White Paper
on the smart specialisation concept developed to ensure a coordinated and optimised Central European approach towards Intra Ocular Pressure (IOP) metrology

D. Pražák[1], R. Ziółkowski[2], D. Rosu[3], M. Schiebl[4], J. Rybář[5], P. Pavlásek[5,6], E. Sınır[7], F. Pluháček[8]

[1] ČMI, Brno, Czech Republic, dprazak@cmi.cz
[2] GUM, Warsaw, Poland, robert.ziolkowski@gum.gov.pl,
[3] PTB, Berlin, Germany, dana.rosu@ptb.de
[4] PTP-BEV, Wien, Austria, markus.schiebl@bev.gv.at
[5] Slovak University of Technology, Bratislava, Slovakia, jan.rybar@stuba.sk
[6] SMÚ, Bratislava, Slovakia, pavlasek@smu.gov.sk
[7] TÜBİTAK UME, Kocaeli, Turkey, ekrem.sinir@tubitak.gov.tr
[8] Palacký University Olomouc, Olomouc, Czech Republic, frantisek.pluhacek@upol.cz

Table of Contents

EXECUTIVE SUMMARY 2

GLAUCOMA PREVENTION - ANALYSIS OF THE CURRENT SITUATION WORLDWIDE 4

DESCRIPTION OF THE INTENSE PROJECT. 5

NATIONAL LEGISLATION CONCERNING MDMF IN USE IN THE COUNTRIES INVOLVED IN THE PROJECT 6

1) AUSTRIA 6
2) CZECH REPUBLIC 9
3) GERMANY 11
4) POLAND 13
5) SLOVAKIA 15
6) TURKEY 16
   (i) Main Regulations and Responsible Bodies 16
   (ii) Guidance Documents and Training of Medical Metrology Experts 17
   (iii) Situation in Governmental (Public) Healthcare Facilities 17
   (iv) The Current Situation for Tonometers 18

OFFER FROM THE CZECH METROLOGY INSTITUTE TO EUROPEAN COUNTRIES 19

INPUT FROM THE POSSIBLE CUSTOMER NMIS 22

1) AUSTRIA 22
2) GERMANY 23
3) POLAND 24
4) SLOVAKIA 25
5) TURKEY 26

DESCRIPTION OF THE DESIRED NEW MODEL OF COMMON APPROACH TO INTRAOCULAR PRESSURE MEASUREMENT IN EUROPE WITH CMI AS PROVIDER OF THE TRACEABILITY ... 28

CONCLUSIONS. 30

Executive Summary

IOP metrology refers to measurements performed using eye tonometers, instruments classified by the EU law as medical devices with a measuring function (MDMF).

The Medical Device Directive (MDD) and its successor, the Medical Device Regulation (MDR) were developed in order to harmonise the requirements for medical devices in the EU region. While for certain aspects in the cycle of a medical device this was achieved, issues arise for MDMF, both during the introduction of the devices on the market as well as during the market surveillance.

In contrast to measuring instruments covered by the Measuring Instruments Directive (MID) or the Non-Automatic Weighing Instruments Directive (NAWID) the technical requirements for MDMF while entering the market are minimal and vaguely formulated:

MDR, Annex I, Chapter II, 15.1: "*Diagnostic devices and* ***devices with a measuring function, shall be designed and manufactured in such a way as to provide sufficient accuracy, precision and stability for their intended purpose, based on appropriate scientific and technical methods. The limits of accuracy shall be indicated by the manufacturer."***

15.2: ***"The measurements made by devices with a measuring function shall be expressed in legal units conforming to the provisions of Council Directive 80/181/EEC."***

This implies that each country, each notified body (NB) and each auditor can decide subjectively which technical requirements suffice for a MDMF to enter the market. For eye tonometers the situation is even more inadequate, as the only ISO standard on the topic of eye tonometers (ISO 8612:2009) does not include technical requirements for these devices. This represents a first step in de-harmonising the field of eye tonometry at the EU level.

The role of NB in the case of MDMF is limited in MDR to aspects related to the conformity of MDMF with metrological requirements. But metrological requirements are not specified in MDR.

MDR, Article 52 Conformity assessment procedures:

"7. Manufacturers of class I devices ... shall declare the conformity of their products by issuing the EU declaration of conformity ..... If those devices ... have a measuring function the manufacturer shall apply the procedures set out in Chapters I and III of Annex IX, or in Part A of Annex XI.

However, the involvement of the notified body in those procedures shall be limited:
……

(b) in the case of devices with a measuring function, to the aspects relating to the conformity of the devices with the metrological requirements."

Furthermore, certain aspects of the market surveillance (e.g. verification of MDMF in operation) are left at the discretion of the individual countries:

MDR, Recital (40): *"Member States should not create obstacles to the placing on the market or putting into service of devices that comply with the requirements laid down in this Regulation.* ***However, Member States should be allowed to decide whether to restrict the use of any specific type of device in relation to aspects that are not covered by this Regulation."***

In response, certain countries developed national laws and by-laws that regulate such unclear aspects and define additional requirements for MDMF in operation (in form of periodical mandatory metrological checks of such devices), thus leading to an unsatisfying, heterogeneous situation and an unclear context for manufacturers, calibration offices and operators of MDMF.

The consortium of the inTENSE EMPIR project worked towards finding a solution to this unsatisfactory situation and produced a smart specialisation concept meant to contribute to an increase in the harmonisation in the field of metrological checks of tonometers.

The consortium brings together three groups of countries.

1. Germany and Czech Republic

These countries have introduced periodical mandatory metrological checks of tonometers as well as have adopted national laws specifying technical metrological requirements based on which the metrological checks are performed.

In specific Czech Republic is the only project partner where some MDMF (like tonometers, sphygmomanometers) are covered by the legal metrology and are listed in the regulation determining measuring instruments which are subject to the mandatory legal verifications.

National metrology institutes (NMIs) of Germany (PTB) and Czech Republic (CMI) have long-lasting experience in the field of the tonometry and are able to ensure measurement traceability and technical consultancy for their countries.

2. Austria and Turkey

These countries have introduced periodical mandatory metrological checks of tonometers however they haven't adopted national laws specifying technical metrology requirements.

Therefore, as a reference point, they indicate international standards, manufacturers specifications and state-of-the-art rules.

3. Slovakia and Poland

These countries neither have introduced periodical mandatory metrological checks nor have adopted national laws specifying technical metrological requirements.

In Poland metrological checks of tonometers should be performed when necessary as it is foreseen in the technical specifications (manuals) issued by the producers. Metrological checks should be done by registered, competent entities authorised by the manufacturer (like customer services).

In Slovakia it is considered to introduce tonometers to legal metrology control.

Glaucoma prevention - analysis of the current situation worldwide

Accurate IOP measurements are essential in glaucoma screenings. Glaucoma is a group of eye diseases which result in damage to the optic nerve and cause vision loss. The most common type is open-angle glaucoma which develops slowly over time and without pain. In the first stage peripheral vision begins to decrease and later central vision is getting worse. If not detected in its early stages, glaucoma can result in permanent blindness.

The World Health Organization published its *World report on vision* in 2019[1]. According to the Report at least 2.2 billion people have a vision impairment globally, and of these, at least 1 billion people have a vision impairment that could have been prevented or is yet to be addressed.

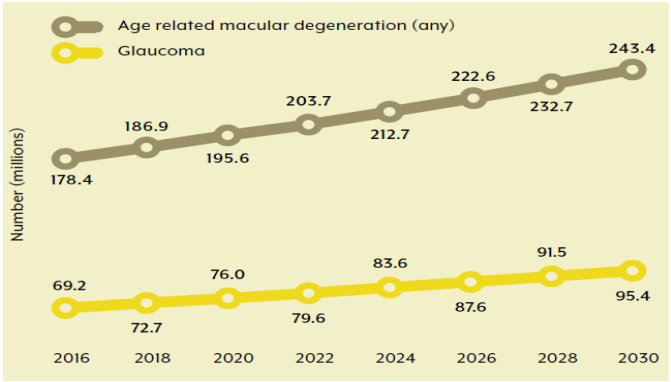
It is estimated that 76 million people worldwide between 40 and 80 years of age suffer from glaucoma in 2020 and 6.9 million people globally have moderate to severe distance vision impairment or blindness due to unaddressed glaucoma.

Population growth and ageing, along with behavioural and lifestyle changes, and urbanization, will dramatically increase the number of people with eye conditions, vision impairment and blindness.

This represents a significant opportunity missed in preventing the substantial personal and societal burden associated with vision impairment and blindness. Eye conditions that can cause vision impairment and blindness are, with good reason, the main focus of prevention and intervention strategies.

The same report shows the projected number of people worldwide with glaucoma and age-related macular degeneration (to year 2030):

Figure 2.6 Projected number of people worldwide with glaucoma and age-related macular degeneration (to year 2030)



Adapted from: Tham YC, Li X, Wong TY, Quigley HA, Aung T, Cheng CY. Global prevalence of glaucoma and projections of glaucoma burden through 2040: a systematic review and meta-analysis. Ophthalmology. 2014;121(11):2081–90; and Wong WL, Su X, Li X, Cheung CM, Klein R, Cheng CY, et al. Global prevalence of age-related macular degeneration and disease burden projection for 2020 and 2040: a systematic review and meta-analysis. The Lancet Global Health. 2014;2(2):e106–16.

Therefore, regular screenings of IOP with reliable instruments are essential. To ensure the correct performance of tonometers in use, some European countries adopted national regulations which impose additional requirements to the EU legislation for this category of devices.
These are implemented through periodic mandatory metrological checks performed either by the national metrology institutes (NMIs) and their local offices or state or private test laboratories depending on the country.

[1] https://www.who.int/publications-detail/world-report-on-vision

Description of the inTense project.

NMIs of Austria (PTP-BEV), Czech Republic (ČMI), Germany (PTB), Poland (GUM), Slovakia (SMÚ) and Turkey (TÜBİTAK UME), together with Palacký University (UPOL) and Slovak Technical University (STU BA) created a consortium to work on a Joint Research Project which succeeded in the European Metrology Programme for Innovation and Research (EMPIR). The designation of the project is *"Developing research capabilities for traceable intraocular pressure measurements"*, with short name *"inTENSE".*

This project worked towards establishing a competence centre for the intraocular-pressure (IOP) metrology at the Czech Metrology Institute (CMI) with CMI as a service provider to other Central European metrology institutes that, for lack of capacity or because of different priorities, can then refer their national customers to CMI.

This focusing of competence at one site will strengthen CMI's research capacity in this area, allowing them to develop calibration services for current and future ophthalmologic instruments. A subsequent expansion of this centre to other European countries and to further medical devices is planned.

Furthermore, the project worked on making the existing (technical) state-of-the-art in IOP metrology accessible to a broader range of countries by condensing the expertise and knowledge at one site in CMI.

The participation of other NMIs in this consortium made it possible to identify their specific needs and capabilities. The establishment of such a competence centre represents a major progress beyond the present state-of-the-art, not technically, but rather with respect to how medical metrology is organised and shared in Central Europe.

This concept will be expanded even further in the future. First, by anchoring it at the most relevant international or European metrological institutions, thus making it sustainable, known and accessible to the widest metrological community. In addition, there will be a first exploration towards an expanded scope of this competence centre: geographically beyond Central Europe and thematically beyond ophthalmologic measurands and towards all quantities in medical device metrology. This long-term goal is too ambitious for a three-year project. However, at the end of this project the ground will have been explored and the next steps will have been prepared.

National legislation concerning MDMF in use in the countries involved in the project

While European legislation highly regulates the market entrance of medical devices, certain aspects of the market surveillance (e.g. metrological checks of devices in use) are left to the discretion of the national legislators. The lack of harmonisation of this area has resulted in a variety of solutions in different countries.

1) Austria

In Austria, three different bodies have been commissioned to implement the statutory provisions in accordance with the Medical Devices Act (Medizinproduktegesetz, BGBl. I No. 657/1996 i.d.g.F) and the Medical Device Operator Regulation (Medizinproduktebetreiberverordnung, BGBl. II Nr. 70/2007[2]). This Regulation applies to the establishment, operation, use and maintenance of medical devices in healthcare facilities.

The Federal Ministry of Labor, Social Affairs, Health and Consumer Protection (BMASGK, Bundesministerium für Arbeit, Soziales, Gesundheit und Konsumentenschutz), Medical Devices Division is responsible for the development of legal bases as well as for strategic matters in the field of medical devices.

The Federal Office for Safety in Health Care (Bundesamt für Sicherheit im Gesundheitswesen, BASG) is the competent authority for operational matters in the medical device sector and it is responsible for questions on medical device vigilance, clinical trials, market surveillance and inspections as well as free sale certificates and uses the **Austrian Agency for Health and Food Safety** (AGES) GmbH (Section Medical Market Supervision) to perform its tasks.

The Federal Office for Safety in Health Care is entrusted with market surveillance of the Austrian medical device market in accordance with Section 6a (4) GESG (Gesundheits- und Ernährungssicherheitsgesetz) and in accordance with the provisions of the Medical Devices Act. As a part of this mandate, the Federal Office for Safety in Health Care (BASG) must ensure that only compliant products are placed on the market. Likewise, the BASG evaluates incoming reports of incidents or corrective measures and initiates any necessary measures to protect Austrian patients. Other tasks such as exemptions for individual patients, delimitations and classifications are defined in the Medical Devices Act (MPG). Free sales certificates for third countries can only be issued by the BASG if the complete conformity of the product can be understood on the basis of the documents to be provided by the applicant. However, the BASG is neither a notified body within the meaning of § 2 Abs. 16 MPG nor supervisory authority of notified bodies. Only the notified body may issue, monitor and renew certificates as part of a manufacturer's conformity assessment procedure.

AGES is the Austrian Agency for Health and Food Security (Agentur für Gesundheit und Ernährungssicherheit) , which as a federal enterprise is also responsible for "medical market supervision". AGES is responsible for the approval and monitoring of medicinal products and medical devices. As this also includes many regulatory tasks, the AGES Medical Market Authority is very closely linked to the Federal Office for Safety in Health Care (BASG). AGES is responsible as the authority for the review of the Medical Device Operator Regulation. This review also includes on-site visits to clinics and hospitals. The client and the owner is the Republic of Austria, represented by the Federal Ministry of Labour, Social Affairs, Health and

[2] https://www.ris.bka.gv.at/eli/bgbl/II/2007/70

Consumer Protection (BMASGK). The Medical Market Authority employs around 280 people. The medical market supervision is certified according to ISO 9001, in addition, the testing activities of the official drug testing laboratory (OMCL) are accredited by the Accreditation Austria.

In accordance with the provisions of the Medical Devices Act (MPG, BGBl. I No. 657/1996 as amended) and the European Union Directives on Medical Devices, Austria has a legal obligation to maintain a register for medical devices and to maintain a register of testing, monitoring and certification bodies. The business unit ÖBIG (**Österreichisches Bundesinstitut für Gesundheitswesen)** of Gesundheit Österreich GmbH is responsible to set up and maintain the register.

Regarding medical devices with measuring function in Austria, it should be noted that in principle medical devices can be kept in a comprehensible and professional manner by the establishment of the healthcare system (i.e. medical centres), taking into account the manufacturer's instructions. At the present time, no information can be provided by the Federal Office for Safety in Health Care (BASG) as to whether any special guidelines such as the guideline for the metrological control of medical devices with measuring function (LMKM) of the Physikalisch-Technische Bundesanstalt (PTB) are applied by health care facilities or by contractors. Additionally, since no accreditation is needed, any company with a business license for mechatronics for medical devices in Austria is allowed to offer and carry out calibration services regarding intraocular pressure devices. Thus, the Federal Office for Safety in Health Care has no list of ophthalmic tonometer testing centres operating in Austria.

Furthermore, the Federal Office for Safety in Health Care notes that with regard to intraocular pressure devices which do not comply with the limits of error according to the instructions for use, the healthcare facilities must take all necessary precautions for the proper maintenance of medical devices. If hazards to patients, users or third parties can occur during measures for the maintenance of a medical device, suitable measures must be taken to avert these hazards from persons. In the case that no limits of error according to the instructions for use is specified by the manufacturer, the Federal Office for Safety in Health Care notes that within the legal framework of Directive 93/42 / EEC, the BASG currently has no known harmonized standards on the subject of eye tonometry.

According to Medical Device Operator Regulation (Medizinproduktebetreiberverordnung, BGBl. II Nr. 70/2007) following medical devices are subjected to metrological checks:

	re-checking period
Medical devices for the acoustic determination of hearing ability (e.g. sound and speech audiometers)	1
Medical devices for determining body temperature:	
Electrical thermometer	2
Medical devices with interchangeable temperature probes	2
Infrared radiation thermometers	1
Medical devices for pressure measurement:	
Medical devices for non-invasive blood pressure measurement	2
Medical devices for determining the intraocular pressure (eye tonometer)	2
Diagnostic pedal crank ergometer for stress tests on the patient	2
Therapy and diagnostic dosimeters	acc. to metrology act
Scales for medical purposes	acc. to metrology act

In summary, the situation in Austria is such that without exception, therapy and diagnostic dosimeters and medical personal scales are subject to the Metrology Act and are therefore also verified. This is the responsibility of the Federal Office of Metrology and Surveying (BEV).

All other medical devices on the list are not subject to compulsory verification according to the Metrology Act but only to compulsory periodic inspection (calibration) according to §7 MPBetreibV. which determines: "*The operator must carry out or have carried out metrological controls, which include calibration and evaluation, for the purpose of traceability to national or international standards...*".

In the field of eye tonometry, the Physico-Technical Testing Service (PTP) of the Federal Office of Metrology and Surveying (BEV) offers calibrations of contact tonometers.

2) Czech Republic

As concerns the medical devices entering the market (conformity assessment), the EU regulation 2017/745 on medical devices (MDR) and EU regulation 2017/746 on in vitro medical devices (IVDR) will come into force on 26th May 2021, replacing Czech Law on medical devices No. 268/2014 Coll. and Czech Government Regulation No. 54/2016 Coll. on technical requirements for medical devices. Simultaneously, Czech Law on technical requirements on the products No. 22/1997 Coll. will be no longer applied to the medical devices after 26th of May 2021, but will be replaced by the Czech Law on conformity assessments of the products introduced to the market No. 90/2016 Coll. which will become applicable to them.

There is also a general Czech Government Regulation No. 117/2016 Coll. on conformity assessments of the products introduced to the market from the point of view of their electromagnetic compatibility.

As concerns the medical devices in service (surveillance), they are covered by the Czech Law on metrology No. 505/1990 Coll. (with the amendments 4/1993 Coll., 20/1993 Coll., 119/2000 Coll., 137/2002 Coll., 13/2002 Coll., 226/2003 Coll., 444/2005 Coll., 481/2008 Coll., 223/2009 Coll., 155/2010 Coll., 18/2012 Coll., 85/2015 Coll., 264/2016 Coll., 264/2016 Coll., 183/2017 Coll.). This law is extended and the details précised by Decree of the Ministry of Trade and Industry No. 262/2000 Coll. (with the amendments 344/2002 Coll., 229/2010 Coll., 125/2015 Coll.) containing some implementing provisions and by Decree of the Ministry of Trade and Industry No. 345/2002 Coll. (with the amendments 65/2006 Coll., 259/2007 Coll., 204/2010 Coll., 285/2011 Coll., 120/20115 Coll.) listing the measuring instruments which are subject to the mandatory verifications and the measuring instruments which are subject to the mandatory type approvals.

The eye-tonometers fall within the category of the instruments subjected to verifications, with a verification period of 1 year for the mechanical and electronic contact eye-tonometers and 2 years for the electronic non-contact eye-tonometers. The periodical verifications are performed by the Czech Metrology Institute (CMI) and other laboratories authorized by the Bureau for Standardization, Metrology and Testing (UNMZ). However, at the moment there is only one laboratory except CMI authorized to verify the mechanical and electronic contact eye-tonometers in the Czech Republic.

These verifications must follow the metrological requirements stated in the so-called General Measures laying down metrological and technical requirements for specified measuring instruments, including the testing methods for verification, which are issued by the CMI[3]. They are General Measure No. 0111-OOP-C038-16 for mechanical and electronic contact ocular tonometers (valid since 7th August 2017 when it replaced older version No. 0111-OOP-C038-13) and No. 0111-OOP-C039-13 for electronic non-contact ocular tonometers (valid since 13th May 2014).

As for the technical standards that are employed, there are ČSN EN ISO 8612 (Ophthalmic instruments — Tonometers), ČSN EN ISO 15004-1 (Ophthalmic instruments — Fundamental requirements and test methods — Part 1: General requirements applicable to all ophthalmic instruments), ČSN EN ISO 15004-2 (Ophthalmic instruments — Fundamental requirements and test methods — Part 2: Light hazard protection), OIML R 145-1:2015 (Ophthalmic instruments – Impression and applanation tonometers – Part 1 – Metrological and technical requirements), OIML R 145-2:2015 (Ophthalmic instruments – Impression and applanation tonometers – Part 2 – Test methods) and OIML R 145-3:2015 (Ophthalmic instruments – Impression and applanation tonometers – Part 3 – Test report format). The series of the

[3] https://www.cmi.cz/node/212?language=en

OIML Recommendations OIML R 145 is explicitly referenced in the General Measure No. 0111-OOP-C038-16.

3) Germany

Prior to the 26th of May 2021, the implementation of the European requirements (MDD) is governed in Germany by the Medical Devices Act (DE: Medizinproduktegesetz, MPG). The document defines the requirements for introducing medical devices on the market and for their operation as well as the necessary surveillance measures.

In addition to the MPG, several ordinances regulate specific aspects of medical devices in Germany. Relevant for the purpose of this paper is the Ordinance on the installation, operation and use of medical devices (DE: Medizinprodukte-Betreiberverordnung, MPBetreibV), document that regulates the installation, operation and use of medical devices in operation. This document addresses the user/operator of medical devices and it defines the requirements for medical devices after they enter the market. These requirements include clear specifications concerning the mandatory metrological checks of certain MDMF:

MPBetreibV, § 14 Metrological checks

> ***(1)*** *For the medical devices specified in Annex 2, the operator shall conduct directly or by way of delegation metrological checks in accordance with the generally accepted state-of-the-art pursuant to paragraph 4 of the aforementioned Annex 2.* ***Proper execution of the metrological checks…. is assumed if the LMKM issued by PTB is complied with…***
>
> ***(3)*** *Unless otherwise stated in Annex 2, only technical standards that are based on a national or international standards and that have sufficiently small error limits and measurement uncertainties may be used for the measurement controls.* ***The error limits and measurement uncertainties are deemed to be sufficiently small if they meet the requirements of the LMKM mentioned in paragraph 1 clause 2*** *or if they do not exceed one third of the error limits and measurement uncertainties of the medical device to be tested.*

The here mentioned **LMKM** are the **Guidelines for metrological verifications of medical devices with a measuring function (DE: Leitfaden zu messtechnischen Kontrollen von Medizinprodukten mit Messfunktion),** a document developed by the national metrology institute of Germany (Physikalisch-Technische Bundesanstalt, PTB) after consultations with the relevant parties in the field. This document describes the procedures for performing the metrological checks of the MDMF subjected to periodical mandatory metrological checks as well as the error limits accepted for each specific device.

The document can be accessed via the PTB's website, both in German (LMKM in German[4]) and English (LMKM in English Part 1[5]) and (LMKM in English Part 2[6]).

[4] https://www.ptb.de/cms/fileadmin/internet/publikationen/ptb_berichte/PTB_Bericht_MM11.pdf
[5] https://www.ptb.de/cms/fileadmin/internet/publikationen/wissensch_tech_publikationen/LMKM-V3-Part1-Englisch_2020.pdf
[6] https://www.ptb.de/cms/fileadmin/internet/publikationen/wissensch_tech_publikationen/LMKM-V3-Part2-Englisch_2020.pdf

The devices subjected to such periodical mandatory metrological checks as well as the check period are indicated in the Annex 2 of MPBetreibV and summarised in the table below:

Type of medical device		Check period /years
audiometer		1
thermometer	a) electronic	2
	b) with exchangeable temperature sensors	2
	c) Infrared	1
sphygmomanometer		2
tonometer		2
ergometers		2
radiation **dosimeters**		2-6

Operators of these MDMF are legally obligated to ensure that their devices were periodically metrologically checked by suitable persons or institutions. These institutions can be private or state offices that comply with the requirements specified in §5 of the MPBetreibV.

After the 26th of May 2021*, with the repeal of the MDD and the entering into force of the MDR, the national legislation in Germany will suffer some changes. As such, the MPG will be replaced by the Medical Devices EU Adaptation Act (DE: Medizinprodukte-EU-Anpassungsgesetz ,MPEUAnpG). However, no significant changes are planned for the MPBetreibV and the metrological verification of MDMF.

**Note: On April 3rd, 2020 the European Commission proposed a one-year delay of the Medical Devices Regulation (MDR) to the European Parliament and Council. On the 23rd of April 2020, it was announced that the European Parliament and the Council adopted the proposal to postpone by one year the date of application of the MDR. This will consequently affect the entering into force of the new German legislation.*

4) Poland

In Poland MDMF are not covered by the Act on Measures dated 11th of May 2001 (consolidated text Journal of Laws 2020 item 140, amendments items 285, 568). **MDMF** (e.g. tonometers) **are not subject of the legal metrology (with the only exception for medical scales)**.

The Central Office of Measures (GUM - Polish NMI) has neither legal competences to deal with medical devices nor metrology experience in this field.

Rules of manufacturing of medical devices, rules of placing them on the market, supervision rules of manufacturing and market surveillance are regulated by the legal parliamentary Act on Medical Devices issued on 20 of May 2010 (consolidated text Journal of Laws 2020 item 186[7]). Works are underway to amend the abovementioned Act in relation to MDR.

The current Act implementing MDD contains minimal requirements for MDMF:

- the result of measurement should be expressed in legal unit of measure and to be comparable to at least one point of reference,

- expected application implies accuracy declared explicitly or alleged, which has to be obtained to avoid undesirable action essential for health or safety of patients.

Essential requirements for medical devices and procedures of conformity assessments can be found in the Ordinance of the Minister of Health released on 19 of February 2016 (Journal of Laws 2016 item 211)[8].

Appendix 1 to the Ordinance point 10:

- MDMF have to be designed and manufactured the way that guarantee stable and precise measurements within the required accuracy, and with taking into account foreseen application. **Manufacturer should define the limits of accuracy.**
- Measurement, monitoring and reading scale have to be designed according principles of ergonomics.
- Measurement results should be expressed in legal units of measurement.

and point 13.6 - 17):

- Technical specifications should contain data concerning declared accuracy of the device.

The Polish law defines neither specific metrological (technical) requirements nor testing methods for MDMF.

The institution responsible for medical devices is The Office for Registration of Medicinal Products, Medical Devices and Biocide Products (URPL) which was created on the basis of the Parliamentary Act issued on 18th of March 2011 (consolidated text Journal of Laws 2020, item 836[9]). The President of URPL is supervised by the Polish Minister of Health.

Before placing MDMF on the market and before its submission to clinical assessment the producer is obliged to perform conformity assessment of the device. The conformity assessment of MDMF has to be conducted in cooperation with a notified body proper due to the scope of notification, on the basis of a contract.

[7] http://prawo.sejm.gov.pl/isap.nsf/download.xsp/WDU20101070679/U/D20100679Lj.pdf
[8] http://prawo.sejm.gov.pl/isap.nsf/download.xsp/WDU20160000211/O/D20160211.pdf
[9] http://prawo.sejm.gov.pl/isap.nsf/download.xsp/WDU20110820451/U/D20110451Lj.pdf

Clinical assessment is performed to prove conformity of the device with the essential requirements concerning features and possible side effects and acceptability of the relation of clinical advantages to the risk occurring under usual condition of use of the device.

Market surveillance is constantly performed by the President of URPL. There are seventeen Polish institutions obliged by the law to cooperate with the Office in the field of supervision like Central Pharmaceutical Inspector, Central Sanitary Inspector, Veterinary Inspection, Office of Competition and Consumer Protection, Technical Supervision Office and others. One of the listed institutions is Central Office of Measures. But the role of GUM in this system is very theoretical.

The system of the market surveillance is mainly based on registration of irregularities or incidents found.

The manufacturer, importer and distributor when placing medical devices on the market which need professional installation, periodical maintenance, service, updating of software, adjustment or calibration is obliged to submit to URPL the list of entities authorised to perform these activities.

The authorised entities have to:

- have appropriate technical equipment, spare parts and consumables,
- possess technical specifications supplied by the producer and approved procedures of performing their activities,
- employ qualified and experienced personnel.

Each healthcare provider is obliged to possess documentation of installation, periodical maintenance, service, updating of software, adjustment, calibrations as well as schedule of future activities. The documentation has to be kept ready for supervision during the operation life of the device and five years after the device was disposed.

There are no official periods for the metrological checks.

5) Slovakia

In order to fully describe the position of eye tonometers within Slovakia from the point of view of the legislation, it must be taken into account that the ophthalmic tonometers as products are medical devices under harmonized law of European Union. As of such these devices must follow the technical regulation for tonometers before placing on the market. This means that the tonometers are placed on the market by conformity assessment by the harmonised European Union law. The relevant documents that apply follow:

- Decision No. 768/2008/EC of The European Parliament and of the Council on a common framework for the marketing of products,
- Regulation (EC) No. 765/2008 of The European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products.

Based on these EU regulations Slovakia uses its national regulation that adapt the previous documents into its own frame which is formed by:

- Act No. 56/2018 Coll. on product conformity assessment, making available of the product on the market and amending acts.

As for the specific technical regulation that focuses on tonometers as devices with measuring function are specified by EU council directive:

- 93/42/EEC concerning medical devices in the ANNEX I. point. 10 Devices with a measuring function.

This directive has been transposed into the law of the Slovak Republic by the Government Ordinances of the Slovak Republic. The specific national document follows:

- No. 582/2008 Coll. laying down detailed technical requirements and conformity assessment procedures for medical devices.

Specifically eye tonometers are covered within Slovakia by the National law frame for technical regulation of measuring instruments which is Act No. 157/2018 Coll. on Metrology and on the Amendment to Certain Acts that establishes obligation of re-verification of legally controlled measuring instruments. List of legally controlled measuring instruments, period for re-verification, metrological requirements and methods for metrological control are establishes in the following act:

- Decree No. 210/2000 Coll. on Measuring instruments and Metrological control.

Based on the scope of the national legislation, eye tonometers are currently not established as the legally controlled measuring instruments.

Future development concerning the position of eye tonometers within the Slovakian legislation is in favour of including these types of measurement devices as legally controlled measuring instruments based on the Paragraph 11 article 1. b) Act on Metrology which states that:

“The measuring instruments used for the protection of health (for example: diagnostic or therapy) can be listed as a legally controlled measuring instruments.”

This fact opens a possibility for the future, as the eye tonometers may become one of the legally controlled measuring instruments.

6) Turkey

The current legal situation, responsible bodies, related documents and perspective of Turkey is outlined below. The interested reader for a more detailed content are referred to [Towards the Harmonization of Medical Metrology Traceability in Europe: An Impact Case Study Through Activities in Turkey & EMPIR Project inTENSE". E. Sınır et al., *2019 IEEE International Symposium on Medical Measurements and Applications (MeMeA)*, Istanbul, Turkey, 2019, pp. 1-6] © [2019] IEEE.

(i) Main Regulations and Responsible Bodies

The supervisory, regulatory and leading authority related to medical devices in Turkey is **Turkish Medicines and Medical Devices Agency – TMMDA (Türkiye İlaç ve Tıbbi Cihaz Kurumu – TİTCK),** the affiliated agency **of the Ministry of Health of Republic of Turkey**. Manufacturing, advertisement and sale of medical devices in Turkey are subject to

1. Medical Device Regulation: Official Gazette No: 27957 dated 07.06.2011. In line with directive 93/42/EEC as amended by 2007/47/EEC.
2. Regulation on Active Implantable Medical Devices: Official Gazette No: 27957 dated 07.06.2011. In line with directive 90/385/EEC as amended by 2007/47/EEC.
3. Regulation on In Vitro Diagnostic Medical Devices: Official Gazette No: 26398 dated 09.01.2007. In line with directive 98/79/EC.

Compliance with the above three directives or bearing of a CE mark is must for a medical device to be placed on the market. The new Medical Device Regulation (MDR) numbered 2017/745 and published in April 2017 in the Official Journal of the European Union (EU), however, will be enforced in Turkey in May 2021, simultaneously with the member states of the EU.

After entering into the market, the mandatory metrological checks of medical devices are governed by the **Regulation on the Testing, Control and Calibration of Medical Devices (Tıbbi Cihazların Test, Kontrol ve Kalibrasyonları Hakkında Yönetmelik)**, published by TMMDA in the Official Gazette numbered 29397 on 25.06.2015. This regulation covers the procedures and principles regarding the application, authorization, monitoring and audits of the organizations that will carry out tests, control and calibration of the medical devices that require user training, maintenance, repair, test, control and calibration during the use of the devices, and qualifications and training of the personnel in these organizations. The manner in which the tests, controls and calibrations of the medical devices are performed, the working principles of the conformity assessment organizations, the personnel qualifications, and the suitability of the equipment owned are included in this regulation. The regulation also includes the provisions regarding the audits of the companies operating in medical test, control and calibration sector at least once a year and the testing, control and calibration of the medical devices are aimed to be carried out by qualified technical personnel.

Provisions for Testing, Control and Calibration are mentioned in the third section, Article 10 of the Regulation, the first two of which are:

"ARTICLE 10 –
(1) *The national and international protocols, guidelines and standards and the criteria of the manufacturer shall be taken into account in the method and period in which the tests, controls and calibrations of the devices shall be carried out.*
(2) Test, control and calibrations are performed at least once a year if there is no specified time concerning test, control and calibration periods of the devices in the national and international protocols, guidelines and standards and the criteria of the manufacturer."

(ii) Guidance Documents and Training of Medical Metrology Experts

Conformity assessment organizations (laboratories) wishing to conduct test, control and calibration of and issue a certificate to a medical device used in healthcare organizations such as hospitals should be authorized by TMMDA in the authorization group(s) mentioned in the Regulation. In this respect, the medical devices are classified into 18 authorization groups ranging from "1. Flow, Weight, Length, Volume, Temperature, Pressure, Cycle" to "18. Medical Air Conditioning Systems."

In order to be authorized in any of the 18 authorization groups, the laboratories must employ a responsible manager and also qualified technical personnel (experts) certified in the related authorization group. The manager and the experts, then, are obliged to have received training from a certified training centre. The information on becoming a certified training centre (also authorized by TMMDA) is given by the document "**Guidance on the Implementation of the Provisions of the Regulation on the Testing, Control and Calibration of Medical Devices (Tıbbi Cihazların Test, Kontrol ve Kalibrasyonu Hakkında Yönetmelik Hükümlerinin Uygulanmasına İlişkin Kılavuz)**, originally published by TMMDA on 25.07.2015 and revised on 23.01.2017. The guide was prepared in accordance with the above-mentioned Regulation on the Testing, Control and Calibration of Medical Devices of 2015 and Ministry of Health Certified Training Regulation published in 2014.

Up to this date, training curricula for the following eight fields have been published within the scope of Ministry of Health Certified Training Regulation: 1. Responsible Manager Training; 2. Experts Training in a. "Flow, Weight, Length, Volume, Temperature, Pressure, Cycle", b. "X-Ray Imaging Systems", c. "Ultrasound-Doppler Imaging Systems", d. "Ventilation Systems", e. "Physiological Signal Monitoring Systems", f. "Electro-Therapy Systems", g. "Electro-Surgical Systems". As it is clear from the above fields, only seven of the 18 authorization groups have been issued with a published training standard in line with the Ministry of Health Certified Training Regulation although all 18 of them were declared as certified training fields. Standard preparation work for the remaining authority groups is still ongoing.

(iii) Situation in Governmental (Public) Healthcare Facilities

The metrology efforts conducted for the medical devices used in state (public) hospitals and other public healthcare facilities are under the responsibility and control of **General Directorate of Public Hospitals** through its **Clinical Engineering Management Unit** under the **Department of Procurement Planning, Stock and Logistics Management**.

Even before the publication of the Regulation on the Testing, Control and Calibration of Medical Devices in 2015 which regulates metrological checks of MDMF in both public and private healthcare, the mentioned unit (formerly Public Hospitals Agency - Department of Stock Tracking and Analysis - Clinical Engineering Management Unit) published a **Biomedical Metrology Activities Guide** in 2014 which was revised in 2016, to ensure the traceability of the health services offered by the public healthcare facilities with the widest and most diverse biomedical technology park in the national framework with the biomedical equipment they own, especially the ones with measurable performance and safety parameters used in healthcare delivery and that can be included in the authorization groups in Annex-2 (Authorization Groups and Explanations) of the Regulation on the Testing, Control and Calibration of Medical Devices, in addition to radiotherapy group devices and clean room validation procedures. The content of the test-control-calibration reports to be given as a result of the biomedical metrology activities is standardized in the annexes with the mentioned guideline.

Annex-2 of the Biomedical Metrology Activities Guide is devoted to **Reference Standards Table**. The standards contained in the Reference Standards Table include the performance and safety criteria. In this table some devices and related standards are highlighted in Green while the others are in Red. For the current situation, compliance with the standards highlighted in green are to be sought. The standards highlighted in Red would be the basis for implementation after obtaining the infrastructure, know-how and personnel competence. The feedback on the applicability of these standards will be collected and re-evaluated until the next revision.

(iv) The Current Situation for Tonometers

Regulation on the Testing, Control and Calibration of Medical Devices makes no direct reference to any named standard for the testing/control/calibration of medical devices, other than mentioning that the national and international protocols, guidelines and standards and the criteria of the manufacturer shall be taken into account, as can be seen from the first two items of Article 10 mentioned in *Main Regulations and Responsible Bodies* subsection above.

The Regulation (in Annex-2), explains the 18 authorization groups to distinguish what types of medical devices fall under a given category. There is no mention of an explicit device name but tonometers are understood to fall under “Medical Lighting Systems” as the devices under this group are explained as “Medical devices used for illumination during surgical procedures, for tissue structuring via energy transfer in dermatological treatment processes, or *devices used for the purpose of diagnosis or treatment in ophthalmic evaluations*”. The training curriculum for this authorization group is not ready yet.

The Biomedical Metrology Activities Guide, on the other hand, includes a Reference Standards Table. The reference standard for Tonometers, TS EN ISO 8612: Ophthalmic Instruments – Tonometers (Oftalmik Gereçler – Tonometreler), falls under “Service Standards to Be Developed/Decided” category and labelled in Red colour which means that the applicability of the mentioned standard for metrology practice for tonometers is not fully accepted yet and it is to be re-evaluated in the forthcoming versions of the guide. As such, this only standard mentioned for tonometers in the guide is not forced to be applied for medical metrology checks because there is no feedback from the medical metrology community or legislative authorities. It is still in suspension.

A general survey among the medical metrology practitioners laid the fact that the current test/calibration reports for the tonometers consists only of electrical safety tests in line with IEC 60601 standards but no performance test/check/measurement is understood to be performed. The service quality standards published by Ministry of Health, General Directorate of Health Services, Department of Quality and Accreditation in Health, however, requires routine adjustment, maintenance and repair activities (along with calibrations) which for tonometers along with some other medical devices translates to checks and adjustment of the devices by manufacturers/distributors/technical services using in general brand specific phantoms and/or standards in periods recommended by manufacturers, hospital needs and frequency of use.

Offer from the Czech Metrology Institute to European countries

The Czech Metrology Institute centre of intra-ocular pressure (IOP) metrology is committed to serve the following purposes in the long-term:

1) To serve as a central hub of an information exchange network in this field. The nodes of the network will be represented by the partners who can offer either their services or expertise in the field of IOP metrology. The working group for eye tonometry can be the starting core of this network. This structure mimics principles of the European Metrology Network (EMN)[10] and it is anticipated that it will in the mid-term perspective either evolve into one or to be incorporated in another suitable EMN. However, CMI commits to keep this hub for the IOP metrology in the long-term even without an existing EMN. In the beginning stages, the web page intense.cmi.cz will serve for this purpose, later on a dedicated web page will be created and maintained by CMI. The information shared in this network is in general considered as publicly available (at least automatically accessible to all the nodes) and all the nodes commit themselves to respect privacy of their clients and partners when sharing new info.

2) To serve as a training site in this field (i.e. impression and applanation tonometers, non-contact, contour and re-bound tonometers). The CMI laboratory in Most, Czech Republic will serve as the training facility for this purpose, with the trainings at the trainees' sites also possible (see below). The creations of other training sites in the other nodes is welcomed and encouraged. Independent on the emerging of new training sites, the CMI commits to keep its training site in the long-term. As for the trainings, the following rules apply:

   2a) For the project partners of 16RPT03 inTENSE and their national stakeholders up to two days of training will be offered free of costs until the end of May 2021. (The trainees bear the costs of their travel, accommodation and subsistence.)

   2b) For other trainees and/or after May 2021, the trainings will be a paid service. Their scope and duration will be adapted to the needs of the trainees and negotiated in advance.

   2c) For the students, there is a possibility of longer internships (several weeks) which can be free if travel, accommodation and subsistence costs are covered e.g. by ERASMUS.

   2d) The paid trainings at the premises of the trainees are possible by prior arrangement. The mentioned above CMI commitment does not apply to them. The scope of the training, its duration and the amount of CMI remuneration will be negotiated each time. The laboratories are required to be adequately equipped (i.e. own the necessary equipment for the training) and provide trainees with at least minimal metrological knowledge.

3) To serve as a source of metrological traceability for IOP standards. It is not expected that the hub located at CMI would offer basic services (i.e. regular verifications and/or calibrations of medical devices) to the end users outside the Czech Republic. This is left to the governmental or private test laboratories in the individual countries. The creations of the advanced laboratories in the other nodes is welcomed and encouraged (preferred from the point of view of the interlaboratory comparisons, see point 4). The hub at CMI will share its know-how with other nodes in such cases, the testing procedures developed by the CMI, the inTENSE project and the network will be made publicly available via the web of the hub. However, regardless whether a new traceability source appears or not, the CMI commits to keep the instrumentation and expertise to serve as the source of traceability in the IOP

[10] EURAMET EMN website: https://www.euramet.org/european-metrology-networks/.

metrology in the long-term. These will only be offered as paid services. The following rules apply:

3a) The traceability of laboratory conditions as well as the determination of the local acceleration due to gravity should be ensured by each national metrology institute (NMI) on its own.

3b) Impression (Schiötz) tonometers – in this case the traceability of the devices or their components or measuring instruments necessary for their checks can be simply performed by any NMI itself. However, CMI can provide these calibrations if any NMI requires such service. The calibration is possible for mechanical or electronic balance (minimal range: 5 g − 18 g, minimal accuracy: ≤ 0,050 g), micrometre (range from 0 mm to minimally 5 mm, minimal accuracy 0,003 mm), protractor (range ±minimal accuracy: 2°), testing spheres of radii 16,00 mm and 14,75 mm (minimal accuracy ≤ 0,05 mm). The protractor and the mechanical devices to mount an impression tonometer under test on the balance are not available on the market, but CMI can share the design and they can be reproduced easily.

3c) Applanation (Goldmann) tonometers – in this case the traceability of the devices or their components or measuring instruments necessary for their metrological checks can be simply performed by any NMI itself. However, CMI can provide these calibrations if any NMI requires such service. The calibration is possible for an optical limit gauge which is needed for checking the glass contact heads. SIOS testing rig can be calibrated by external weights (range: 0 − 10 g (100 mN), resolution: 1 mg (0.01 mN) [internal 0.1 mg], standard uncertainty of force sensor: < 0.5 mg).

3d) Non-contact (air-puff) tonometers (NCT) – in this case the traceability depends on the transfer standard available. There are three commonly known standards: Flapper (PTB-jig), rubber / silicone eye sets, electronic eye.

3di) The flapper is a very precise standard, but it cannot be utilised for all types of the NCTs. The periodical calibrations of this device can be performed by CMI. The flapper can be manufactured in the Czech Academy of Sciences – Research centre for special optics and optoelectronics. Whether or not the flapper is adequate for the verification/check of a certain device will be established in a consultation process between CMI and the customer.

3dii) The rubber eyes and/or the electronic eyes are produced by the individual NCT-manufacturers for their NCTs while they also ensure their traceability. They are usually not compatible with the NCTs produced by other manufacturers, and sometimes even not with other types of devices produced by the same manufacturer. Whether or not a certain set of rubber eyes and/or electronic eye is adequate for the verification/check of a certain device will be established in a consultation process between CMI and the costumer.

3e) Dynamic contour tonometers of the PASCAL type tonometer have a manufacturer's device to be tested in one pressure point. A more universal device (either from the manufacturer or own design) consisting of a manometer with 0.01 mmHg resolution, a pressure source and a buffer pressure vessel can be built easily. The traceability can be simply performed by any NMI itself. However, CMI can provide these calibrations if any NMI requires such service.

3f) A calibration device for Tono-Pen tonometers (McKay-Marg principle) produced by company Reichert is dedicated solely for the traceability of this type. It consists of a model eye and a reference manometer which can be calibrated by any NMI itself. However, CMI can provide these calibrations if any NMI requires such service.

4) To organize inter-laboratory comparisons in the field of IOP metrology. One of the aims of the network will be to recommend an interval for such comparisons for various IOP measurement principles. Although the CIPM MRA and its KCDB is the ultimate pattern for this, the network will never have any formal position to require any comparisons and/or quality system demands (which are the responsibility of the respective national authorities) and the participation will be voluntary. According to the respective type of tonometer, they can be organized either with a travelling transfer standard or to take place in the CMI laboratory in Most.

5) To develop the new verification/check procedures available to the network unless it could violate the device manufacturer's know-how rights and provide the certifications of the new types of IOP testing devices.

6) To provide expertise in the field of the new measurands. This could be a challenging task and there is no guarantee that the centre in Most will always be able to do that on its own. In such cases the Working group on Eye-tonometers will be approached for advice or another bilateral or multilateral cooperation with the manufacturers, academia and other relevant players in the field will be actively sought.

Input from the possible customer NMIs

1) Austria

Since the introduction of the Medical Device Operator Regulation (Medizinproduktebetreiberverordnung, BGBl. II Nr. 70/2007[11]), no legal regulations in the area of legal metrology exist for eye tonometry. Therefore, BEV is not directly affected. Responsible for the implementation of the Medical Device Directive and subsequently the Medical Device Operator Regulation is the Federal Ministry of Social Affairs, Health, Care and Consumer Protection. During the project, contact to the responsible authorities has been established. At present, however, there is no desire for closer cooperation.
However, BEV-PTP has profound experience and knowledge in the testing and calibration of applanation and impression tonometry. The clientele mainly includes private ophthalmologists as well as hospitals. About 250 devices are calibrated per year. For such purpose, BEV-PTP is well equipped with appropriate test benches. Staff training is carried out in-house by PTP-BEV.

In order to evaluate and demonstrate the calibration and testing performance of both PTP-BEV and CMI in the field of applanation and impression eye tonometry, PTP-BEV can act as a partner laboratory in inter-laboratory comparisons between these two laboratories on a regular basis. In that sense PTP-BEV can act both as customer and partner of the medical metrology centre which is being established by the Czech Metrological Institute (CMI).
Concerning non-contact tonometers the PTP-BEV is also equipped with appropriate test equipment , so called “Flapper”, but such calibrations have not been offered for years by PTP-BEV since information of manufacturers would be missing, how to select a suitable test mode for the devices so that a test can be performed with the current test equipment. Here on the other hand PTP-BEV can provide test equipment for inter-laboratory comparisons between CMI and BEV. Whether PTP-BEV will resume a calibration service for priority Austrian customers regarding non-contact tonometers depends on the cost of the procurement of additional necessary equipment. The PTP-BEV would then have to decide whether this would generate enough revenue. However, when PTP-BEV reintroduces such calibration services, the training opportunities offered by the CMI will be of great importance to future new employees.

[11] https://www.ris.bka.gv.at/eli/bgbl/II/2007/70

2) Germany

According to Section 32, (3) of the Medizinproduktegesetz (MPG),
(3) The Physikalisch-Technische Bundesanstalt is responsible for ensuring the uniformity of metrology in medicine and shall:
1. perform expert evaluations of medical devices with measuring function,
2. develop and, upon request, test reference measuring procedures, standard measuring devices and test devices,
3. provide scientific advice to the competent authorities and notified bodies.

As in Germany periodical metrological checks are mandatory, and new and modern devices are being produced constantly, PTB is responsible for the verification of new test procedures and test devices developed by manufacturers for certain categories of medical devices with a measuring function (audiometers, clinical thermometers, non-invasive blood pressure devices, eye tonometers, ergometers and therapy and diagnostic dosimeters).

PTB is interested in keeping these legal responsibilities, but due to a change in priorities at management level, an outsourcing of certain technical aspects in this field is thought. In this scope, a close cooperation between PTB and CMI was initiated in 2008, with PTB providing technical, scientific and legal advice to CMI. The end goal of this cooperation was to establish CMI as an expert in the field of metrological eye tonometry and a service provider to PTB and customers of PTB. As a service provider, CMI will perform the verification/checks and certification of transfer standards, test devices and test procedures for German customers in the field of eye tonometry. As a consequence of the cooperation between the two NMIs, the EMPIR project inTENSE launched in 2017 and ended in 2020 was written together with other NMIs interested in potentially taking advantage of CMIs offer.

PTB is also interested in expanding CMIs competence to other medical devices and establishing a centre of competence for medical device metrology at the site of CMI and take advantage of its services for other types of medical devices as well. In this scope, a new EMPIR project adOSSIG on metrology for blood pressure measurements was successfully submitted. During this project, a centre of competence for blood pressure metrology will be established, able to provide services to all interested European NMIs.

3) Poland

Participation in the inTense project gave GUM possibility to gather the basic knowledge about the metrological checks of different types of tonometers in use. The most advantageous part of the project from the GUM perspective was the workshop in Warsaw held in September 2019. Due to the pandemic a hands-on training at CMI in Most did not take place. However, such a training is still possible even after the end of the project.

As GUM has no legal competences and practical experience related to tonometers the future of the metrological checks of MDMF in use depends on the attitude of two institutions:

- the Ministry of Health,
- the Office for Registration of Medicinal Products, Medical Devices and Biocide Products (URPL).

The representatives of these institutions were engaged in the Warsaw workshop and they were informed about the project's vision and the current legal framework in Germany and Czech Republic, as well as the regulations in Turkey.

Before the end of the project, due to the pandemic, the official correspondence with the above institutions could not be completed and binding arrangements were not made.

However, GUM is ready to play the role of an intermediary between CMI and Polish medical institutions if the Minister of Health decides to introduce metrological checks of tonometers in use.

From 26th of May 2021, new devices will have to meet the requirements of MDR in order to be placed in the European market.

Because of MDR, the Polish Ministry of Health has prepared a draft of the new parliamentary act on medical devices. The new draft was prepared in October 2019 and widely consulted in the country at the turn of the year.

At the time of writing of this document, the draft was not yet adopted by the government and was not transferred to the parliament.

An interesting proposal of a new law provision can be found in the art. 46 of the draft.

This provision says that:

*"2. **The minister** competent for health matters on the basis of the notifications of the President of URPL, **may specify, by regulation,** requirements or restrictions regarding the distribution, issuing, use of a given generic group of products, including **requirements regarding** the qualifications of operators or installations, periodic maintenance, periodic or ad hoc service, software updates, **periodic or ad hoc inspections, adjustments, calibrations, checks or safety checks of a given type of devices, including requirements for the technical equipment of entities performing these activities and qualifications of the persons employed therein**, taking into account the safety of patients, operators and third parties, provided for the use and function of the devices and the related risks."*

This is an attempt of introduction of so called statutory delegation enabling the Minister of Health to issue new regulations to the parliamentary act if necessary. If this provision remains in the final text of the act it could be the basis for internal regulations concerning the technical requirements as well as the introduction of metrological checks of MDMF.

4) Slovakia

The current situation within the Slovak Republic regarding the eye tonometry does not reflect the need for reliable measurements of intraocular eye pressure that is used as a primary means of diagnosing eye glaucoma in its initial stages.

As of now eye tonometers are not considered as the legally controlled measuring instruments. Their supervision from the side of metrology is only voluntary which can result into possible false diagnosis.

A dialog has been opened between the medical experts and the responsible Slovak office of standards, metrology and testing. This dialog has resulted into an effort to include tonometers into the list of legally controlled devices with a minimal required verification interval.

Prior to the inclusion of eye tonometers into the list of controlled measuring instruments preparatory efforts must be realized. These efforts are intended to prepare the national metrological system to be able from the side of available experts that have the necessary knowledge from this specific field, technical equipment and personal capacity. In order to enable a smooth transition toward a controlled tonometer system the following steps need to be addressed:

- Assurance of knowledge transfer in the form of trainings and workshops,
- Technical assistance with the creation of necessary infrastructure for the verification of eye tonometer devices,
- Verification and validation of created methods within Slovakian metrological laboratories,
- Partial transfer of customers who could not be provided with the requested services by the Slovakian metrological laboratories yet to CMI,
- Regular bi- or multilateral comparisons of laboratories in order to test capabilities within the field of eye tonometer verification.

All of the above-mentioned points could be provided by the emerging medical metrology centre which is being established by the Czech Metrology Institute (CMI).

5) Turkey

The centre at CMI offers services of IOP Metrology. The initial service to be received by TÜBİTAK UME from the mentioned centre is foreseen to be getting the fundamental training in IOP Metrology. TÜBİTAK UME has a dedicated Medical Metrology Laboratory established in 2014 upon the finalisation of the Medical Metrology Feasibility Project. The main objective of the laboratory is to establish the traceability chain of measurement quantities related to medicine and medical devices. Personnel of the Medical Metrology Laboratory were also invited to attend the training that was planned to take place at Most, Czech Republic on two different occasions of different dates in March 2020 and the laboratory approached the invitation quite positively by agreeing to send one of their researchers to the training as well as the participation of the inTENSE contact person of TÜBİTAK UME. The unprecedented events of Covid-19 outbreak, however, prevented this to take place due to the travel restrictions and the preventive measures taken at the CMI site. At least two personnel of TÜBİTAK UME are still considered to attend the training until May 2021. Combined with the Good Application Guideline (Deliverable 8) and possible other standardisation and/or guidance document(s) expected to emerge from the inTENSE project, this training will give the researchers of TÜBİTAK UME the chance to anticipate the requirements for the establishment of a traceability chain within Turkey in IOP Metrology. This will also require an information exchange, services, and know-how transfer from the side of CMI.

The training of TÜBİTAK UME personnel will only be the first step in establishing an IOP Metrology traceability chain in Turkey. As mentioned in *Guidance Documents and Training of Medical Metrology Experts* subsection, any conformity assessment organization that will be conducting metrological checks (test, control, calibration) on medical devices with a measurable performance parameter and issuing certificates for these devices shall first receive authorization license from Turkish Medicines and Medical Devices Agency, TMMDA, and they must employ a responsible manager and qualified technical personnel to perform the mentioned metrological checks. The technical competence of the conformity assessment organization (laboratory) and its personnel is to be assessed by TMMDA. According to the Regulation on the Testing, Control and Calibration of Medical Devices and the related Guidance document, the responsible manager and the technical staff of the laboratory must receive training from an authorized training centre with respect to the authorization groups mentioned in the regulation. In order for the authorized training centres to provide training to the candidate responsible managers and technical personnel, there must exist a training standard on the relevant training field that is published within the scope of Ministry of Health Certified Training Regulation. Out of 18 authorization groups, only seven of them have a published training standard in addition to the training standard on responsible manager training. The tonometers are understood to fall under the Medical Lighting Systems category. This authorization group still lacks a published training standard, but the standard preparation work is still ongoing.

Once TÜBİTAK UME personnel receive training from the established centre at CMI, TMMDA can be informed on the training requirements for IOP Metrology and tonometer calibrations that will help them further the endeavour of publishing a training standard on Medical Lighting Systems, an authorization group of medical devices including tonometers. The training standard content outlined in above-mentioned Regulation, Guideline and their annexes gives chance to CMI to anticipate the general questions that might be asked in a future agreement on information exchange and know-how transfer between TÜBİTAK UME and the CMI and in the probable following take-up of these services by conformity assessment organizations (laboratories) that are providing on-site services to healthcare facilities in Turkey.

According to the Regulation and the guidance document, public and private law legal entities and real persons who wish to organize certified training programs must make an application to TMMDA with a dossier content of which is defined in the guidance document. Once the submitted documents are accepted to fulfil the criteria, the candidate training centre is assessed by TMMDA on-site and only after a successful evaluation a protocol is signed between TMMDA and the centre, and a "certified training program implementation authorization certificate" is issued to the centre. Although the possibility of CMI being a training centre does not seem impossible as defined by the existing Regulation, it is practically not envisaged to be able to fulfil all necessary conditions, be inspected by TMMDA and provide training to a high number of candidate test, control, calibration experts. The training, on the other hand, of the trainers who will be providing either the theoretical or hands-on education to candidate experts in the certified training centres seems likely by the services of CMI. In this respect, TÜBİTAK UME personnel who will be trained in the first training sessions at CMI may be trainers of the future education specialists and/or they can themselves be the ones providing trainings in the certified training centres. If this path of training of the trainers is followed, however, it will still be necessary to transfer the mentioned know-how and establish and maintain the laboratory and device infrastructure required of a proper IOP Metrology training environment.

Another pathway of improving the existing situation in terms of metrological checks of tonometers in use in Turkey is expected to be through the knowledge produced of documentation effort from the inTENSE project and maintained at CMI. As mentioned in *Situation in Governmental (Public) Healthcare Facilities* subsection, The Biomedical Metrology Activities Guide referencing the national and international standards to be followed for in-use metrological controls of MDMF is possibly to be updated by the information contained in the Good Application Guideline (Deliverable 8) and possible other standardisation and/or guidance document(s) to be expected of the inTENSE project.

To be a part of the working group of eye tonometry would be identified as another objective of TÜBİTAK UME by engaging in the information exchange network as a potential natural node, as the nodes in this network are welcome and encouraged to build their own laboratories making use of the expertise developed at CMI. The potential delivery of calibration systems and tools in addition to the information to Turkey from CMI shall then be the next step for the creation of such testing facilities on IOP Metrology and also for the creation of IOP Training Facilities in line with the current directives and regulations in Turkey discussed above.

Description of the desired new model of common approach to intraocular pressure measurement in Europe with CMI as provider of the traceability.

The accuracy of measurements performed using MDMF is crucial to ensure successful diagnosis and treatment. However, at the moment, this is regarded as less essential than for instance the accuracy of water or electrical energy consumption measurements.

Neither MDD nor MDR did establish specific technical requirements for MDMF which creates a confusing situation not only for state institutions active in the field of MDMF, but in the same time for notified bodies, manufacturers and medical device operators.

In case of many measuring instruments there are technical requirements agreed on the EU level and included in legal acts.

There are two good examples of common regulations:

- Directive 2014/31/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of non-automatic weighing instruments
- Directive 2014/32/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of measuring instruments.

Directive 2014/32/EU applies to the measuring instruments defined in the instrument-specific annexes from III to XII concerning water meters, gas meters and volume conversion devices, active electrical energy meters, thermal energy meters, measuring systems for continuous and dynamic measurement of quantities of liquids other than water, automatic weighing instruments, taximeters, material measures, dimensional measuring instruments and exhaust gas analysers.

These directives contain specific technical requirements for measuring instruments which are now transposed to national legislations.

MDMF are subject to time and use linked degradation that affects their measurement performance. To ensure a correct and safe performance of these devices also after they enter to the market, some countries introduced periodical mandatory metrological checks for MDMF in use.

Nevertheless, only two European countries Germany and Czech Republic adopted national laws specifying technical metrological requirements based on which the metrological checks are performed.

Other countries refer to international standards (if they exist), manufacturers specifications and state-of-the-art rules.

While such technical metrological requirements help to partially rectify the inadequate handling of MDMF by EU legislation, it would be ideal to correct this situation at the stage of introducing MDMF to EU market.

It should be done by **defining specific technical metrological requirements for some MDMF (e.g. tonometers) that apply to all EU countries** ensuring in this way not only a clear path for all players involved in the field, but also **the harmonisation at EU level.**

This is also in order to avoid the undesired cases in which, certain MDMF that passed the conformity assessment based on the EU legislation will be rejected during periodical mandatory metrological checks (e.g. in Germany or Czech Republic).

One very ambitious option in achieving this goal would be to initiate a cooperation between EURAMET (or a network of NMIs with expertise in the field of IOP metrology) and the Medical Device Coordination Group (MDCG) in order to develop a common specification on the topic of eye tonometers.

This would highly help in achieving a common approach in all EU countries Such an ambitious plan needs a long-term strategy as well as a bigger network of NMIs and expertise, not only in the field of IOP metrology, but generally in the field of MDMF metrology. For this purpose, plans considering the establishment of a European Metrology Network for Medical Device Metrology are ongoing.

For the current project, the plan proposed by the inTENSE consortium is to create a network of experienced and inexperienced NMIs in the field of IOP metrology that would work together in achieving a certain level of harmonisation. This will not only support the increase in harmonisation but will also support a quick development of the IOP metrology market at EU level. This network will be supported by a physical centre for IOP metrology located at CMI in the Czech Republic. CMI will play a central role as a service provider for other interested NMIs and other stakeholders in the field (e.g. training centre, organiser of interlaboratory comparisons and supplier of the traceability for interested NMIs or accredited laboratories).

Conclusions.

Medical devices make an essential contribution to healthcare in the EU for the benefit of the European citizens. From bandages to X-ray scanners, dentures to hip joints and in-vitro diagnostic devices that monitor diabetes or identify infections; medical devices are crucial in diagnosing, preventing, monitoring and treating illness, and overcoming disabilities.

Unfortunately, MDMF sink in the sea of medical devices. As their correct performance is essential with crucial consequences to our society, there is no reason to hold them to lower standards compared to other non-medical measuring instruments. Therefore, action should be taken to create common technical requirements at EU level.

An alternative option would be the creation of a Medical Metrology Network to support the Medical Device Regulation on voluntary basis.