved air flow by their own inertia. Very small particles of just a few (tens of) nanometers, under the bombardment of gas molecules on their surface, diffuse through Brownian motion. The distances covered by these processes are usually small, relevant for filtration (see below), but not for how an aerosol will distribute, say, in a seminar room or a restaurant; the air flow is more important. Particles do also fall, but against the enormous drag force described by Stokes' law. In still air, a particle with a diameter of 1 micrometer and the density of water takes over 7 hours to fall 1 meter, a 10 micrometer particle still takes 5 minutes, and a 0.1 micrometer particle would theoretically take over 300 hours. Most importantly, though, in everyday life situations, still air practically does not exist: turbulence, convection, and air flows ensure that much larger particles can stay suspended [9] and could easily travel the distances commonly recommended for infection prevention.

Aerosol particles exhaled by humans can have diameters down to 0.2 micrometers [14] (particle size is practically always given as the diameter of an equivalent sphere, an approximation that goes a long way, even if

some particles are not spherical). Whether a particle will sink faster or slower, diffuse to or impact on a surface, or get caught in a filter, is first and foremost governed by its size. This means that for filtration in a mask, it is irrelevant whether the particle is a soot particle, a droplet with or without viruses, or some other (mixture of) material(s). Over the course of their time suspended in air, the size of particles can change, for example through evaporation or condensation of water. Aerosols that are produced in the human lung or other parts of the respiratory tract, an environment that is usually more humid than the surrounding air, are exhaled and suspended in drier ambient air. As water evaporates from the aerosol particles, they shrink to a smaller size, increasing the time they will remain suspended. This also applies to droplets that would theoretically, in their original size, settle very quickly (in still air): they will evaporate (and have a lot of time to do so if the air is not still), and shrink until they become aerosol particles that can remain suspended for many hours.

Particle-filtering half masks reduce the number of inhaled aerosol particles through two main aspects of their design: a) filtration efficiency of the material and b) the seal between the mask and the wearer's face.

As for the filtration, it is interesting to note that particle filters do not work like sieves (separating objects larger than the openings of the sieve from objects that are smaller). Rather, particles get removed from the air by several different processes (Figure 1): Very small particles migrate to the closest filter fiber due to their Brownian motion (diffusion). Larger particles may impact on a filter fiber because their own inertia does not allow them to follow the streamlines of the air flow (impaction). A particle can also simply get caught by a filter fiber because of its geometric extent (interception). Finally, electrostatic forces can be a very effective and important factor. Once an aerosol particle is stuck to a filter fiber, it will not get removed, as it would take extremely large forces to overcome the adhesion. Each of these mechanisms is more effective in one particle size range than in another (Figure 2): while impaction and interception are the most important mechanisms for particles larger than a few hundred nanometers, diffusion is the dominant process for particles smaller than 100 nanometers. In between, typically in the range between 0.1 micrometers and 0.5 micrometers, all three of these mechanisms are less effective. In this size range, for every filter material and air flow velocity, there is a most penetrating particle size, the size at which filter collection efficiency reaches a minimum: if filter penetration is tested for this size, it can be assumed that the filter will work as well or better for both larger and smaller particle sizes.

As for the seal around the wearer's face, its importance can hardly be overstated. The filter material may be highly effective (as can be the case for surgical masks

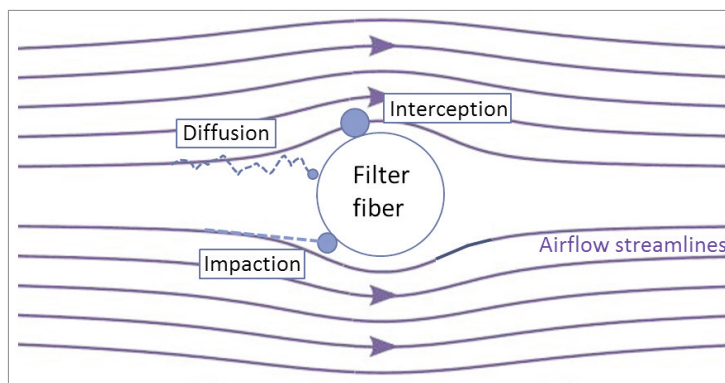


Figure 1: Conceptual drawing for the filtration processes diffusion, interception, and impaction on a filter fiber (Streamline image from Wikimedia Commons [13], adapted)

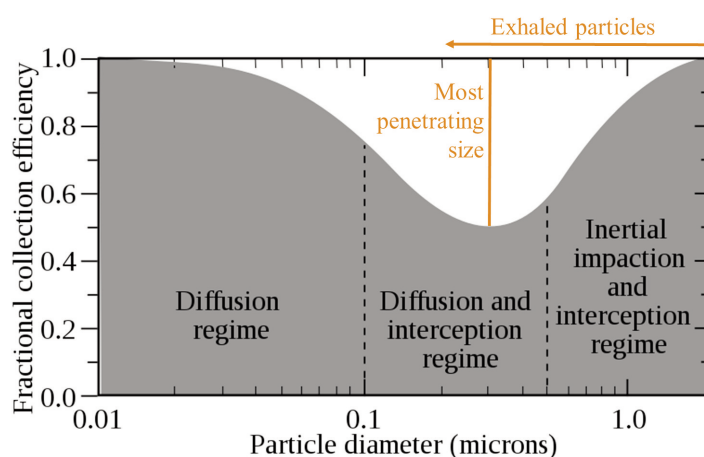


Figure 2: Filter collection efficiency vs. particle size, most effective filtering mechanism for three size ranges, most penetrating particle size, and size range of exhaled particles (Figure from NIOSH [15], adapted)

[6]), but for the filter to do its job, all the air breathed needs to pass through it. A loosely fitting mask (as surgical masks often are) cannot effectively protect against aerosol particles because much of the air will move around the mask, following the path of least resistance, and the vast majority of aerosol particles will follow. Even the smallest leaks can reduce the efficiency of a filter piece considerably: Drewnick et al., for example, found a 50 % decrease in filtration efficiency for a leak of just 1 % of the filter area [6]. While the filter collection efficiency (Figure 2) is a matter of the filter material, the fit is a matter of mask and head harness design, individual facial features, and also proper donning. A suboptimal mask design will not provide a leak-proof fit for most wearers, whereas even a good design may still not fit some individuals, who may then have to opt for a different mask design. In professional settings, special training, fit checking or fit testing may be offered or even required – a review of the importance



of fit testing in the context of the current pandemic is given by Regli et al. [16].

It must be noted that while viruses, including the SARS-CoV-2 virus [1,2,3], have been found in droplets and exhaled particles, the actual amount of virus-containing aerosol that needs to be inhaled for effective transmission of the disease, and the importance of this transmission path in the COVID-19 pandemic is a matter of ongoing research [9,17,18,19,20]. Under the impression of the pandemic, however, many governments, institutions, and individuals wish to be on the “safe side”, so the demand for particle-filtering half masks remains high.

### 1.3 European certification system for particle-filtering half masks

A particle-filtering half mask introduced to the European market as personal protective equipment (PPE) must fulfill the essential health and safety requirements of the European regulation (EU) 2016/425 on personal protective equipment. In this regulation, particle filtering half masks are classified as products protecting against risks of category III: “risks that may cause very serious consequences such as death or irreversible damage to health” [21]. The Directive specifies that for this category, a manufacturer must go through a strict conformity assessment procedure in cooperation with a notified body. The procedure consists of a type examination (“module B”) followed by controls on the subsequent production for conformity to the type (“module C2” - internal production control in combination with supervised product checks, or “module D” - quality assurance of the production process through audits).

The type examination is passed smoothly if the mask is produced and successfully tested according to the harmonized standard EN 149:2001 + A1:2009 [22] (“EN 149”, for short), which includes a suite of examinations and rigorous metrological tests. The origin of this standard is in workplace safety, i.e., its original goal is not necessarily protection against infectious disease, but

against industrial dusts, mists, or other unhealthy particulate emissions found in various work environments. EN 149 defines three types of “FFP (filtering face piece) masks”, which offer different levels of protection, according to the performance requirements given in *Table 2*. An overview of mask properties subject to testing is given in *Table 3*. The tests are performed on a number of samples of the mask type, some of which have undergone one or more types of prior treatment: temperature cycles, mechanical strength conditioning, flow conditioning, or simulated wearing treatment. While the list in *Table 3* is not exhaustive, it does give an impression of the level of scrutiny exercised before a particle-filtering half mask type is approved.

In addition to thorough examination and testing of the materials, there are several tests that involve human subjects (see also *Section 2.3*). Since particle-filtering half masks have recently been used in a much larger range of settings than various controlled workplace environments, it is important to note that the test persons and test design do not necessarily represent the public at large and all their activities: first, the standard states that test persons are to be selected who are already familiar with the use of this type of equipment. Second, the activities performed by the test persons are intended to simulate typical work situations; the standard also refers to “shifts” in the context of continuous wearing duration and reusability. For total inward leakage, all test persons are required to be clean-shaven, as facial hair impedes the formation of a tight seal between face and mask (the standard requires this to be noted in the mask’s information brochure). Also, all test persons are adults: as has been stated in PPE-R/02.049, the standards were “not written with consideration of the requirements of children” [23].

After passing the tests and evaluation by the notified body, a type examination certificate is issued. The manufacturer may now affix the specified CE marking on the masks and their packaging (*Figure 3*) and introduce them to the European market. Throughout production, the conformity to type is under continuing supervision by the notified body through module D or C2, as described above.

Table 2: Performance requirements for the three classes of FFP masks

Maximum permitted values	FFP1	FFP2	FFP3
Penetration of filter material in %	20	6	1
Inward leakage in % (individual result)	25	11	5
Breathing resistance (inhalation at 95 L/min) in mbar	2.1	2.4	3.0
Carbon dioxide content of the inhalation air in %	1	1	1

Table 3: Overview of testing requirements in EN 149

Test setup	Examination content
Visual inspection	Packaging suitable, information brochure complete, designations correct, any visible damage?
Material	Mechanical failure of materials?
Practical performance/field of vision/compatibility with skin	Wearable, field of vision sufficient, air flow through gaps between face and mask, adverse skin reactions?
Head harness	Robust, holding mask firmly in position?
Total inward leakage	Inward leakage of sodium chloride aerosol through mask worn by test person: below maximum permitted value?
Penetration of filter material (sodium chloride aerosol)	Sodium chloride aerosol penetration of filter material below maximum permitted value?
Penetration of filter material (paraffin aerosol)	Paraffin aerosol penetration of filter material below maximum permitted value?
Flammability	Mask material flammable?
Carbon dioxide content of the inhalation air	Carbon dioxide content of inhalation air below maximum permitted value?
Exhalation valve	Functional and robust?
Breathing resistance	Breathing resistance below maximum permitted value?
Clogging	Breathing resistance and penetration below permitted value after clogging with mineral dust?

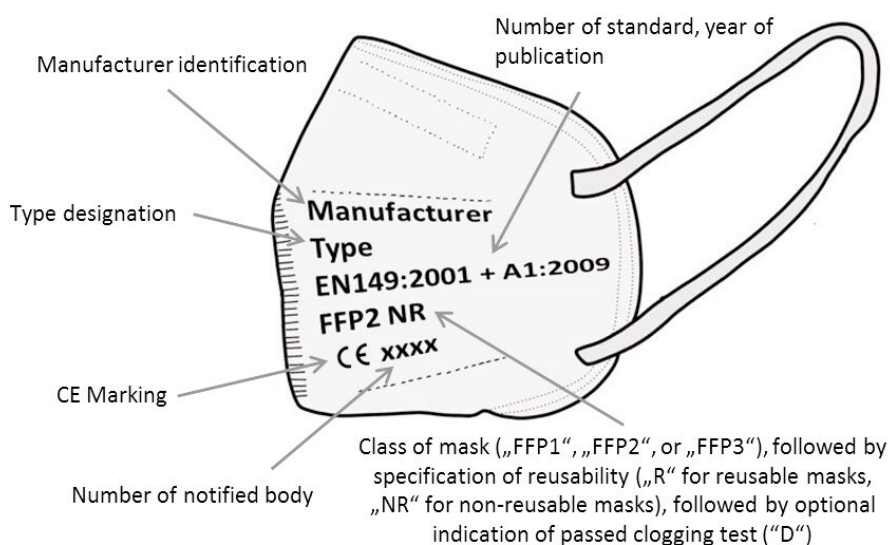


Figure 3: Correct European conformity designation on a particle-filtering half mask

## 2 Testing laboratory for particle-filtering half masks

### 2.1 A new lab within a week: CPA testing

When the SARS-CoV-2 pandemic reached Europe (including Austria, in late February 2020), the need for particle-filtering half masks increased rapidly. Shortages ensued, not only of the masks, but also of testing and certification possibilities. Masks were imported from overseas; however, they were often produced to different technical standards and lacked European certification, limiting their official uses. Also, some lots were found to be lacking in quality and effectiveness. Meanwhile, local Austrian producers responded proactively by ramping up mask production or setting up completely new production branches. They were impeded not only by technical challenges, but also by the fact that testing laboratories and certification authorities were severely overburdened in all European countries.

To alleviate this situation, a shortened testing principle for Corona SARS-CoV-2 pandemic respiratory masks (“CPA masks”) based on selected tests from EN 149:2001 + A1:2009 (“CPA testing”) was devised with its legal basis in the Recommendation (EU) 2020/403 from 13 March 2020 [24]. This testing procedure was approved in Austria through an order of the Federal Ministry for Digital and Economic Affairs (BMDW GZ 2020-0.198.830) [25]: if part of a governmental buying process supplying medical professionals, particle-filtering half masks without CE marking and the underlying

certification procedures could be used after successfully passing CPA testing. On 21 March 2020, BEV received the official task to set up a laboratory capable of performing the CPA testing procedure, with a thoroughly ambitious deadline of just one week. Through a fortunate concurrence of organizational talent, specialized knowledge, and good contacts to the University of Vienna (the Aerosol and Environmental Physics group provided help and instrumentation at very short notice), BEV was able to comply: a setup for CPA testing was completed within just ten days. The first mask was tested on 30 March 2020, and it was not the last one: over the course of the following six months, the laboratory processed almost 8000 CPA masks.

### 2.2 A laboratory infrastructure within four months: building the EN 149 mask testing laboratory

With the CPA setup soon operating at full capacity, BEV began to build the laboratory infrastructure for the full suite of 18 tests required in EN 149:2001 + A1:2009. The goal was to be fully operational within just a few months (see also *Figure 4*), because CPA testing was temporary and contingent on the emergency situation. BEV had both the technical and the legal expertise to bring the mask testing laboratory into existence, but doing the actual work in the pre-assigned time frame was a major undertaking.

First, it took a fast-moving, well-organized and highly effective management. Practically all available resources were focused on the parallel, and equally

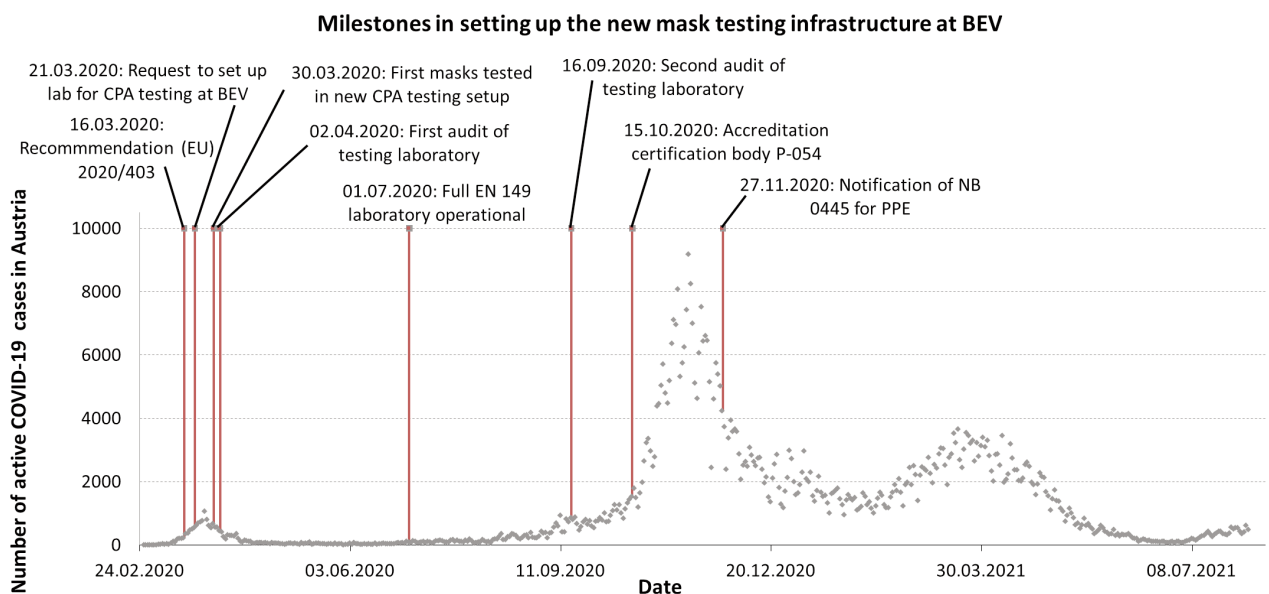


Figure 4: Timeline of the setup of the mask testing and certification infrastructure at BEV (data on active COVID-19 cases from BMSGPK [26])



urgent tasks of a) building the labs, b) ongoing CPA testing, and c) integration of mask testing into the organization. BEV's normal day-to-day business was reduced to the bare necessary minimum. A maximum of flexibility and effort was required from employees to work effectively on completely new projects that had "fallen into their laps", without much chance of prior planning or preparation. Moreover, the pandemic situation in spring of 2020 was still one of a strict lockdown without widely available testing for SARS-CoV-2: personnel on site was reduced, as vulnerable employees were required to stay home, and a rigorous time table with strictly separated teams (and backup teams in case of illness or quarantine) was devised for all laboratory tasks. Experimental setups and organizational structures were planned in phone calls and web meetings. Last but not least, new personnel with appropriate background had to be found and hired, for running the lab after the current employees returned to their old jobs.

The short deadlines posed a particular challenge for the purchase and setup of new laboratory equipment: specialized instrumentation and equipment with long delivery times even under normal circumstances needed to be procured immediately, fast decisions needed to be made to buy "the last two units in stock" or "our only demo model". Sometimes, imagination, improvisational talent, and the highly capable machine workshop saved the day. New setups need space, which had to be found, cleared, and remodeled to meet specific requirements such as ventilation systems or pressurized air supply. For some of the setups, there were steep learning curves: interpreting the requirements of the European standard correctly and finding suitable components, or devising traceability strategies for complicated measurands such as aerosol particle concentration or size distributions. Just like with any new measurement setup, intense testing was required, of both hardware and newly written software, with all the setbacks and difficulties to be expected on the way to the final success that is a working test rig. Last but not least, the test rigs needed to be not only working, but also working correctly and reliably: all measurement instruments used had to go through traceable calibration – a (relatively) easy "in house" task for some, and a tricky challenge for others.

Setting up procedures and workflows was no small task either: All requirements had to be fully understood and implemented. The use of laboratory time, work time, and samples needed to be optimized while avoiding any possibility of confusion. New laboratory manuals, forms, and reporting documents needed to be written and integrated into the quality management system. The processing of the new kind of orders needed to be integrated into BEV's existing transaction system "on the fly", as orders were arriving continuously and multiple urgent customer requests were attended to

every single day. Also, a close eye had to be kept on possible changes in the legal situation (both for the mask testing itself and for the general lockdown regulations) due to the highly dynamic pandemic situation.

In the end, the hard work paid off: On 1 July 2020, the new laboratory was operational and the first CPA setup dismantled. The mask testing laboratory was successfully audited on 2 April and 16 September 2020. Since then, the laboratory has been a lively and prosperous part of BEV, continuing to contribute its part to fighting the SARS-CoV-2 pandemic in Austria. With the legal basis for CPA testing expired, much of the day-to-day business now comprises partial testing for new products in development, or for buyers of masks wishing to reassure themselves of the quality of their purchase, but also the full testing suite of EN 149:2001 + A1:2009 for products undergoing conformity assessment. Additionally, the laboratory has been participating in a considerable number of comparison measurements with similar laboratories, old and new, across Europe.

### 2.3 The fully operational mask testing laboratory - a technical glimpse

Some of the more complex setups required by EN 149 involve the testing of masks for transmission, total inward leakage, and clogging, using defined test aerosols. In this section, the setup for total inward leakage testing is briefly introduced. It combines two critical aspects of a mask's effectiveness for protecting against aerosol particles (see also *Section 1.2*): a) filtration efficiency and b) the leak tightness of the seal between the mask and the wearer's face. The leakage is determined while the mask is worn by a moving test person exposed to sodium chloride (NaCl) aerosol.

The setup, shown in a schematic sketch in *Figure 5*, consists of a large aerosol chamber (1) equipped with a treadmill (2), an aerosol generation system (3, 4, 5, see also below), and an outlet (7) for measurement of NaCl concentration (8) and particle size distribution (9) of the test aerosol. The mask under test is prepared with inlet tubing for measurement of differential pressure (11) and for NaCl concentration between the mask and the wearer's mouth (10). The differential pressure measurement serves to distinguish inhalation from exhalation. A test person (12) wearing the prepared mask enters the chamber. NaCl aerosol is generated (3), dried (4), mixed with clean, dry compressed air (5), and passes into the aerosol chamber (6). While the test person performs a prescribed sequence of five different motions, such as walking, moving their head, or speaking, the NaCl concentration between the mask and the wearer's mouth is measured. The total inward leakage is calculated as

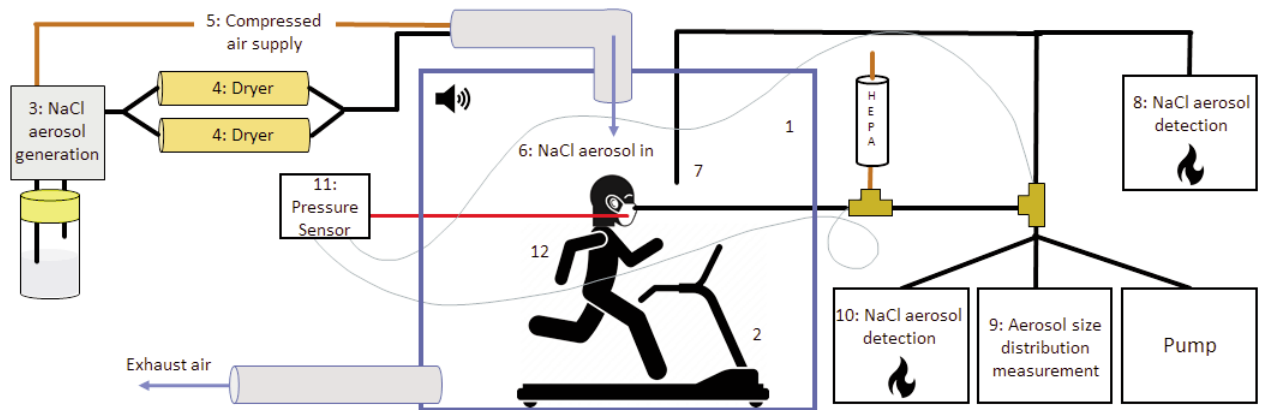


Figure 5: Schematic sketch of the test setup for total inward leakage testing

the ratio of the NaCl concentration behind the mask, and the NaCl concentration in the chamber close to the wearer's head, for inhalation only. The test sequence is performed with ten different test persons, yielding a total of 50 individual measurements. On an FFP2 mask type, total inward leakage may not exceed 11 % for more than 4 out of the 50 individual measurements (see also *Table 2*). Additionally, there is a requirement on the averages: the arithmetic mean over a test sequence may not exceed 8 % for more than two test persons.

The technical challenges of this setup include the production of NaCl aerosol particles in a large enough quantity to supply the chamber, maintaining a stable aerosol particle concentration and size distribution in time and space, and the integration of individual physiological differences into the test evaluation. The latter is addressed by choosing a range of face types determined by measuring and categorizing facial dimensions, usually according to ISO/TS 16976-2 [27].

An example illustrating the importance of the total inward leakage test is shown in *Figures 6* and *7*. These graphs are partial results of a comparison measurement on an FFP2 mask type with five participating laboratories. *Figure 6* shows the results of the NaCl penetration measurement for 9 masks of the same type with different prior conditioning. It can easily be seen that the filter material was impeccable: the maximum permitted value of 6 % penetration was far from being reached. The results for total inward leakage for the same mask type shown in *Figure 7* (results of only three runs shown for readability) give a rather different impression. The maximum permitted value of 11 % is exceeded in 20 individual measurements. The most obvious conclusion to draw from this is that good filter material does not guarantee good protection against particles - a good, comfortable and leak-proof fit is essential. As discussed in *Section 1.2*, there is an

interplay of mask design and individual wearer; however, passing the total inward leakage test is essential before placing the mask on the European market.

### 3 Notified body NB 0445 for personal protective equipment

In light of the unpredictable dynamic of the ongoing pandemic, but also in the general spirit of preparedness, the continuing existence of not only a mask testing laboratory, but also a certification body, was recognized as part of Austria's critical infrastructure. The establishment of a new independent certification body at BEV (alongside the existing NB 0445 for the Measuring Instruments Directive 2014/32/EU and Directive 2014/31/EU on non-automatic weighing instruments) was also launched in spring 2020, alongside the construction of the mask testing laboratory, and completed by the end of the year.

The establishment of the certification body and its placement within the existing structure of BEV required several steps: first, the legal and procedural requirements had to be researched and implemented, all the procedures had to be defined, and personnel had to be trained. After three months, the certification body P-054 for particle filtering half masks according to ISO/IEC 17065 applied for accreditation to the Slovak National Accreditation Service (Slovenská Národná Akreditacia Sluzba). The accreditation audit took place on 14 and 15 October 2020 and was a success: P-054 proved a high level of organization, expertise, and independence, as well as a sound quality management structure.

Finally, a request for notification as notified body for respiratory protective devices (particle filtering half

masks) for appendix V and VII of the EU Directive 2016/425 on personal protective equipment was filed. The subsequent evaluation assessed the certification body's technical expertise and ability to conduct the conformity assessment procedure (module B and C2), as well as its independence, impartiality, and integrity. The assessment was positive, and the notification was

effective on 27 November 2020. The NB 0445 can be found in the European database<sup>28</sup> of notified bodies (Nando) with a new entry for "Regulation (EU) 2016/425 Personal protective equipment". With both a notified body for personal protective equipment, and a working testing laboratory, an important part of Austria's strategy to fight the SARS-CoV-2 pandemic is completed.

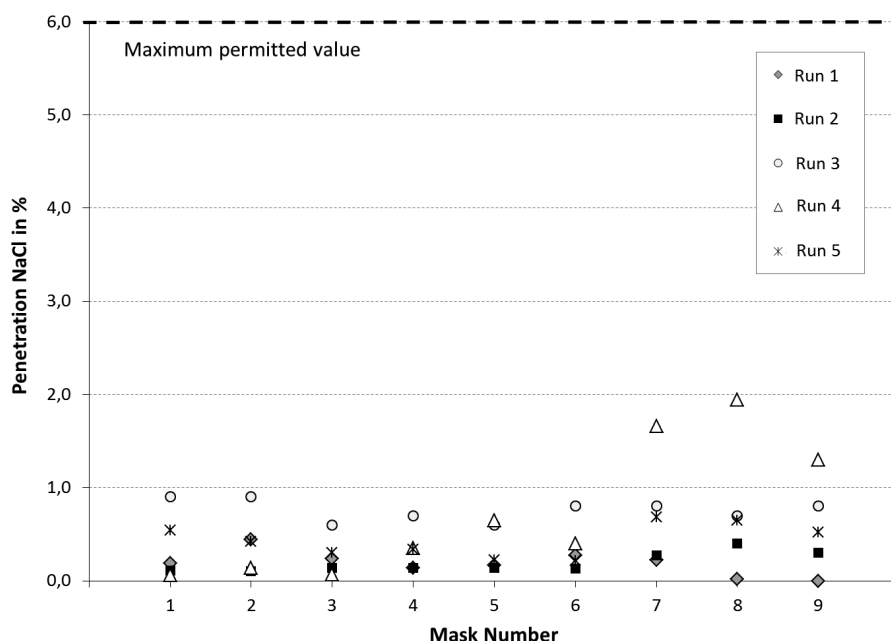


Figure 6: Results of NaCl penetration test: 5 runs of 9 masks each with different prior conditioning

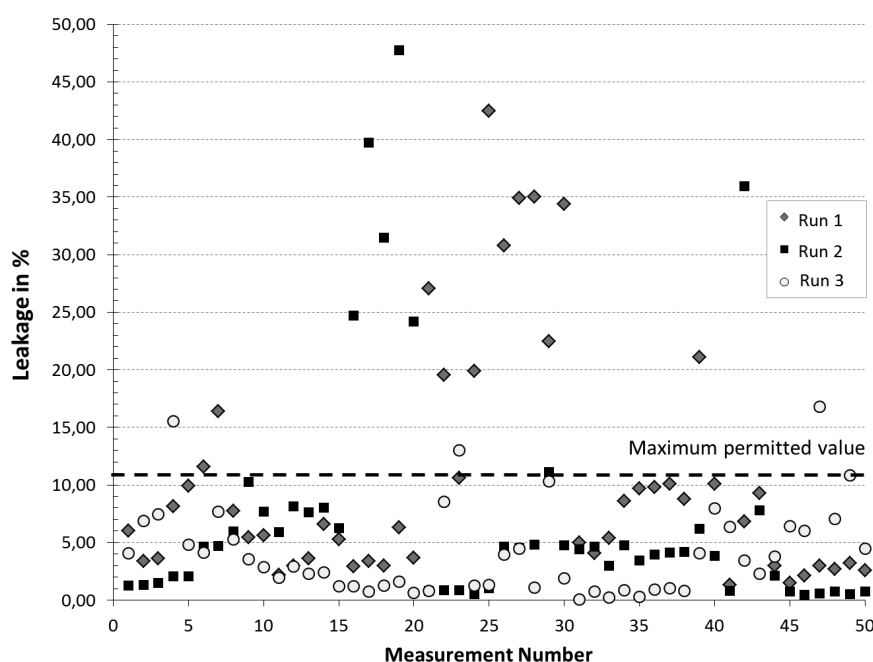


Figure 7: Results of the total inward leakage test - three runs, each consisting of 50 measurements: 10 test persons, each performing 5 defined sequences of movements

## 4 Concluding remarks

Particle filtering half masks are an important component of fighting the COVID-19 pandemic and minimizing possible transmission paths. Reliable testing and certification of the masks is essential. The success of establishing a full mask testing infrastructure at BEV within only 8 months has been made possible by a combination of fortunate factors: the concurrence of very specific legal and specialized technical expertise, political will, effective and fast management, and a diligent, competent, and motivated work force. The extraordinary circumstances of the SARS-CoV-2 pandemic fostered a general sense of solidarity and mutual support not only within BEV, but also extending to

manufacturers of instrumentation and expert institutions. BEV harnessed the power of combining and concentrating all forces to come to a fast, successful, and sustainable result, serving society in helping to resolve the present crisis and be better prepared for the future. ■

## Acknowledgements

The contributions of Jürgen Gratzl, MSc (Figure 5 and technical input) and Maida Dedovic, BSc (plot of active cases and milestones in Figure 4) are gratefully acknowledged.

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## SAMPLING

# A sound basis for MID acceptance sampling: executive summary

CORD A. MÜLLER

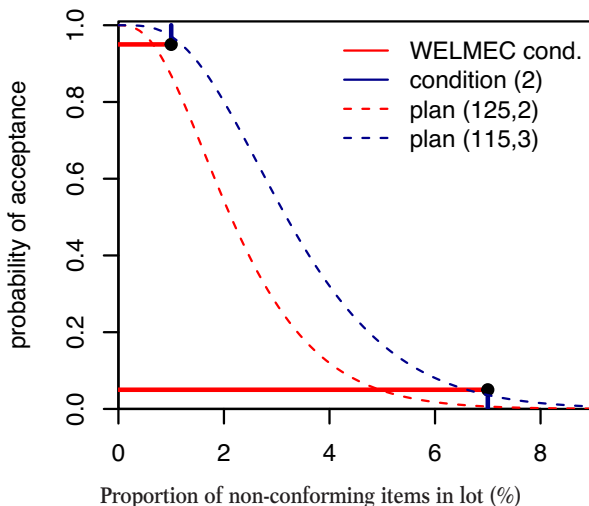
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## Abstract

The European Measuring Instruments Directive 2014/32/EU (MID) allows for statistical product verification. The conditions formulated in the conformity assessment modules F and F1 require a mathematical interpretation before sampling plans can be computed and used in practice. We find conceptual and practical shortcomings for the prevalent interpretation in WELMEC Guide 8.10 and propose a revision featuring sound and efficient sampling plans. Furthermore, we recommend a clarifying reformulation of the MID.



(a) WELMEC condition (1) and alternative condition (2) (thick red and blue line, respectively, attached to the MID points), and OCs of admissible sampling plans (dashed lines).

## The status quo and its shortcomings

The conformity assessment modules F and F1 of the MID require the sampling system to ensure the following two, mathematically somewhat imprecise conditions:

- “(a) a level of quality corresponding to a probability of acceptance of 95 %, with a non-conformity of less than 1 %;
- (b) a limit quality corresponding to a probability of acceptance of 5 %, with a non-conformity of less than 7 %.”

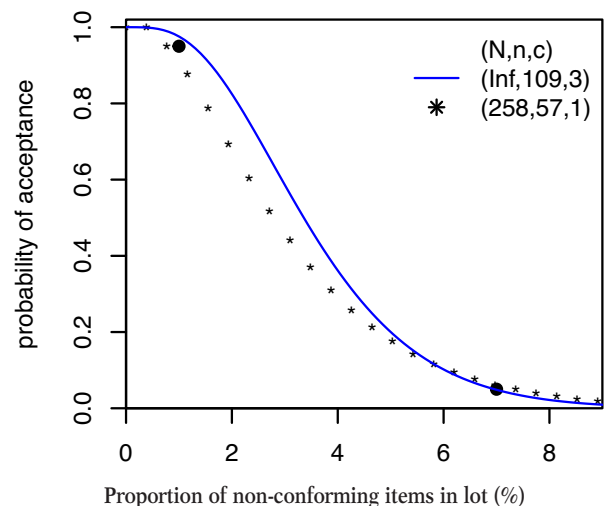
The performance of a sampling plan is visualised by its operating characteristic (OC), showing the acceptance probability as a function of the quality level (percentage of nonconforming products in the lot), see Figure 1a. WELMEC Guide 8.10 interprets the MID conditions (a) and (b) as follows:

“The OC curves have to be on the left hand side of the points mentioned”, (1)

referring to the points (1 %, 95 %) and (7 %, 5 %) of acceptable and limiting quality, respectively, displayed as black dots in Figure 1a. Any OC curve passing through the thick red lines in Figure 1a (such as the dashed red curve) fulfils the WELMEC condition (1).

This interpretation entails several shortcomings:

- The rejection probability of a lot with an acceptable quality level (AQL) of  $p = 1\%$  is at least 5 %. Thus, the producers are not protected against so-called type I



(b) OC of two optimal sampling plans – plan (109; 3) for infinite lot size and plan (57; 1) for lot size  $N = 258$  – as generated by the hypothesis test (3).

Figure 1: Operating characteristics and MID conditions

errors of rejecting good-quality lots (whereas the consumers' risk is bounded by an acceptance probability of at most 5 % at a limiting quality level of 7 % or worse).

- For lots of finite size (always the case in modules F and F1), the OC is a set of discrete points, as shown in Figure 1b. The question whether such a given OC "curve" passes "to the left" of a given point or not is, therefore, ill-defined and cannot be answered without further assumptions.
- Full sampling (i.e. testing all items of the lot) does not always comply with the WELMEC condition (1), although it determines the quality level of the lot at hand with certainty.
- Setting only conditions of consumer-protection type violates the framework of a statistical hypothesis test, which guarantees that sampling plans are well-behaved functions of their input parameters.

These limitations, both conceptual and practical, call for an alternative approach.

## 2 Alternative, hypothesis-based interpretation

For large-size lots, we propose an alternative interpretation of the MID conditions:

"The OC curves of sampling plans have to pass above or through the point (1 %, 95 %), and below or through the point (7 %, 5 %)." (2)

Any curve passing through the short thick blue lines in Figure 1a fulfils this condition (such as the dashed blue curve). Note the qualitative difference to the WELMEC condition (1) regarding the AQL point (1 %, 95 %). Crucially, the interpretation (2) can be generalised to arbitrary lot sizes by formulating it as the hypothesis test

$$H_0: p \leq 1\%, H_A: p \geq 7\%, \text{ with type I and II error rates } \alpha, \beta \leq 5\%. \quad (3)$$

Here,  $H_0$  is the null hypothesis (acceptable quality) that can only be rejected in favour of the alternative hypothesis  $H_A$  (inacceptable quality) by sufficiently strong evidence. The hypothesis test (3) cures the above-mentioned shortcomings, because it

- bounds the risk of false decisions symmetrically from above and thus protects producers and consumers alike,
- provides unambiguous decisions for infinite as well as finite lot sizes,
- yields well-defined sampling plans with minimal sample sizes, and
- allows for full inspection, required especially for smaller lots.

Based on this approach, we have computed the smallest sample sizes as function of lot sizes, shown in Figure 2. We have also derived a nearly optimal, yet simple sampling system (see Figure 2 and Table 1) that is more efficient and statistically better behaved than the schemes identified previously. We therefore propose to include these sound and efficient acceptance sampling plans for the MID in a future revision of WELMEC Guide 8.10.

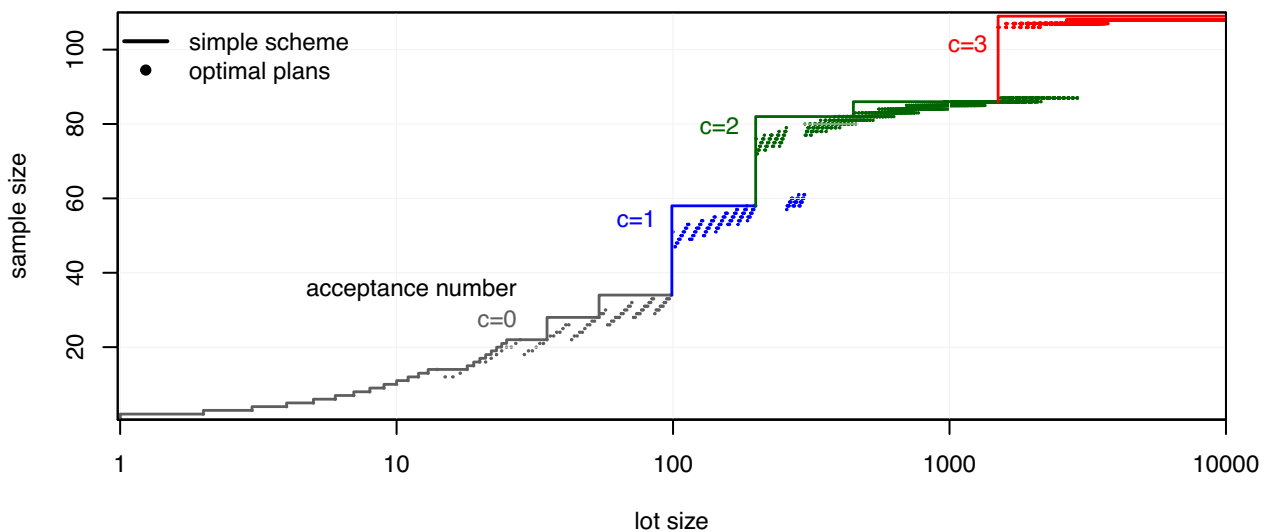


Figure 2: Optimal sampling plans (dots) and proposal for a simplified sampling scheme (solid line) as listed in Table 1

Table 1: Simplified, nearly optimal sampling scheme for hypothesis-based MID acceptance sampling.  
By construction, the producers' and consumers' risk never exceed 5 %

Lot size $N$		Sample		Producers' risk $\alpha$ [%]		Consumers' risk $\beta$ [%]	
from	to	$n$	$c$	from	to	from	to
1	14	$N$	0	0	0	0	0
15	18	14	0	0	0	0	3.92
19	25	$N-4$	0	0	0	2.00	3.51
26	35	22	0	0	0	0.96	4.37
36	54	28	0	0	0	0.78	4.73
55	99	34	0	0	0	0.93	4.68
100	199	58	1	0	0	1.00	4.84
200	449	82	2	0	2.85	1.97	4.96
450	1499	86	2	1.74	4.98	3.36	4.99
1500	$\infty$	109	3	1.55	2.43	4.07	4.85

Lastly, we recommend a clarifying reformulation of the MID with only a minor change in wording. All previously mentioned advantages are reached by formulating no. 5.3 in module F and no. 6.4 in module F1 as follows:

“The sampling system shall ensure:

- a probability of acceptance of *no less than 95 %* for levels of quality of 1 % non-conformity *and less*;
- a probability of acceptance of *no more than 5 %* for a limit quality of 7 % non-conformity *and more*.”

This minor modification (the few new or modified words are highlighted) eliminates the present deficiencies. Condition (a) now reflects the null hypothesis in test (3) with a type I error rate  $\alpha \leq 5 \%$ , and condition (b) the alternative hypothesis with a type II error rate  $\beta \leq 5 \%$ . Moreover, a future revision of the MID may

regulate the levels of risk or quality more flexibly to account for safety or economic aspects of measurement tasks.

Further details can be found in [1], including an interactive spreadsheet and a web app, which comprise the strictly minimal sample sizes shown in Figure 2.

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## HEALTH

## Proposal for improving metrological control in health

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### 1 Introduction

The main activity of the OIML is the development of Recommendations and Documents used in legal metrology. In this context, the OIML is the main standard-developing organization that contributes to the global harmonization of conformity assessment procedures [1].

The main type of publications developed and published by the OIML are International Recommendations, which aim to present a regulatory model that Member States are committed to implementing in their legal metrology systems [2].

In the field of health, the OIML has published 12 Recommendations. Although this number covers various types of measuring instruments, it represents a small share when compared to other standard-developing organizations. As an example, the series of ISO/IEC 60601/80601 standards comprises approximately 90 normative documents.

Therefore, it is necessary to reflect on the importance of legal metrology for health and how it can contribute to the development of the new paradigm presented by Health 4.0.

### 2 Health 4.0

Technological developments over the years have made it possible to expand the usefulness of the internet to almost all areas of human life. Recently, people are no longer the only users of the worldwide network and have started to share it with equipment that has a certain degree of autonomy to send and receive data from other

equipment. This was called the Internet of Things (IoT) which, driven by the development of Artificial Intelligence and Cyber Physical Systems, brought about a new industrial revolution, called Industry 4.0 [3].

This revolution has expanded to other sectors, reaching for example the healthcare environment, in what has come to be called Health 4.0. Basically, this new model of action focuses on virtualization to achieve a distributed healthcare system in which treatments are more personalized [4]. Examples of applications include Telemedicine, Virtual Home Care, Medical Adherence Tracking, Emergency Response Systems, and the near real-time updating of electronic patient records [5].

However, this paradigm shift depends on the successful implementation of non-invasive digital measurement technologies that comprise the activities of collecting physiological parameters that are useful for the diagnosis, treatment, and monitoring of patient health [6].

In the context of Health 4.0, this can be associated with wearables, which are measuring instruments carried by the patient with minimal discomfort, thanks to advances in miniaturization and the development of systems based on wireless sensors [5]. It is estimated that 700 million people already own wearables (including non-medical devices) and that this market will move around US\$70 billion in the next years [7,8].

In Brazil, 615.721 units of wearables such as fitbands and smartwatches were sold in the first quarter of 2021, pointing to an increase of 28 % compared to the same period in 2020. For 2021 and until 2024, the expectation is of double-digit annual growth, driven by increased health concerns in the COVID-19 pandemic. This behavior is expected to grow, including the companies themselves buying accessories for use by their employees [9].

The importance of this technology for Health 4.0 lies in the fact that every medical analysis and decision is based on the values measured by wearables. Therefore, the measurement error of this equipment can have a direct impact on health treatments and, consequently, it is necessary to ensure that it is maintained at acceptable levels.

In this sense, the metrological control model currently proposed by the OIML can be an effective tool. As an example, Figure 1 (see next page) shows the data referring to the type approval of sphygmomanometers carried out in Brazil by the National Institute of Metrology, Quality and Technology (INMETRO).

The graph shows that the failure rate over the past three years is approximately 50 %. Observing the causes of non-approval, it appears that the three most frequent ones refer to the clinical investigation report, the indication error, and the lack of electromagnetic compatibility, which are non-conformities that are difficult to detect by the users.

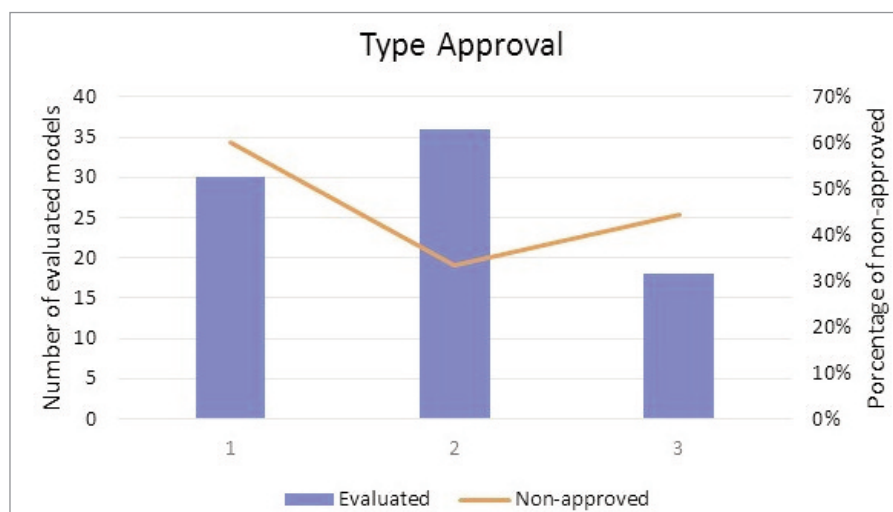


Figure 1 - Type approval in sphygmomanometers carried out by INMETRO

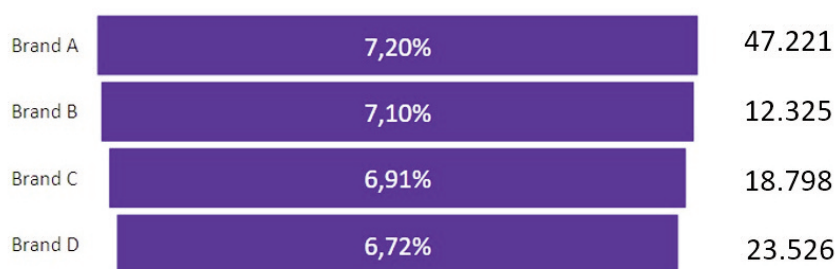


Figure 2 - Failure rate in verification of the most commercialized sphygmomanometer brands in Brazil

Another example concerns verification. Figure 2 shows the failure rate of the four most commercialized sphygmomanometer brands in Brazil. If the verifications were not carried out, these faulty instruments (1 in 14 instruments sold) would have a great impact on society, as many are used by numerous patients in clinics and hospitals.

However, the changes presented by Health 4.0 require that the metrological control be adjusted in order to maintain its effectiveness.

### 3 Proposal

The proposal presented in this article addresses two aspects of metrological control: how to control, and which instruments to control.

#### 3.1 How to control

First, it should be taken into account that Health 4.0 aims to decentralize healthcare, enabling the patient to be monitored and assisted wherever they may be. This means that there will be more measuring instruments in use and distributed, which makes the verification task more time-consuming and costly. To get around this, metrological control must have tools that allow for a more intelligent planning of the execution of activities. In Brazil, the digitalization of metrological control began in 2011 through the Integrated Management System (IMS). This technical and administrative control tool gathers all the relevant information on services provided and instruments under metrological control. The platform is accessed by metrological agents from the states and by administrators. Although it was designed to standardize the processes of the Brazilian

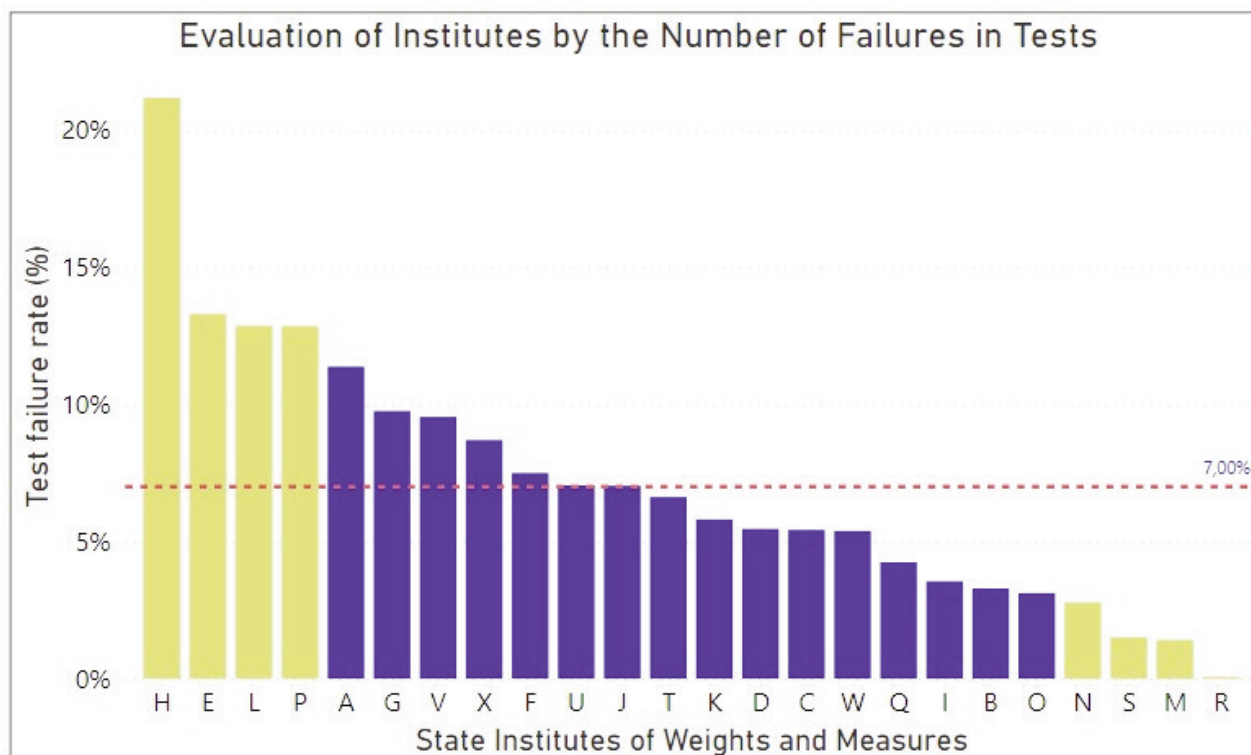


Figure 3 - Failure rate of sphygmomanometers at verification by state in Brazil

Network of Legal Metrology and Quality (RBMLQ-I) by supporting managers in strategic decisions [10], this platform can serve for technical data mining and its database can be used for processing in artificial intelligence.

Having a holistic view of the entire metrological control process will allow metrologists to reduce costs and increase the assertiveness of their performance, directing field work teams to act only on those points that showed some irregularity in the previous analysis by data processing. One example is the field inspection of fuel pumps, which require complex and time-consuming logistics, with location interdiction and this has a financial impact on the holder. Once you know the places that were previously classified as suspected of fraud, assertiveness will bring greater effectiveness in the inspection.

Another example is the percentage of sphygmomanometer failures by state in Brazil that appears in Figure 3. Average deviations can indicate problems with methodologies or traceability being applied, so states that are at the extremes of the pass or fail rate (in yellow) should be evaluated or audited. In addition, Table 1 shows the number of verifications carried out per year in each state, which allows service demand to be forecasted in order to plan training and acquire standards, for example.

The growing demand for initial verification and the reduction in human resources meant that INMETRO had to find alternatives to ensure that all sphygmomanometers were tested before entering the market. Companies were then authorized to declare conformity of their instruments in replacement of the initial verifications. Data from 2016 to 2020 show the quantity of declarations issued by authorized companies (Figure 4).

The number of declarations in 2020 reflects INMETRO's action in provisionally authorizing companies (data in yellow) since RBMLQ-I had to stop a number of activities due to the COVID-19 pandemic. As a result, the year 2020 had a reduction of only 2–3 % in tests of the total verifications and declarations of conformity compared to the previous year, showing a solid system against external fluctuations.

Stored data are also useful for predictive analytics such as determining the probability that an instrument will not fail over time (Figure 5). One of the next actions to be implemented is the detection of probable false statements made by companies through artificial intelligence, using a binary classification algorithm with machine learning of the data extracted from RBMLQ-I and random manipulation to generate true and false data, respectively.

Table 1 - Number of sphygmomanometer verifications carried out in each state in Brazil

Number of verifications per year						
Region	2016	2017	2018	2019	2020	Total
Midwest	235	179	1.108	901	320	<b>2.743</b>
Northeast	5.848	7.280	7.435	7.997	3.980	<b>32.540</b>
North	832	884	759	583	262	<b>3.320</b>
Southeast	10.243	14.227	22.473	37.611	15.235	<b>99.789</b>
South	10.788	5.274	5.676	8.296	2.668	<b>32.702</b>
<b>Total</b>	<b>27.946</b>	<b>27.844</b>	<b>37.451</b>	<b>55.388</b>	<b>22.465</b>	<b>171.094</b>

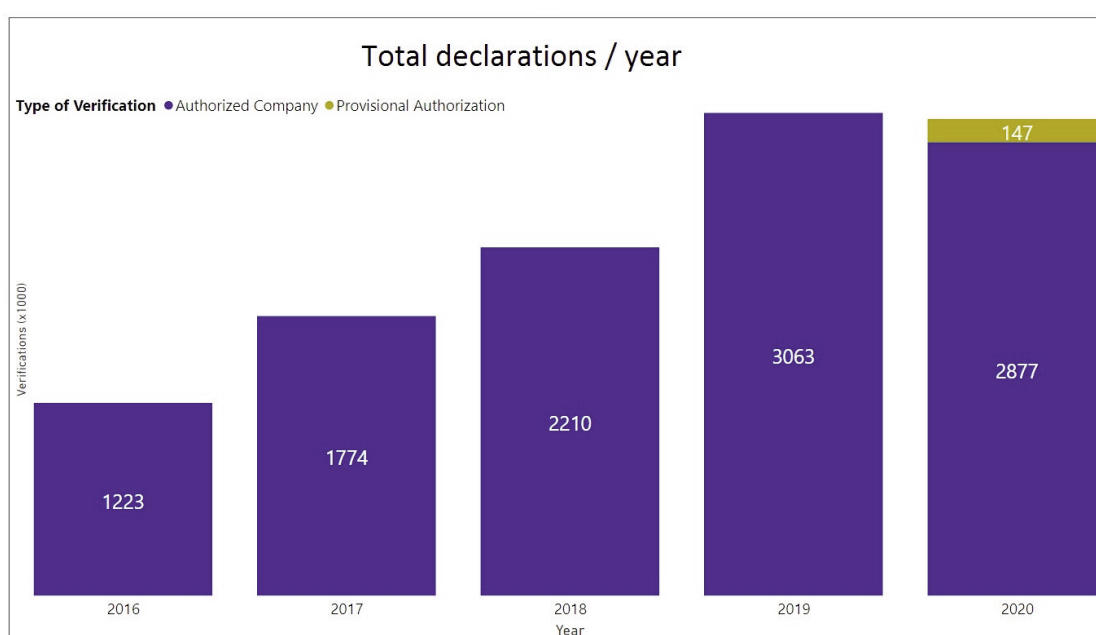


Figure 4 - Quantitative of declarations of conformity issued by authorized companies regarding sphygmomanometers

### 3.2 Which instruments to control

Regarding the scope of metrological control, it is necessary to consider the large number of physiological parameters that can be monitored. The application of legal metrology to all of them may be unnecessary, as it would result in excessive costs to society. Therefore, it is necessary to make a careful choice of the types of measuring instruments that will be submitted to metrological control.

A relevant criterion is the impact that diseases have on the population. Globally, chronic noncommunicable diseases (NCDs) represent 74 % of annual deaths and are responsible for more than 15 million premature deaths annually in the age group between 30 and 69 years of age. In low- and middle-income countries, they

account for 85 % of deaths that occur mainly due to the lack of testing and monitoring equipment needed for screening, diagnosis and treatment [11]. In this context, the World Health Organization (WHO) has published a document containing lists of priority medical devices in order to help health professionals implement interventions that are essential for the detection and management of NCDs throughout the continuous treatment, leading to fewer hospitalizations and deaths and the saving of health resources. Among this equipment, the document mentions sphygmomanometers, clinical thermometers, oximeters and glucometers [12].

In addition, the protocols applied in Primary Health Care (PHC) were revised to address situations of respiratory epidemics, such as the COVID-19 Pandemic, so that the first assessment carried out to identify flu syndrome symptoms comprises the checking for cough,

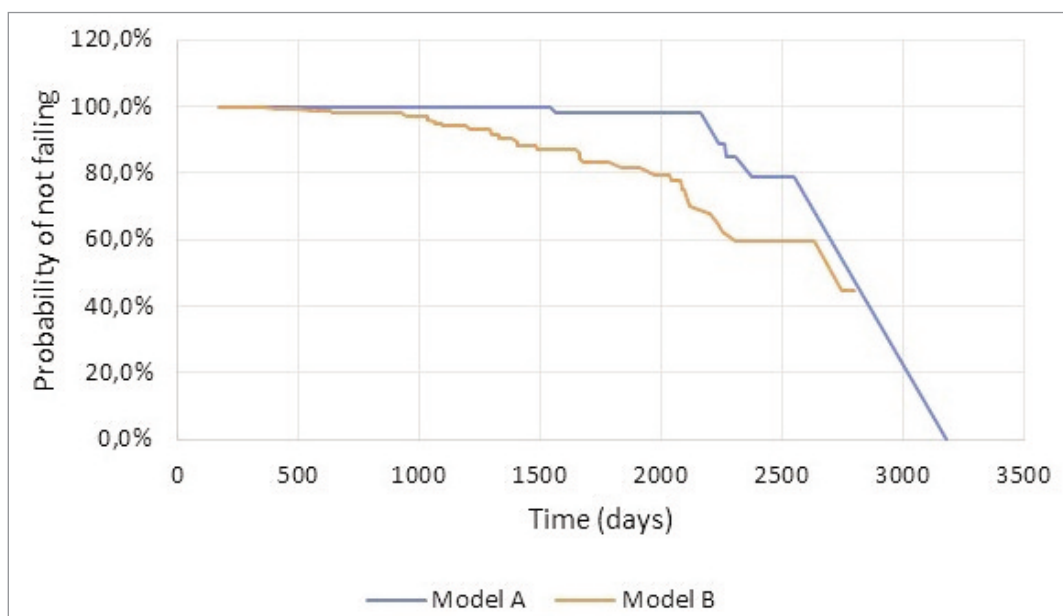


Figure 5 - Reliability curves of two sphygmomanometer models

sore throat, and difficulty in breathing, as well as detecting a body temperature greater than 37.8 °C. Patients with these symptoms and who have comorbidities, if they also present peripheral oxygen saturation (SpO<sub>2</sub>) less than 95 % in room air or hypotension, are classified as having a severe flu-like illness and are referred to a referral center of specialized care [13].

Thus, the importance of monitoring capillary blood glucose and blood pressure in the PHC of people with NCDs, as well as body temperature and SpO<sub>2</sub> measurements for identifying patients with severe flu-like illness, is evident. Although the OIML has Recommendations for the metrological control of clinical thermometers and sphygmomanometers, clinical infrared thermometers, which have been widely used during the COVID-19 pandemic, as well as continuous measurement sphygmomanometers, glucometers and pulse oximeters, are not addressed. Thus, it is understood that these four instruments should be submitted to metrological control as a priority. However, some obstacles first need to be overcome.

### 3.3 Issues

Clinical infrared thermometers (CIRT) capture the energy radiated by an individual through electromagnetic waves, converting them into a temperature value and showing the result on the instrument's display. The result depends on the place the measurement is taken, which is usually the forehead, and differences of

up to 0.8 °C can occur if wrongly applied to the arm or leg [14].

Despite their practicality in use, the dissemination of guidelines for the correct operation of these instruments has been necessary, due to the dissemination of erroneous information on social media and the fact that many models are marketed without an instruction manual or with a manual containing non-conformities in relation to clinical validation, laboratory accuracy, and environmental conditions [15]. In addition, a project prepared by INMETRO in partnership with the Oswaldo Cruz Foundation (Fiocruz) intends to establish a correlation between the results of clinical investigation and laboratory calibration in order to obtain standards that make the validation of CIRTs more repeatable and faster.

Continuous measurement sphygmomanometers have emerged as a promising option because they measure blood pressure non-invasively, without occlusion of the artery and instantaneously. This is possible due to the determination of the Pulse Transit Time (PTT), which is the time taken by the heartbeat to travel through the artery and reach the periphery, through pulse decomposition analysis (PDA) corresponding to changes in the volume of a blood vessel located, for example, in a finger and measured by photoplethysmography (PPG). However, the degree of uncertainty in the adjustment parameters determined from PDA models found in the literature is high (about 30 %), which implies the need for many cardiac cycles (about 1 minute) for the estimated blood pressure to have an acceptable uncertainty [16]. On the other hand, a



standard that specifies the procedures and requirements for the clinical investigation of this type of instrument is being elaborated in ISO[17].

Glucometers are important for the control of diabetes mellitus, as they allow the monitoring of the blood glucose level through two techniques. One is to analyze a small blood sample, usually taken from the fingertip with the aid of a lancing device, placed on a biosensor strip which contains an enzyme capable of reacting with blood glucose. This reaction generates an electrochemical response that can be measured by electronic circuits, the signal strength of which can be related to the glucose concentration of the blood sample and the measurement result displayed on the glucometer's display. As it is an easy method to check, capillary blood glucose is widely used in clinics, emergencies, public campaigns, and at-home self-monitoring [18].

The other technique consists of continuous glucose monitoring (CGM), which allows the measurement of interstitial fluid glucose concentration (which correlates with plasma glucose) over short time intervals and presents continuous curves for evaluation. Continuous measurement allows current glucose levels to be identified as well as future trends in glucose rise, stability or fall. The system works by applying a small capillary thickness sensor in the subcutaneous tissue, which transmits the information to a monitoring device that can work alone or embedded in insulin pumps and with smartphone apps [19].

Despite recent improvements in the accuracy of glucose sensors, the methods still have clinically relevant differences [19]. Several factors related to instrument handling can also contribute to incorrect results, such as inadequate use or expired validity of the strips and lack of cleaning and periodic tests, in addition to the hematocrit rate in the blood (while most equipment covers the range from 30 to 55 % hematocrit rate in blood, the minimum range should be 25–55 % and the optimal range 10–65 %) [20,21]. In Brazil, one-time evaluations of models available on the market have detected a high number of non-conforming instruments and led to the cancellation of marketing authorizations [22,23].

The pulse oximeter is a small, lightweight monitor that has two light emitters, one in the red range and the other in the infrared range, and a display that indicates SpO<sub>2</sub> levels through spectrophotometry, which consists of illuminating the skin to detect changes in light absorption of oxygen (oxy-hemoglobin) and deoxygenated blood (reduced hemoglobin) using the wavelengths of 660 nm (red) and 940 nm (infrared) [24]. The use of wireless handheld pulse oximeters in doctors' offices is on the rise, consequently many models of different brands and prices have been marketed [25].

However, these instruments have presented problems related to natural wear or misuse of the cable and sensor, in addition to a deterioration in their accuracy in the face of motion artifacts [16,26]. In addition, the various test devices and simulators available on the market for measuring oximeters do not assess the complex interactions that occur between the oximeter sensor optics and the skin surface and, therefore, can only be used to verify the functionality of the monitors and electrical integrity of sensors. Accuracy can be assessed by comparison with invasive measurement, in humans, or by comparison with another oximeter that has metrological traceability [27].

In addition to these four types of instruments, heart rate is a physiological parameter that is usually measured in conjunction with oximeters and blood pressure monitors. In the case of oximeters, calibrations can be performed with electrical signal generators applied directly to instrument inputs that use cables to connect the sensors [26]. Thus, the set formed by monitor, cable, sensor, and patient are not evaluated. With regard to wearables, studies indicate that there is no good accuracy of heart rate measurement [28].

## 4 Conclusions

Technological advances in the development of medical devices and the treatment of collected data have enabled the remodeling of healthcare processes in order to streamline and personalize medical treatments. However, this paradigm shift poses risks to users with regard to the reliability of the instruments used to measure physiological parameters.

In this sense, examples of the capacity of legal metrology to act as a prevention and control tool were presented. However, given the diversity of types of wearables and the quantity that must be sold, the metrological control needs to be adjusted.

In order to control the large number of instruments that are expected to be in use in the coming years, it is proposed that the structure of legal metrology in the field of health be focused on intelligent supervision, through the use of tools that allow planning inspection actions in the field only for those instruments that show evidence in the data analysis. As an example, the system used by INMETRO (IMS) was presented, which presents functionalities that can be explored and improved to contribute to this advance.

As for the diversity of instrument types, it is proposed that metrological control prioritize actions over clinical infrared thermometers, continuous monitoring sphygmomanometers, oximeters and glucometers, as they are closely linked to the treatment of chronic noncommunicable diseases and to primary health care services. ■

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## HEALTH

# Determining the measurement uncertainty of hospital and healthcare centre weighing systems

## A study survey in Ruvuma (Southern Region of Tanzania)

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### Abstract

In modern medical practices it is now a trend to transfer much of the diagnosis of disease and patient treatment monitoring from the clinician to medical devices. This study examines the measurement uncertainties of medical weighing devices presented to support physicians and healthcare personnel decisions concerning the diagnosis, monitoring, treatment and prescription of medical treatments with a degree of assurance. The study stresses the need for enhanced measurement traceability<sup>1</sup>, and highlights the specific role of the science of measurement in healthcare and strategic methods to improve the legal control framework for medical device regulations, taking into consideration the fact that measurement is a tool that underpins other areas of scientific research.

<sup>1</sup> Measurement traceability (VIM 2.41)  
property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty

## 1 Introduction

### 1.1 Background information

The International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) is a member of the Executive Committee of the Joint Committee for Traceability in Laboratory Medicine (JCTLM) together with the International Bureau of Weights and Measures (BIPM), the International Laboratory Accreditation Cooperation (ILAC) and the International Council for Standardization in Haematology (ICSH). The Federation is charged with producing and promoting educational materials to demonstrate the value of traceability in laboratory medicine as a means to reduce variability between methods in the interests of improved clinical outcomes and patient safety [1–5].

The concept of measurement traceability and its benefit of improving the overall measurement process in clinical and laboratory medicines is explained in reference [6]. Generating analytical results that are comparable with and independent of the measurement system, time, and location is essential for the utility of laboratory information supplied in healthcare.

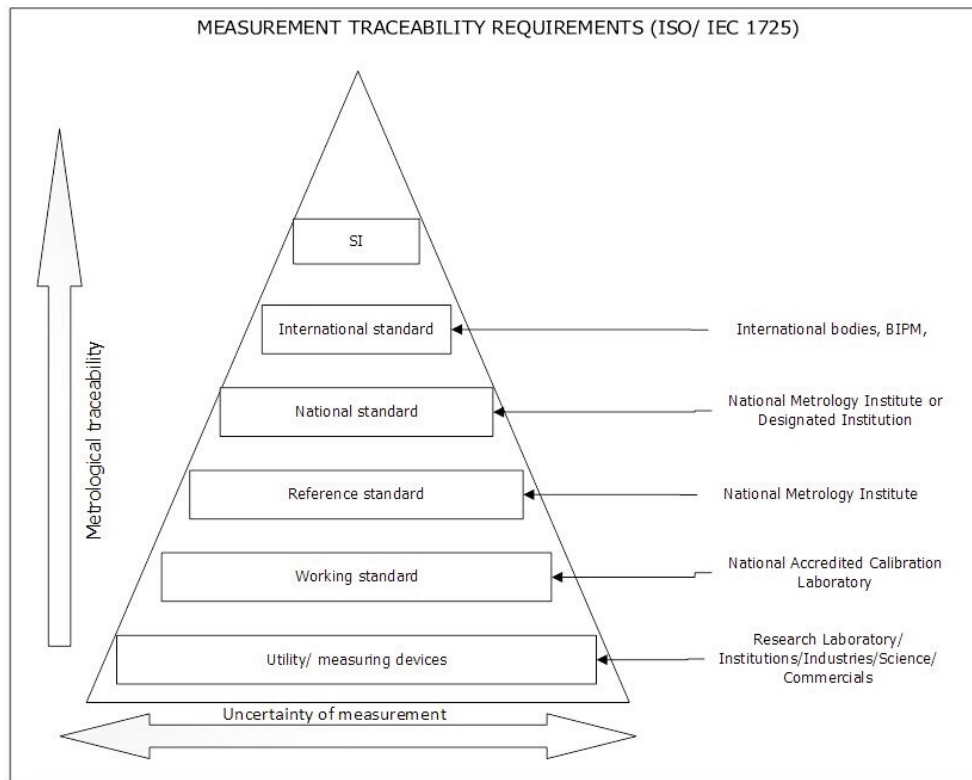
In modern medical practices it is now a trend to transfer much of the diagnosis of disease and patient treatment monitoring from the clinician to medical devices [7]. A study conducted in the USA and the UK shows that technical complications represent the third largest category of adverse events, accounting for 13 % of adverse events [8].

According to the World Health Organization (WHO), the term medical device means:

*Any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of*

- a) diagnosis, prevention, monitoring, treatment or alleviation of disease,*
- b) diagnosis, monitoring, treatment, alleviation of or compensation for an injury,*
- c) investigation, replacement, modification, or support of the anatomy or of a physiological process,*
- d) supporting or sustaining life,*
- e) control of conception,*
- f) disinfection of medical devices providing information by means of in vitro examination of specimens derived from the human body;*

*and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means [9].*



Traceability of measuring instruments as defined by ISO/IEC

The same definition is also provided by the International Organization for Standardization (ISO) through its standard ISO 13485 for medical devices [10].

In any instrument or apparatus, the measurement process is to determine a value and provide some sort of information known as “*measured values*”. In all cases, the measurement gives only incomplete information and is always corrupted by errors and thus generates uncertainty [11,12]. Measurements provided by an instrument provide quantitative knowledge and information about things and phenomena and are frequently used to support or disprove a model or theory [12].

Metrology is the science of measurement. Its principles apply to all measurements made anywhere and for any purpose, and metrology provides the basic framework necessary to perform, analyse, and arrive at sound conclusions based on measured results [13].

Metrology is a broad subject and there is no discipline that does not involve measurements or that does not seek to measure. It is known for a fact that the principles of measurement are always the same. Uncertainty and measurement error are terms that arise whenever measurements are made.

Uncertainty and error of measurement always surface and they are often incorrectly interchanged. The best explanation of these two terms has been described in OIML G 1-100 *Evaluation of measurement data - Guide to the expression of uncertainty in measurement*

[14], the Guide produced as a collaborative project among several renowned global bodies:

- Bureau International des Poids et Mesures (BIPM),
- International Electrotechnical Commission (IEC),
- International Federation of Clinical Chemistry and Laboratory Medicine (IFCC),
- International Laboratory Accreditation Cooperation (ILAC)
- International Organization for Standardization (ISO),
- International Union of Pure and Applied Chemistry (IUPAC),
- International Union of Pure and Applied Physics (IUPAP),
- International Organization of Legal Metrology (OIML).

#### (i) Measurement uncertainty

Measurement uncertainty is defined as a “parameter, associated with the result of a measurement, that characterizes the dispersion of the values that could reasonably be attributed to the measurand” [15].

The technical definition of standard uncertainty is obtained from NPL guidance in *The Beginner's Guide to Uncertainty of Measurement* by Stephanie Bell that the uncertainty of a measurement is expressed as a margin equivalent to  $\pm$  one standard deviation.

## (ii) Error of measurement

Error of measurement is defined as a result of a measurement minus a true value of the measurand.

### 1.1 Tanzania digital health strategy

Tanzania envisions better health outcomes through a digitally enabled health system, with a mission to accelerate the transformation of the Tanzanian health care system through innovative, data-driven, client-centric, efficient, effective, and integrated digital health solutions [16]. A huge number of medical devices have to operate under the approved standards [17]. The information given by medical experts states that if the mass of the patient is inaccurately measured, then the possibility arises of medical complications in future diagnostics which then compromises the efficiency and effectiveness of the patient's diagnosis. This means correct and accurate data in medical practice improves the quality of healthcare services.

### 1.2 Measurement in the health sector

In contexts such as industrial technology, military applications, and trade and commerce, the operational model of measurement traceability is almost the same and the measurement principle is always the same no matter what. Measurement practices concerning medical devices have to follow suit and more quality improvements have to be made, since healthcare is by far the most important aspect of the human being.

Traceability of measurements as described in ISO/IEC 17025:2017 *General requirements for the competence of testing and calibration laboratories* requires all measurement devices to be traceable to the international level.

Organizations such as the *International Federation of Clinical Chemistry and Laboratory Medicine* (IFCC) and the *International Laboratory Accreditation Cooperation* (ILAC) have worked closely as joint committee members in producing the *Guide to Expression of Uncertainty of Measurements* (GUM)[18].

The model diagram below shows the framework for the proposed legal control requirement for measurement uncertainties.

#### 1.1.1 Research hypothesis/Question

- (i) Do healthcare services have the required legal metrology framework for guiding and assisting medical practices?
- (ii) Are regulators capable of implementing metrological control on healthcare measuring devices?

#### 1.1.2 Research objective

##### (i) General objective

The general objective is to investigate the accuracy and measurement uncertainty of weighing devices in providing reliable indications of patient mass measurements in healthcare.

##### (ii) Specific objectives

- to test and verify conditions of hospital weighing scales devices;
- to examine the uncertainty of measurement results obtained through tests conducted to determine the device performance;
- to investigate technical mis-measurements exhibited by medical practitioners on devices operating in the field;
- to propose the legal metrological control for medical devices.



The picture shows the weighing of children under the age of 5 years old at the clinic centre at Songea municipality in Ruvuma. Children's weight is important for the determination of the growth curve.



## 1.2 Problem statement

Physical and mental health is very important to all individuals in any modern society and public health is vital to the advancement of any society; it is an important component on which the economy of any country, state or continent depends on.

Hence, standard practices and correct implementation of healthcare have to be prioritized over and above everything. A simple mistake, failure or misconduct in health services can trigger a catastrophe. In a study by Karaböce B, Durmu HO, and Çetin E. [19] the authors explain that patient health is essential, therefore medical devices used in providing or supporting the health sector must comply with the established requirements in addition to being efficient and well equipped.

A device or system used to determine the mass of a patient must be as accurate and precise as required. A patient's mass is not the only variable considered when prescribing medication or diagnosing a patient's illness, but it does play a vital role to aid a physician, doctor or medical practitioner in making viable decisions on individuals' wellness.

Incorrect information produced by the weighing system or device can lead a physician to make an incorrect diagnosis of a patient which can in turn lead to a restrictive therapeutic prescription that may impact organs of the body such as the liver, heart and other organs.

This study investigated the technical flaws of healthcare weighing devices as tools to support medical experts in making reliable decisions.

## 1.3 Significance of the study

It is important that devices for checking, diagnosing, investigating, tracing, counting, etc. indicate precisely the correct measurements.

Medical personnel must have confidence in the measurement result produced by any medical device in use.

## 2 Literature review

Studies have been conducted in medical metrology which led to further studies to highlight the fact that traceability of measurements is essential for medical diagnoses using medical devices. Below are some related studies conducted to describe the importance of metrology in the medical field.

## 2.1 Related work

The issue of the miscalculation of a body mass, incorrect reading, or incorrect indication of a measuring device have been reported in many countries. In the state of Pennsylvania, statistics show that the number of cases of error recorded by the Pennsylvania Patient Safety Authority is 480. Breakdowns described in the reports most frequently involved failures to obtain accurate patient body mass measurements [20].

A study conducted by Squara P., Imhoff M., and Cecconi M. [21] describes how erroneous measurements can jeopardize patient safety and expose critically ill patients to severe hazards. They concluded that a basic understanding of metrology is essential for the daily practice of medicine. In intensive care, clinical decision-making is often determined by measurements of physiological<sup>2</sup> and other variables to an extent unrivalled by most other medical specialties.

To identify the important factors of medical metrology, a study carried out by Shirmohammadi S, Barbe K, Grimaldi D, Rapuano S, and Grassini S. [22] explains the basis for medical diagnosis, prognosis, and evaluation and identifies metrology as a cornerstone of medical research and clinical practice; this implies clinical laboratory scientists must have confidence in the results indicated by their instruments or their measurement methods to make the correct decisions for their patients' health.

A study was conducted by Badnjevi A., Gurbeta L., Boškovi D., and Džemi Z. [23] on the importance of legal metrology in medical devices. They concluded that in spite of the experience and medical knowledge of the medical practitioner, correct diagnosis and appropriate patient treatment largely depend on the accuracy and functionality of medical devices. Hence it is necessary to carry out as strict and independent testing of the functionalities of medical devices as possible in order to obtain the most accurate and reliable diagnosis and therefore decide on the patient's treatment.

The study by Karaböce B., Durmu H.O., and Çetin E. [19] demonstrates a lack of measurement traceability in the medical field compared to the military, industrial and trade fields. The study concluded that all measurement devices used in the medical field must be controlled periodically and all measurements must be standardized as a quality control regime.

Reports published in the New York Times have considered the medical problems that can arise when

<sup>2</sup> Physiological is the way in which a living organism or bodily part functions.

the patient's mass is not correctly measured; this can have serious consequences for the patient including liver functions, kidney functions and multiple effects on the body's metabolism [24].

The Institute for Safe Medication Practices of Canada (ISMP) published a report in 2016, describing a case concerning a patient who was weighed inaccurately and who was prescribed medication, and later diagnosed with an intracranial haemorrhage after taking pills which were not intended for his mass category and which necessitated emergency surgery. Another similar case is described in the report where a patient was prescribed an incorrect dose of medicine due to an incorrect calculation. It was only after several days of treatment that the physician noticed the Body Mass Index (BMI) was incorrectly recorded.

The accuracy of the measurement results in monitoring the growth of children under the age of five years old is also important to the wellbeing of the country. Looking into recommendations by the World Health Organization (WHO) in their publications *Child growth standards based on length/height, mass and age* this information shows that, obtaining quality measured data is needed for evaluating the healthy growth of children up to the age of five [25].

A physician needs to be sure of the body mass of their patients. This information is important in monitoring for example the progress of pregnancies, heart failure, and when adjusting medications. According to the referenced medical studies, clinical decisions based on inaccurate scales have the potential to cause iatrogenic complications in patient care [26].

In one case, three London hospitals carried out a study on 474 out of the 1012 patients. The body masses of those 474 patients were not recorded. The results were not surprising, as out of those 474 patients 39 % were prescribed a narrow therapeutic<sup>3</sup> antibiotic (a small difference between the minimum effective concentrations and the minimum toxic concentrations in the blood). The observation shows that without proper body mass measurement the number of therapeutic prescriptions is higher than necessary, resulting in potential toxicity to patients [27].

The study conducted by Harris, Ellison, Holliday, & Nickson (1998) did show inaccuracy of weighing scales at clinics in a South Thames Region NHS. The study found an inconsistency in the weighing practices of about 1–1.5 % conducted by medical practitioners [28].

A study conducted by Kerac, Seal, Blencowe, & Bunn (2009) [29] confirmed the importance of

improving mass-for-height assessment and classification of nutritional status, and it also described the improvement of weighing systems as an equal tool for monitoring children's progress towards nutritional recovery.

The objective of this study is an attempt to highlight the scientific facts of the situation and investigate the damage which might occur if simple systems and the proper medical metrological framework are not installed in a country's health sector.

## 3 Research methodology

### 3.1 Study material

The study will be based on test reports by the Tanzanian Weights and Measures Agency. Testing will be conducted in private and public health institutions situated within the Ruvuma region.

### 3.2 Data collections

Data will be collected through inspections and by testing the performance of device functions obtained from the device tested and data recorded on specific inspection and test forms.

#### 3.2.1 Data descriptions

The tested devices will produce results of mass in kilograms (kg) compared to the working standard<sup>4</sup> which has a higher degree of accuracy than the tested instruments.

#### 3.2.2 Data sampling procedures

A questionnaire will be used to collect comments from individual users (physicians, doctors, nurses and other hospital personnel) in their day to day activities.

#### 3.2.3 Sampling methods and analysis software

The study will use the R Statistical package for the analysis of data.

<sup>3</sup> Therapeutic is the branch of medicine concerned with the treatment of disease and the action of remedial agents.

<sup>4</sup> Working standards are working tools to a high degree of accuracy which are used by the regulatory authority to verify any measuring device used in a commercial, industrial, medical, etc. situation.



Table 1: Summary of methodology

S/N	Specific objective	Data required	Data collection methods and tools used	Analysis tools
1	To test and verify conditions of hospital patient scales	Mass data measured in kg	National and international testing guidelines	Test forms and examination test
2	To examine measurement results obtained through metrological tests conducted to determine the accuracy of the devices	Measurement results in kg	Standard testing procedures and guidelines	R statistical package
3	To identify uncertainty of the measurement results exhibited by devices used by the practitioner on devices used in practice	Test report	R statistical package	R statistical package
4	To investigate measurement flaws exhibited by the medical practitioner on the use of devices	Questionnaire	Question and comments	Questionnaire
5	To propose legal metrological control for hospital patient weighing systems.	Test reports	Expert opinions and standard guidelines	Technical expertise

## 4 Data analysis and simulation

The data obtained will be simulated to mimic the conditions and performance illustrated by the medical devices. The performance will be compared to the legal allowable tolerance for the device class as categorized by manufacturers and the regulatory body.

The output of the data will be determined based on the data science concepts of understanding and learning through the data produced by the machine. The results will give a perspective as to whether the devices are in an adequate condition to support medical personal in healthcare service provisions. ■

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## HEALTH

# The challenges of medical metrology

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## Introduction

A wide variety of medical measuring devices are used in health care, from diagnosis to treatment and monitoring. This ranges from commonly used medical devices such as clinical thermometers and sphygmomanometers used to determine the body temperature and the blood pressure values of individuals, to much more complex medical devices such as magnetic resonance scanners.

Reliable and accurate measurements using medical measuring devices are imperative in ensuring correct disease diagnosis and treatment as they are proven to be very sensitive to measurement errors. Even small errors caused by device failure, maintenance issues, or operator error can have critical ramifications [1]. Data and statistics made available by the World Health Organization show that 23 % of European Union citizens claim to have been directly affected by medical errors. Of these, medical device failure accounts for 13 % of all types of adverse events, being classified as the third largest category of medical errors [2]. In addition, unfamiliarity with a certain technology or operating procedure, and the use of devices for clinical indications outside their original scope ("off label use"), can cause device failure even in the absence of any inherent design or manufacturing defects.

Furthermore, the absence of calibration, or calibrations performed inadequately during the maintenance cycle of medical devices, can severely jeopardize their safety and performance. These issues are, unfortunately, often overlooked or underestimated, but it remains imperative that medical devices are continuously assessed not only when they are introduced to the market but also after they were put into operation. A significant percentage of the medical errors caused by medical device failure or misuse could be prevented by careful and regular monitoring and maintenance of the medical devices in use.

## Medical device metrology

The role of medical device metrology is to improve the accuracy and reliability of measurements performed in a professional medical context, thus reducing misdiagnosis and, in consequence, improving the quality of life of individuals worldwide while simultaneously reducing the burden on the healthcare system. This can only be achieved by providing clear and unified guidelines not only during the pre-market review phase (product control), but also for the continued assessment of medical devices after they are put into operation (market surveillance). Such a harmonised context will particularly benefit institutions that are responsible for the verification and calibration of medical devices in use, as it will enable them to perform their business according to the latest state-of-the-art and ensure a uniform and high-quality metrological service worldwide. Moreover, manufacturers of new medical devices and distributors will deal with a homogeneously developed regulatory situation not only at market introduction but also with respect to market surveillance.

This harmonisation is unfortunately currently missing in many developing countries where health technology assessments are rare, and where little regulatory controls exist. Even in the European Union (EU), where the regulations for introducing a medical device on the market are harmonised, a significant variation exists in the requirements during market surveillance. As such, several EU countries require periodical metrological checks of medical devices after these are put in use, while others refrain from imposing such requirements. Moreover, the list of medical devices for which such metrological checks are compulsory varies from country to country and no unified guidelines for the metrological checks of such devices exist; countries perform the required metrological checks based on existing ISO standards, national guidelines, or OIML Recommendations.

Several organisations that support legal metrology in general have taken on an important role in the regional and global harmonisation of the regulatory requirements for medical measuring devices: the International Organization of Legal Metrology (OIML), the European Cooperation in Legal Metrology (WELMEC) and the European Association of National Metrology Institutes (EURAMET). EURAMET represents the national metrological organisations of EU and EFTA countries, coordinates the metrological activities of its members, and supports numerous health-related projects that have significantly improved the metrological capabilities in the European region, combining the expertise and resources from various national metrology institutes and designated institutes. It is worth mentioning here two projects that focus on developing improved and

harmonised metrological capabilities for traceable intraocular pressure measurements (inTENSE) [3] and blood pressure measurements (adOSSIG) [4] in Europe. These projects not only contribute to the harmonisation of the medical device field in Europe, but are the starting point for the development of new OIML and ISO documents, thus supporting the development and adoption of international harmonised requirements in the afore-mentioned fields. The final objective is to create a medical device metrology network with a coordinated approach to medical device metrology despite varying national regulatory requirements.

Medical devices metrology is a very complex field, in which competence in the metrological core sector of physical quantities alone is not sufficient. In addition, a fair amount of medical competence is required. This is due to the fact that in the field of medical devices traceability frequently cannot be established along the classical metrological pathway. For instance, suitable standards are not always available, since medical measurands normally relate to a certain physiological context or condition. Any medical standard has to accurately reproduce not only the physical quantity but also the corresponding physiological condition, therefore, and more often than not such a solution just does not exist. As a consequence, traceability is often established by alternative models, where simulators, transfer standards or phantoms substitute for reference and working standards, while the role of the primary standards is (conceptually) assumed by a sufficiently large cohort of human subjects and clinically tested medical devices or databases of physiological test signals derived from that cohort take the role of a secondary standard. This is for example the case for non-contact tonometers where transfer standards are employed to compare the device to be tested to an identically manufactured device, which was clinically tested in conformity with ISO 8612. As such a traceability chain is more complex, and up to now only a few countries make use of this model, a new OIML Recommendation describing this procedure is currently being developed under OIML TC 18 *Medical Measuring Instruments* [5].

Not many national metrology institutes possess the resources necessary to tackle this demanding field and develop procedures to ensure the metrological traceability of medical devices. Therefore, an interdisciplinary and collaborative approach, with permanent exchange between national metrology institutes as well as between the metrology world and all the other players involved in the life cycle of medical devices (regulators, manufacturers, users, and scientists) is the only option to ensure a harmonised medical metrology field and optimum safety and performance of medical devices.

## Upcoming challenges

The rapid advancement in medical technology has undoubtedly improved the quality of life of billions of people worldwide. The metrology world, however, and all other institutions whose role it is to ensure the supervision of medical devices, are at risk of becoming overwhelmed by the pace of these changes. An adequate, fast approach as a response to the rapid developments in the medical devices field urgently needs to be developed.

Arguably, the biggest challenges in medical devices metrology are brought about by digital transformation. The first wearable devices were certified as medical devices; they are not only used in home care, and the first indications of their use in health care facilities are starting to appear. Wearable devices that can monitor blood pressure and heart rate (e.g. bracelets or watches), sweat sensors able to detect sugar levels in diabetic patients, or oximeters intended to monitor a patient's oxygen saturation are only some of the new technologies in the field.

These technologies are intended to improve and personalise patients' healthcare, but in order for such technologies to be accepted by the medical community and health care systems, an increase of trust in the reliability and safety of such devices has to be provided. From the metrological point of view, this implies the need to develop completely new traceability chains, as such devices often use a different technology compared to their traditional counterparts. Deep learning (DL) and other implementations of Artificial intelligence (AI), and data science in general have high potential for offering significant support in future clinical decision making. The great benefit for patients and the tremendous potential for the economy is leading to a rapidly increasing number of AI applications being seen in the health sector. Such newly developing areas promise faster diagnosis, and as a consequence earlier access to the necessary treatment, a reduction of the burden on the healthcare system, as well as an equal access to high standard medicine all over the world.

However, there are currently no universally accepted procedures that can objectively and reproducibly validate AI technologies. Partially due to a lack of resources, and partially due to the complexity of building up such advanced capabilities, only a minority of national metrology institutes are currently taking their first steps towards a standardised quality assessment of machine learning approaches in the medical field. A similar state of affairs can be found in healthcare facilities, particularly in developing countries or in rural/remote regions even in the most advanced countries as well as in the case of competent authorities for the market surveillance of medical devices.

Under these circumstances, the most viable solution to support rapid progress in this field and make it available to all the institutions involved in this chain is to create a network that gathers together metrology experts, medical experts and manufacturers who are able to develop clear, harmonised and internationally accepted evaluation methods which can be used to assess data quality for machine learning and artificial intelligence applications.

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## HEALTH

# China's good practices in legal metrology in conformity with international regulations

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## Abstract

Metrology plays an increasingly important role in the medical and healthcare sector, especially in the fight against the COVID-19 pandemic. In this sense, legal metrology for healthcare should attract continuous attention and investment.

China has been an active player in drafting and revising various OIML International Recommendations and other International Standards, and in promoting the OIML Certification System (OIML-CS), so as to implement mutual recognition and facilitate the global trade of measuring instruments under legal metrological control in conformity with international regulations.

**Key words:** legal metrology, sphygmomanometer, International Recommendation, OIML-CS

*Measurement for Health* is the theme of World Metrology Day in 2021. Metrology plays an increasingly crucial role in the medical and healthcare sector. It has contributed greatly to the well-being of each of us, especially in the fight against the COVID-19 pandemic, which in turn has led to a growing awareness of its significance. Metrology is fundamental in ensuring reliable and accurate measurement results by measuring equipment, such as for setting up the testing system of personal protection masks, applying human body temperature medical

thermometers, designing and testing new ventilator systems needed in hospitals, identifying and counting virus molecules in test samples, measuring the efficacy of vaccine doses, and monitoring the vital signs of critically ill patients.

As China fought against the COVID-19 nationwide, body temperature measurement of massive numbers of people was mandatory in public places such as transportation hubs, shopping malls, supermarkets, and hospitals.

Governments at all levels have made every effort to coordinate the supply of infrared thermometers, and relevant metrological institutes have provided measurement services 24 hours a day, ensuring the traceability of all these infrared thermometers. Furthermore, China's metrology institutes have endeavored to develop certified reference materials (CRMs) of in vitro transcribed RNA for coronavirus that can provide reference values for the 2019-nCoV nucleic acid testing (NAT) for the measuring reliability and accuracy of test kits.

Since globalization and market internationalization have developed at a very fast rate, international cooperation in the medical and healthcare field as well as environmental protection have also become increasingly important, and as a result there has been a growing demand for internationally compatible and harmonized metrological activities.

It was stated in the *Message from the BIPM and BML Directors for World Metrology Day 2021* that "international standards should be developed for all types of medical devices with a measuring function, including automated blood-pressure instruments, ophthalmic instruments and medical syringes". Medical equipment is certainly worthy of attention for technical development and global application. China is an active participant in drafting and implementing the relevant OIML Recommendations on medical equipment such as sphygmomanometers, striving to protect people's health as its ultimate goal.

Hypertension is a high-risk factor that induces cardiovascular and cerebrovascular diseases as a "silent" killer, and is a threat to more than 1 billion people worldwide. Accurate blood pressure measurement is critical for identifying and correctly controlling blood pressure fluctuations. A non-invasive sphygmomanometer is a type of measuring instrument for measuring human blood pressure. Its performance determines the measurement results obtained, which are important to ensure people's health. The global trade volume of sphygmomanometers is estimated at nearly USD 1 billion, and continues to increase. Countries such as China, Japan, Germany, Singapore, and Brazil, are major manufacturers of non-invasive sphygmomanometers. In 2019, China's total volume of trade in sphygmomanometers reached USD 510 million.

Under such circumstances, internationally harmonized standards are essential for the global sphygmomanometer industry. At present, the international standards on sphygmomanometers include IEC 80601-2-30:2018 *Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers*, ISO 81060-1:2007 *Non-invasive sphygmomanometers - Part 1: Requirements and test methods for non-automated measurement type*, and ISO 81060-2:2018 *Non-invasive sphygmomanometers - Part 2: Clinical investigation of intermittent automated measurement type*.

In February 2021, the OIML published two International Recommendations on non-invasive sphygmomanometer R 148 (to replace R 16-1) and R 149 (to replace R 16-2), consisting of the metrological and technical requirements and test procedures for these instruments. The revision of these two Recommendations was led by China as the Project Group Convener with contributions from PG members.

OIML International Recommendations are intended as model regulations for a number of categories of measuring instruments in legal metrology, involving metrological and technical requirements and test procedures for legal metrology, which provide the basis for eliminating technical barriers to trade (TBT) between countries and ensuring the compatibility of international standards or technical documents.

OIML R 148 and R 149 were revised to integrate the technical requirements of existing international standards, and improve the specifications of sphygmomanometers based on real-world practices. The upcoming situation of mercury sphygmomanometer replacement has also been carefully studied, where the requirements for control of mercury usage and its test method for mercury sphygmomanometers are included, and the technical requirements for mercury-free digital auscultation sphygmomanometers refined.

All of these changes will have a long-term impact on the industrial development of sphygmomanometers and the market share of different types of products, especially on the implementation of the *Minamata Convention* on mercury for human health and environmental protection. It can also accelerate the application of mercury-free sphygmomanometers and enable more

countries, especially emerging economies, to afford qualified sphygmomanometers at lower prices.

China carries out good practices in legal metrology that are compatible with international regulations. In China, the measuring instruments for trade, safety protection, medical care and public health and environmental monitoring are subject to legal metrological control. The State Administration for Market Regulation of P.R. China (SAMR) has mobilized resources to formulate the catalogues of measuring instruments for mandatory control, in which the listed measuring instruments shall be subject to type evaluation and/or mandatory verification in accordance with China's national technical specifications.

At present, an increasing number of OIML Recommendations have been transferred into China's technical specifications, such as those for non-automated weighing instruments, electrical energy meters, water meters, etc. The Chinese government metrological authority encourages national metrology institutes to actively contribute to the drafting and revision of OIML Recommendations.

Additionally, China has been promoting the implementation of the OIML-CS, which is designed to realize "one test, one certificate for global mutual recognition" of measuring instruments, thus enabling China to be more compatible with international practices. China will continue to work with the rest of the world to further promote the OIML-CS by building up the technical capacities of laboratories, training more experts for OIML-CS review, so as to reduce trade barriers, enhance mutual trust, and facilitate international trade of measuring instruments.

At present, countries all over the world pay more and more attention to the legal metrological control of measuring instruments in the medical and healthcare field, and continue to carry out research on relevant measuring technologies and test methods. It is suggested that international organizations step up coordination of national standards of various countries in the medical and healthcare field, allocate a degree of importance to the development trend of new measuring instruments, and jointly explore key issues such as the scope and management methods for measuring instruments under legal metrological control. ■

## HEALTH

## Report on the meeting of the OIML Task Group on Medical devices

16 April 2021

IAN DUNMILL, BIML Assistant Director

During the 55th CIML Meeting in October 2020, OIML members expressed the need for more guidance at the international level on the regulation of medical devices with a measuring function in the context of the COVID-19 pandemic. An OIML Task Group was therefore set up to consider how the OIML could respond to these needs, and 14 people attended its first online meeting on 16 April 2021.

Roman Schwartz, CIML President, and Ian Dunmill, BIML Assistant Director, gave some introductory remarks about the background to setting up this Task Group and participants then discussed the problems and possible OIML strategies and solutions which could be followed.

### What are the issues for medical devices in legal metrology?

Peter Mason, CEEMS AG Chairperson, explained his discussion paper *Medical devices: The issues*, which had been distributed before the meeting. This covered the following themes:

- Are there clear “standards” which must be met?
- Is the quality infrastructure necessary to test medical devices with a measurement function available?
- What sort of regulatory regime is required?
- How should these issues be addressed?
  - Who should take responsibility?
  - The role of the OIML and the BIPM

In relation to issue 3 of Peter Mason’s paper “What sort of regulatory regime is required?”, there was a discussion on the importance of convincing not only governments, but also the medical community of the importance of legal metrology in this field.

During the discussion on this item, Rafael F. Farias Farias (Brazil) gave a short presentation of *Suggestions for OIML Task Group on medical devices used in legal metrology*. This included instruments which he and his colleagues felt should be covered by OIML Recommendations, as well as what aspects should be covered by these Recommendations.

This presentation also highlighted the previously unconsidered problem of certain instruments which transmit and verify data over the internet. It was felt that many regulators may not yet have considered this matter of convergence, and that such instruments needed to be identified.

A list of medical devices with a measuring function developed by Stephan Mieke (Germany) was also presented and discussed, which provided a table showing the applicable standards and OIML Recommendations for each instrument.

A discussion on the scope of the OIML’s interest also made clear the view that the Organisation should work on those instruments which were used in a professional context.

There was also discussion of the problems relating to the post-market legal metrology activities of verification and inspection in the field of medical devices. These were identified as being inconsistent and lacking in guidance in many countries, even in those which made use of the OIML Recommendations as the basis for their legislation.

### Actions

The Task Group agreed the following actions, which are to be led by the BIML:

#### Infrared thermometers

Brazil agreed to consider whether they could take over the currently vacant secretariat TC 18/SC 2 *Medical thermometers*, as well as the convenership of a possible project to revise R 115 *Clinical electrical thermometers with maximum device*, or to develop a new OIML Recommendation, to cover Infrared thermometers (ISO 80601-2-56:2017).

#### Sphygmomanometers

P.R. China had been responsible for convening the recently completed TC 18/SC 1/p 1 and p 2 projects, which developed R 148:2020 *Non-invasive non-automated sphygmomanometers* and R 149:2020 *Non-invasive automated sphygmomanometers*. The BIML

agreed to contact them to see whether they might take on the convenership for two new projects to further revise these two Recommendations to cover verification and inspection in more detail. Although the ISO standard on this subject (ISO 81060-3) also covers continuous blood pressure measurement, it was proposed that a new revision of R 148 and R 149 should not cover this aspect at the moment, although it could be interesting to review this in a few years' time when the IEC standard on the subject had advanced to the FDIS stage.

### Pulse oximeters

The Task Group considered that there is a need for a new project to cover these instruments, which are covered by ISO 80601-2-61:2017. The BIML agreed to look for a Member State which could take on the convenership of a new project on these instruments. It should also be clear that the OIML's work should be restricted to those instruments used by professionals, and would not cover, for example, wearable devices for use by the general public.

### Adequacy of the Quality Infrastructure

Peter Mason suggested that consideration should be given to a joint document with the BIPM and possibly the WHO on the adequacy of the quality infrastructure in support of measuring instruments in the light of the COVID-19 pandemic.

### WHO

The BIML agreed to continue to follow up the possibility of cooperation between the WHO and the OIML. The results of this meeting seem to fit well with their aim of guidance on the regulation of essential medical devices with a measurement function. ■

For more information on the papers and presentations from the Task Group meeting, please contact Ian Dunmill at the BIML.

# OIML Certification System (OIML-CS)



## Introduction

The OIML-CS is a system for issuing, registering and using OIML Certificates and their associated OIML type evaluation reports for types of measuring instruments (including families of measuring instruments, modules, or families of modules), based on the requirements of OIML Recommendations.

The OIML-CS comprises two Schemes: Scheme A and Scheme B. Competence of the OIML Issuing Authorities and their Test Laboratories is demonstrated through self-declaration under Scheme B and accreditation or peer assessment under Scheme A.

The aim of the OIML-CS is to facilitate, accelerate and harmonize the work of national and regional bodies that are responsible for type evaluation and approval of measuring instruments subject to legal metrological control. In the same way, instrument manufacturers, who are required to obtain type approval in some countries in which they wish to sell their products, should benefit from the OIML-CS as it will provide evidence that their instrument type complies with the requirements of the relevant OIML Recommendation(s).

It is a voluntary system and OIML Member States and Corresponding Members are free to participate. Participating in the OIML-CS commits, in principle, the signatories to abide by the rules of the OIML-CS that are established in OIML B 18:2018 *Framework for the OIML Certification System (OIML-CS)*. Signatories voluntarily accept and utilize OIML type evaluation and test reports, when associated with an OIML Certificate issued by an OIML Issuing Authority, for type approval

or recognition in their national or regional metrological controls.

The OIML-CS was launched on 1 January 2018 and has replaced the former OIML Basic Certificate System and the OIML Mutual Acceptance Arrangement (MAA).

Further information can be found at:

<https://www.oiml.org/en/oiml-cs>

For enquiries regarding the OIML-CS, please contact the OIML-CS Executive Secretary Paul Dixon ([executive.secretary@oiml.org](mailto:executive.secretary@oiml.org)).

## OIML certificates

OIML certificates issued under Scheme A and Scheme B can be downloaded from the database on the OIML website at [https://www.oiml.org/en/oiml-cs/certificat\\_view](https://www.oiml.org/en/oiml-cs/certificat_view).

The database also includes certificates issued under the former OIML Basic Certificate System and the MAA. Although these two systems are no longer in operation, the certificates remain valid.

## OIML Issuing Authorities, Utilizers and Associates

A summary of the approved OIML Issuing Authorities is published on the next page, followed by a summary of those Utilizers and Associates that have declared that they will accept OIML certificates and/or OIML type evaluation reports as the basis for a national or regional approval.



# OIML Certification System (OIML-CS)

## List of OIML Issuing Authorities and their scopes

*The list of OIML Issuing Authorities is published in each issue of the OIML Bulletin and can be downloaded at [www.oiml.org/oiml-cs/oiml-issuing-authorities](http://www.oiml.org/oiml-cs/oiml-issuing-authorities)*

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		R 21:2007	R 46:2012	R 49:2006	R 49:2013	R 50:2014	R 51:2006	R 60:2000	R 60:2017	R 61:2004	R 61:2017	R 75:2002	R 76:1992	R 76:2006	R 85:2008	R 99:2008	R 106:2011	R 107:2007	R 117:1995	R 117:2007	R 117:2019	R 126:1998	R 129:2000	R 134:2006	R 137:2012	R 139:2014	R 139:2018
AU1	National Measurement Institute Australia (NMIA)					■							■	■													
CH1	Federal Institute of Metrology (METAS)						■							■													
CN2	National Institute of Metrology, China (NIM)						■	■	■	■	■		■	■													
CZ1	Czech Metrology Institute (CMI)				■		■				■			■						■	■				■		
DE1	Physikalisch-Technische Bundesanstalt (PTB)						■	■	■	■		■															
DK2	FORCE Certification A/S				■	■	■	■	■	■	■			■			■	■					■	■	■	■	■
FR2	Laboratoire National de Métrologie et d'Essais (LNE)			■	■		■	■	■					■								■					
GB1	NMO				■		■	■	■				■	■						■	■						
JP1	NMIJ/AIST						■	■	■				■	■					■	■	■						
NL1	NMi Certin B.V.	■	■	■	■	■	■	■	■	■	■		■	■	■			■	■	■	■		■	■	■	■	■
SE1	Research Institutes of Sweden (RISE)						■	■	■	■	■			■	■				■	■	■						
SK1	Slovak Legal Metrology (SLM)			■	■									■													

# OIML Certification System (OIML-CS)

## List of Utilizers, Associates and their scopes

*The list of Utilizer and Associate scopes is published in each issue of the OIML Bulletin  
and can be downloaded at [www.oiml.org/oiml-cs/utilizers-and-associates](http://www.oiml.org/oiml-cs/utilizers-and-associates)*

Updated: 2021-10-06

1 = Scheme A only  
2 = Scheme A and MAA  
3 = Scheme A and B  
4 = Scheme A, B and MAA  
5 = Scheme B only

		R 21:2007	R 35:2007	R 46:2012	R 49:2006	R 49:2013	R 50:2014	R 51:2006	R 55:1998	R 59:2016	R 60:2000	R 60:2017	R 61:2004	R 61:2017	R 75:2002	R 76:1992	R 76:2006	R 81:1998	R 85:2008	R 88:1998	R 93:1999	R 99:2008	R 102:1992	R 104:1993	R 106:2011
AU	National Measurement Institute, Australia (NMI)				1	1					1					1	1								
BE	Federal Public Service Economy	3		3		3	3	3			1		3		3		1		3			3			3
CA	Measurement Canada										2	1			1		2								
CH	Federal Institute of Metrology (METAS)			1	2	2	1	1			2		1			1	2								1
CN	State Administration for Market Regulation (SAMR)							1			2	1	1	1		2	2								
CO	Superintendencia de Industria y Comercio (SIC)	3		3	4	4	3	3			2		3		3	2	2		3			3			3
CU	Oficina Nacional de Normalización (NC)	3	3	1		1	3	1	3	3	1	1	3	3	3	1	3	3	3	3	3	3	3	3	3
CZ	Czech Metrology Institute (CMI)					1		1						1			1								
DE	Physikalisch-Technische Bundesanstalt (PTB)	5		3	3	4	3	3			2		3		3		2					5			1
DK	FORCE Certification A/S				2	2	1	1			2	1	1	1			2								1
FR	Laboratoire National de Métrologie et d'Essais (LNE)	1		1	1	1	1	1			1		1		1	1	1	1	1			1			1
GB	NMO Certification	3			4	4	3	3			2		3			2	2		3						3
IN	Legal Metrology Division, Department of Consumer Affairs	3		3		4	3	3			2		3		3		2		3						1
IR	Iran National Standards Organization (INSO)				4	4					2	1				2	2								
JP	NMIJ/AIST										2	1				2	2								
KE	Weights and Measures Department		3	3	4	4		3			4	4	3	3		4	4		3						3
KH	National Metrology Centre (NMC)	3		3	3	3	3	3			1		3		3	1	1		3			3			3
KI	Ministry of Commerce, Industry and Cooperatives	5	5	5	1	1	5	1		5	1	1	5	5	5	1	1	5	5						5
KR	Korea Testing Certification (KTC)															2	2								
LV	LNMC Ltd. Metrology Bureau																								
NA	Namibian Standards Institution			3	4	4	3	3			2		3			2	2		3						3
NL	NMI Certin B.V.	3		3	3	4	3	3			2	1	3	3	3	1	2		3			3			3
NZ	Trading Standards (Ministry of Business, Innovation and Employment) (MBIE)				4	4	3	3			2					2	2		3						3
RU	VNIIMS																								
RW	Rwanda Standards Board	3	3	3	3	3		3	3	3	1	1	3	3		1	1					3	3	3	3
SA	SASO (Saudi Standards, Metrology and Quality Organization)			3		1						1					1								
SE	RISE Research Institutes of Sweden AB							3			2	1	3				2		3						
SK	Slovak Legal Metrology (SLM)				2	2											2								
TN	National Agency of Metrology (ANM)	3		3	2	2	3	3			2		3				2		3			3			3
UG	Uganda National Bureau of Standards (UNBS)			3	1	3					1	1				1	1								
US	National Conference on Weights and Measures (NCWM)										2														
ZA	NRCS: Legal Metrology				3	3		3			1					1	1		3						3
ZM	Zambia Metrology Agency	3		3	3	3	3	3			1		3		3	1	1		3			3			3

# OIML Certification System (OIML-CS)

## List of Utilizers, Associates and their scopes (Cont'd)

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		R 107:2007	R 110:1994	R 117:1995	R 117:2007	R 117:2019	R 122:1996	R 126:1998	R 128:2000	R 128:2000	R 128:2000	R 128:2000	R 133:2002	R 134:2006	R 136:2004	R 137:2012	R 139:2014	R 139:2018	R 143:2009	R 144:2013	R 145:2015	R 146:2016	R 148:2020	R 148:2020	R 150:2020
AU	National Measurement Institute, Australia (NMI)																								
BE	Federal Public Service Economy	3			3					3						3	3								
CA	Measurement Canada																								
CH	Federal Institute of Metrology (METAS)	1						1		1			1		1										
CN	State Administration for Market Regulation (SAMR)																								
CO	Superintendencia de Industria y Comercio (SIC)	3		3	3			3		3			3		3	3	3								
CU	Oficina Nacional de Normalización (NC)	3	3		3		3	3	3	3		3	3	3	3	3	3	3	3	3	3	3			
CZ	Czech Metrology Institute (CMI)				1	1										1									
DE	Physikalisch-Technische Bundesanstalt (PTB)	3			3	1				3			1	5	3										
DK	FORCE Certification A/S	1			1	1				1	1		3		1	1	1								
FR	Laboratoire National de Métrologie et d'Essais (LNE)	1			1			1		1			1		1	1	1								
GB	NMO Certification	3		3	3					3			3												
IN	Legal Metrology Division, Department of Consumer Affairs	3			3					3			1		3	3									
IR	Iran National Standards Organization (INSO)																								
JP	NMIJ/AIST			1	1	1																			
KE	Weights and Measures Department			3	3			3					3	3	3	3	3								
KH	National Metrology Centre (NMC)	3		3	3			3		3			3		3	3									
KI	Ministry of Commerce, Industry and Cooperatives		5	1	1							5	5		5	5	5								
KR	Korea Testing Certification (KTC)																								
LV	LNMC Ltd. Metrology Bureau							3					3												
NA	Namibian Standards Institution	3		3	3			3		3			3												
NL	NMI Certin B.V.	3		3	3	1		3		3			3		3	3	3								
NZ	Trading Standards (Ministry of Business, Innovation and Employment) (MBIE)	3		3	3					3			3												
RU	VNIIMS			3	3																				
RW	Rwanda Standards Board		3	3	3		3	3		3		3	3		3				3	3		3			
SA	SASO (Saudi Standards, Metrology and Quality Organization)				3																				
SE	RISE Research Institutes of Sweden AB			3	3																				
SK	Slovak Legal Metrology (SLM)																								
TN	National Agency of Metrology (ANM)	3		3	3			3		3			3		3	3									
UG	Uganda National Bureau of Standards			1	1	1							3		3										
US	National Conference on Weights and Measures (NCWM)																								
ZA	NRCS: Legal Metrology	3		3	3			3		3			3		3	3									
ZM	Zambia Metrology Agency	3		3	3			3		3			3		3	3									

## Promotion of the OIML Bulletin: Become a Mentor



### The OIML Bulletin is one, if not the only, international publication dedicated to legal metrology topics.

In accordance with CIML Resolutions 2019/30 and 2020/21, there is a clear desire for the Bulletin to be an attractive publication for legal metrology worldwide, and for it to be an excellent advertisement for our Organisation.

This can be achieved through long-term planning of the future editions and identification of key topics of high interest, for instance, legal control of measuring instruments in the fields of energy, health and the environment, where important aspects such as new technology, legal requirements, or test/verification procedures will be addressed.

In addition, support is sought from CIML Members and Corresponding Member Representatives who are ready to take on the responsibility of acting as “**Mentors**” for certain key topics / editions and technical articles. These are not necessarily expected to be written by the “**Mentors**” themselves, but by experts that a “**Mentor**” has identified and contacted.

In order to identify key topics of significant interest and “**Mentors**” to lead them, it was proposed by the CIML President that the BIML prepares, and makes publicly available on the OIML website, a plan for the upcoming eight to ten editions of the Bulletin.

The table on the following page is intended to be “dynamic”, i.e. proposed key topics may be moved to other editions depending on available “**Mentors**” and authors for technical articles. The table can also be found at [www.oiml.org/en/publications/bulletin/future-editions](http://www.oiml.org/en/publications/bulletin/future-editions).

All CIML Members and Corresponding Member Representatives are encouraged to support the OIML Bulletin, to share their legal metrology experiences with the legal metrology community worldwide, and to take responsibility either as a “**Mentor**” for one of the next editions of the Bulletin, or by promoting it at TC/SC/Project Group meetings, RLMO meetings, CEEMS AG meetings, and other opportunities.

CIML Members and Corresponding Member Representatives who would like to be a “**Mentor**” for a specific edition / key topic, or who would like to suggest that a new key topic be added to the list, are asked to contact the BIML ([chris.pulham@oiml.org](mailto:chris.pulham@oiml.org)).



<b>Edition</b>	<b>General key topic</b>	<b>Mentor</b>	<b>Article submission #1</b>	<b>Article submission #2</b>	<b>Article submission #3</b>	<b>Other</b>
2022	(Metrology for protecting the) Environment					
	National / Regional Metrology Systems					
	Measurement related to traffic	PTB / METAS	Speed meters (overview of current technologies)	Soot particle measurement	Smart metering, e-vehicle charging	
	Training of inspectors / verification officers		E-Learning material already available	Revised OIML D 14		
	Pre-packages / Statistical control	Some RLMOs?	Theoretical principles / basics	Various systems in different regions	Report on OTE 2022 in Bad Reichenhall (DE)	
	Intellectual property		Role of patents in legal metrology			



# info

The OIML is pleased to welcome the following new

## ■ CIML Members

### ■ Finland:

Ms. Sari Hemminki

### ■ Morocco:

Mrs. Fadwa Maliki

### ■ Romania:

Mrs. Roberta Todor

### ■ Russian Federation:

Mr. Evgeny Lazarenko

### ■ South Africa:

Mr. Trevor Tshepo Modiba

### ■ Tanzania:

Ms. Stella Rwehabula Kahwa

## ■ OIML meeting

18-22 October 2021

16th International Conference on Legal Metrology and 56th CIML Meeting

## ■ Committee Draft

Received by the BIML, 2021.07 – 2021.10

General requirements for software-controlled measuring instruments

1 CD

TC 5/SC 2/p4

DE

2021-10-08

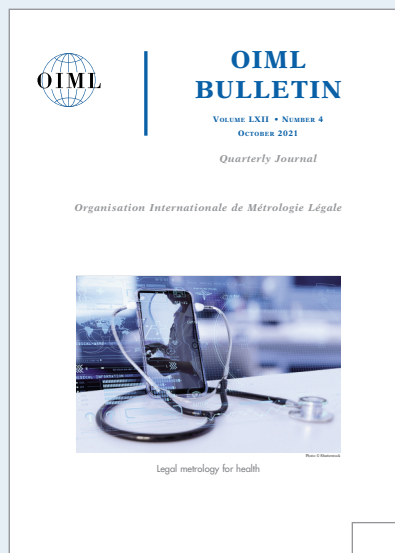
## John Barton

It is with great sadness that the U.S. National Institute of Standards and Technology's (NIST) Office of Weights and Measures (OWM) shares news of the death of staff member Mr. John Barton, a valued and dedicated member of the NIST OWM staff and well-respected expert in static and dynamic weighing systems.

OIML Members will remember John for his participation in a number of OIML projects and work groups, particularly in the area of weighing systems and transportation measurement systems. Most recently John served as Convener of OIML TC 9/p 1, which developed OIML R 60:2017 *Load cells*. He also served as the U.S. technical point of contact for other OIML Technical Committees, including those responsible for R 50 *Continuous totalizing automatic weighing instruments*, OIML R 106 *Automatic rail weighbridges*, R 134 *Automatic instruments for weighing road vehicles in motion*, and R 21 *Taximeters*.

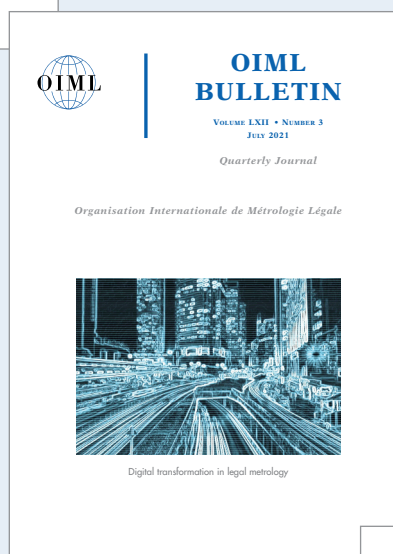
John is remembered by his colleagues and by the whole OIML community as a kind, thoughtful person with a great sense of humor and as someone who was always willing to help others. John is survived by his mother, Jeanette; wife, Darlene; son Kyle; daughter Savannah; and grandson, LJ. ■





# Call for papers

**OIML Members**  
**RLMOs**  
**Liaison Institutions**  
**Manufacturers' Associations**  
**Consumers' & Users' Groups, etc.**



- Technical articles on legal metrology related subjects
- Features on metrology in your country
- Accounts of Seminars, Meetings, Conferences
- Announcements of forthcoming events, etc.



The **OIML Bulletin** is a forum for the publication of technical papers and diverse articles addressing metrological advances in trade, health, the environment and safety - fields in which the credibility of measurement remains a challenging priority. The Editors of the Bulletin encourage the submission of articles covering topics such as national, regional and international activities in legal metrology and related fields, evaluation procedures, accreditation and certification, and measuring techniques and instrumentation. Authors are requested to submit:

- a titled, typed manuscript in Word or WordPerfect either on disk or (preferably) by e-mail;
- the paper originals of any relevant photos, illustrations, diagrams, etc.;
- a photograph of the author(s) suitable for publication together with full contact details: name, position, institution, address, telephone, fax and e-mail.

*Note: Electronic images should be minimum 150 dpi, preferably 300 dpi.*

Technical articles selected for publication will be remunerated at the rate of 23 € per printed page, provided that they have not already been published in other journals. The Editors reserve the right to edit contributions for style, space and linguistic reasons and author approval is always obtained prior to publication. The Editors decline responsibility for any claims made in articles, which are the sole responsibility of the authors concerned. Please send submissions to:

The Editor, OIML Bulletin  
 BIML, 11 Rue Turgot, F-75009 Paris, France  
 (chris.pulham@oiml.org)

