Management of Medical Equipment in Eastern Europe

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Board Member of IFMBE Clinical Engineering Division
Councillor for Regulatory Affairs of EAMBES
Disclosure

• The presenter declares no conflict of interest with the materials provided.
FDA MAUDE (Manufacturer and User Facility Device) Data on deaths and injuries caused by faulty medical device (10-year available data)

<table>
<thead>
<tr>
<th>Medical device</th>
<th>Deaths</th>
<th>Injuries</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infusion and perfusion pumps</td>
<td>&gt;800</td>
<td>&gt;1300</td>
</tr>
<tr>
<td>Defibrillators</td>
<td>&gt;700</td>
<td>&gt;1000</td>
</tr>
<tr>
<td>Paediatric incubators</td>
<td>&gt;300</td>
<td>&gt;500</td>
</tr>
<tr>
<td>Therapeutical ultrasound</td>
<td>&gt;200</td>
<td>&gt;400</td>
</tr>
</tbody>
</table>

Data on deaths and injuries caused by faulty medical device (10-year available data)
PART 1

MEDICAL DEVICE INSPECTION LABORATORY

VERLAB
SOLUTION MEDICAL DEVICES METROLOGY STANDARDIZATION

LEGAL METROLOGY FRAMEWORK FOR MEDICAL DEVICES

✓ Safety
✓ Performance
✓ Accuracy
✓ Reliability

✓ Inspection
✓ Etalon
✓ Calibration
✓ Traceability

✓ National Body

✓ ISO 9001
✓ ISO 17020
✓ ISO 17025
✓ IEC 60601

MEDICAL MEASUREMENT RELIABILITY IS ENSURED BY TRACEABILITY CHAIN

National Institute of Metrology
- Represents the SI units and ensure international comparability
- Calibration Laboratory
- Calibration by National Institute of Metrology
- Testing laboratory
- Calibration by accredited laboratory
- Measuring equipment
- Measurements and tests as part of quality assurance process

SOLUTION

DOCUMENTATION
Medical Device Inspection Laboratory - VERLAB

Founded in 2014 - > Small – size – enterprise (SME)
VERLAB IS:

**Appointed** by the Institute of Metrology of B&H as Metrology laboratory, for provision of testing services and verification of etalons and devices in healthcare in the field of medical instruments with measurement function in Bosnia and Herzegovina.

**Accredited** laboratory, by the Institute for Accreditation of Bosnia and Herzegovina (BATA), according to BAS EN ISO / IEC 17020: 2013 standard, to perform inspection in the field of blood pressure measuring devices.

**Certified** Laboratory, by Bureau Veritas (UKAS Management Systems), according to ISO 9001: 2015 standard, for performance of medical device inspection procedure in healthcare.
• Organigram of the enterprise
Medical Device Inspection Laboratory - VERLAB

- Organigram of the Laboratory

Director → Technical Manager → Laboratory Staff → Medical Devices
Medical Device Inspection Laboratory – VERLAB - services

Verification of defibrillators

Verification of ECG devices

Verification of pediatric and neonatal incubators

Verification of respirators

Verification of infusion pumps

Verification of therapeutic ultrasounds
Medical Device Inspection Laboratory – VERLAB - services
Verlab has calibrated working etalons (phantoms) of renowned manufacturers such as Fluke Biomedical, IMT and Messa Labs.
Fluke Biomedical Prosim 6/8
Phantom for inspection of ECG devices, patient monitors and blood pressure devices

Fluke Biomedical Impulse 7000 DP
Phantom for inspection of defibrillators

Fluke Biomedical ESA 620
Phantom for inspection of electrical safety for medical devices
**Medical Device Inspection Laboratory - VERLAB**

- **Fluke Biomedical**
  - **INCU I**
  - Phantom for inspection of infant incubators

- **Ohmico Instruments**
  - **Ultrasound Powermeter**
  - Phantom for inspection of therapeutic ultrasounds

- **IMT**
  - **PF 301**
  - Phantom for inspection of mechanical ventilators and anesthesia machines
Messa Labs 90XL
Phantom for inspection of dialysis machines

Fluke Biomedical VT 305
Phantom for inspection of mechanical ventilators and anaesthesia machines
All processes in the Laboratory are conducted according to ISO 17020 procedures as follows:

- Document Control Procedure
- Procedure for tracking records
- Procurement Procedure
- Procedure for calibration and maintenance of inspection equipment
- Training procedure
- Risk Management Procedures
- Procedure for re-examination of requests, tenders and contracts
- Customer Relationship Process
- Procedure for handling of equipment

- Procedures for handling samples for inspection
- Procedure for Inspection of Medical Devices
- Appeal Procedure
- The process of controlling the unconformity of the inspection process
- Procedure for corrective and preventive actions
- Internal Audit Procedure
- Procedure for management control
- Procedure for the Protection and Data Security
- Working procedures
VERIFICATION = INSPECTION

“a measures to determine all or some of the following elements: that the trademark and / or the certificate are valid, that no trademark is damaged, there has not been obvious changes of the device, its errors do not exceed the maximum permissible errors in use.”
STEP 1 – REQUEST FOR VERIFICATION

Healthcare institution sends formal request for verification of medical devices
STEP 1I – EVALUATION OF REQUEST

Healthcare institution sends formal request for verification of medical devices

The request is evaluated by the inspection laboratory and approved.
Healthcare institution sends formal request for verification of medical devices.

The request is evaluated by the inspection laboratory and approved.

Appointment for verification is agreed with healthcare institution.
Healthcare institution sends formal request for verification of medical devices

The request is evaluated by the inspection laboratory and approved.

Appointment for verification is agreed with healthcare institution.

Qualified personnel performs verification process of medical devices in healthcare institutions or in laboratory premises.
Healthcare institution sends formal request for verification of medical devices.

The request is evaluated by the inspection laboratory and approved.

Appointment for verification is agreed with healthcare institution.

Qualified personnel performs verification process of medical devices in healthcare institutions or in laboratory premises.

Verification is a periodical process! 1 year period.
**VERIFICATION/INSPECTION OF MEDICAL DEVICES – Process Steps**

**STEP V – REPORTING & COMMUNICATION**

1. Healthcare institution sends formal request for verification of medical devices.

2. The request is evaluated by the inspection laboratory and approved.

3. Appointment for verification is agreed with healthcare institution.

4. Verification is a periodical process! 1 year period

5. Qualified personnel performs verification process of medical devices in healthcare institutions or in laboratory premises.

6. All measurements are stored in an online database.
STEP V – customer service

- The software is implemented in Oracle Application Development Framework Technology (ADF) and it is used to facilitate gathering of documents such as Inspection Certificates, Working Orders, Inspection Reports, Calculated Errors, and also to keep track of dates for next inspection.

- The software can be accessed online via Inspection Laboratory (Verlab) website, and all clients, as well as employees can login using their own username and password which makes all inspection data confidential.
STEP V – customer service


STEP V – customer service
Public available...

KANTON SARAJEVO

Legenda: ● - verifikovano | ● - djelomično verifikovano (u toku postupak verifikacije) | ● - isteka verifikacija | ● - nije nikad verifikovano

Privatna zdravstvena ustanova

- Alea Dr Kandić
- Ambulanta FDS
- Apoteka Libero Sarajevo
- Apoteka VIta Sarajevo
- Bahceli Health Services Sarajevo
- Banja Terme Ilidža
- Centar za estetsku hirurgiju "Naša mała klinika"
- Centar za fizikalnu medicinu i akupunkturu – Prof.dr. Dijana Avdić
- Centar za srce – Dr Mirsad Kacila
- Chicago Vien Institute Sarajevo
- D.Med Healthcare BH D.O.O.
- Internistička ordinacija Dr Avdija Bašić
- Internistička ordinacija Dr Harun Bilatović
- Internistička ordinacija Dr Jelić
- Internistička ordinacija Dr Šída Kasumagić
- Internističko kardiološko ordinacija "Dr Vedad Mujačić"
- Kardiološki centar Dr Ismet Pezo
- Mesut d.o.o. Sarajevo Centar
PART 2

2015-2017 RESULTS OF INSPECTION OF MEDICAL DEVICES

BOSNIA AND HERZEGOVINA

CASE STUDY
Bosnia and Herzegovina Case Study

2015-2017 Results

Increase in number of inspected devices for **79.16%** in 2016 in respect to 2015.

Increase in number of inspected devices for **59.62%** in 2017 in respect to 2016.


Avarege faulty rate decreased for around 10% in 2016 in respect to 2015.

Avarege faulty rate decreased for around 2% in 2017 in respect to 2016.


### Turkey and Herzegovina Case Study
2015-2017 Results

<table>
<thead>
<tr>
<th>Medical devices</th>
<th>Total number of inspected devices</th>
<th>% of accurate devices</th>
<th>% of faulty devices</th>
</tr>
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<tr>
<td>Anaesthesia machine</td>
<td>264</td>
<td>87.12</td>
<td>12.88</td>
</tr>
<tr>
<td>Dialysis machine</td>
<td>324</td>
<td>94.75</td>
<td>5.25</td>
</tr>
<tr>
<td>Defibrillator</td>
<td>835</td>
<td>94.85</td>
<td>5.15</td>
</tr>
<tr>
<td>ECG</td>
<td>2126</td>
<td>96.19</td>
<td>3.81</td>
</tr>
<tr>
<td>Infusion pumps and perfusors</td>
<td>934</td>
<td>87.9</td>
<td>12.1</td>
</tr>
<tr>
<td>Neonatal and pediatric incubator</td>
<td>159</td>
<td>77.3</td>
<td>22.7</td>
</tr>
<tr>
<td>Patient monitor</td>
<td>866</td>
<td>91.57</td>
<td>8.43</td>
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<td>Respirator</td>
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<td>87.64</td>
<td>12.36</td>
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<td>70</td>
<td>92.0</td>
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1. High risk types of medical devices susceptible to safety and performance malfunctions
2. Bosnia and Herzegovina Case Study 2015-2017 Results
3. Legal Metrology Framework for Medical Devices

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LEGAL METROLOGY FRAMEWORK FOR MEDICAL DEVICES
### Bosnia and Herzegovina Case Study

2015-2017 Results

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<td>324</td>
<td>94.75 (3)</td>
<td>5.25</td>
</tr>
<tr>
<td>Defibrillator</td>
<td>835</td>
<td>94.85 (2)</td>
<td>5.15</td>
</tr>
<tr>
<td>ECG</td>
<td>2126</td>
<td>96.19 (1)</td>
<td>3.81</td>
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<td>934</td>
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### Accurate Device Trend

- Highest accuracy rate achieved for ECG, defibrillators, and dialysis machines
Bosnia and Herzegovina Case Study

2015-2017 Results

RESULTS

Critical percentage of faulty rate!

LEGAL METROLOGY FRAMEWORK FOR MEDICAL DEVICES


Bosnia and Herzegovina Case Study
2015-2017 Results

**RESULTS**

Critical percentage of faulty rate!


LEGAL METROLOGY FRAMEWORK FOR MEDICAL DEVICES

Bosnia and Herzegovina Case Study
2015-2017 Results

RESULTS

**Bosnia and Herzegovina Case Study**

2015-2017 Results

**LEGAL METROLOGY FRAMEWORK FOR MEDICAL DEVICES**

**Increase of faulty rate!**

**Results**


## Overview of cost savings by medical institutions on maintenance of medical devices

**Bosnia and Herzegovina Case Study**

2015-2017 Results

<table>
<thead>
<tr>
<th>Institution</th>
<th>Total % of saving after implementing regulations (one year period)</th>
</tr>
</thead>
<tbody>
<tr>
<td>University Clinical Centers (CoE)</td>
<td>74.7%</td>
</tr>
<tr>
<td>Hospitals</td>
<td>79.3%</td>
</tr>
<tr>
<td>Primary healthcare institution</td>
<td>81.6%</td>
</tr>
<tr>
<td>Medical private institutions</td>
<td>76.8%</td>
</tr>
<tr>
<td>Total</td>
<td>78.0%</td>
</tr>
</tbody>
</table>

• Example of cost-benefit:

... that an intensive care unit has 10 respirators for patients. The recommendation of the manufacturer (distributor) is to have an attestation four times annually. The price of the attest is 500KM per device. The total price per year (without the cost of preventive maintenance and calibration) is 20,000KM for this intensive care. Regarding the legal procedure, the annual price will be 2.800KM.

... that an intensive care unit has 10 respirators for patients. The recommendation of the manufacturer (distributor) is to have an attestation two times annually and changes the oxygen sensor (although it is a minimum of 12 months) on the respirator. The price of an attest is 500KM, and the price of an O2 sensor is 1,000KM. The total annual price (without the cost of preventive maintenance and calibration) is 30,000KM. Regarding the legal procedure, the annual price will be 2.800KM.
LEGAL METROLOGY FRAMEWORK FOR MEDICAL DEVICES

Bosnia and Herzegovina Case Study

2015-2017 Results
CMBEBIH 2019
International Conference on Medical and Biological Engineering

Share the Vision!

Bosnia and Herzegovina

FINAL CALL FOR PAPERS
Extended deadline paper submission:

www.cmbebih.com
Contact:
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