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Innovazione e accessibilità:  
il governo delle tecnologie sanitarie come sfida sociale



# Benchmark delle attività di IC, una panoramica degli indicatori presenti in letteratura

**ERNESTO IADANZA, PhD**

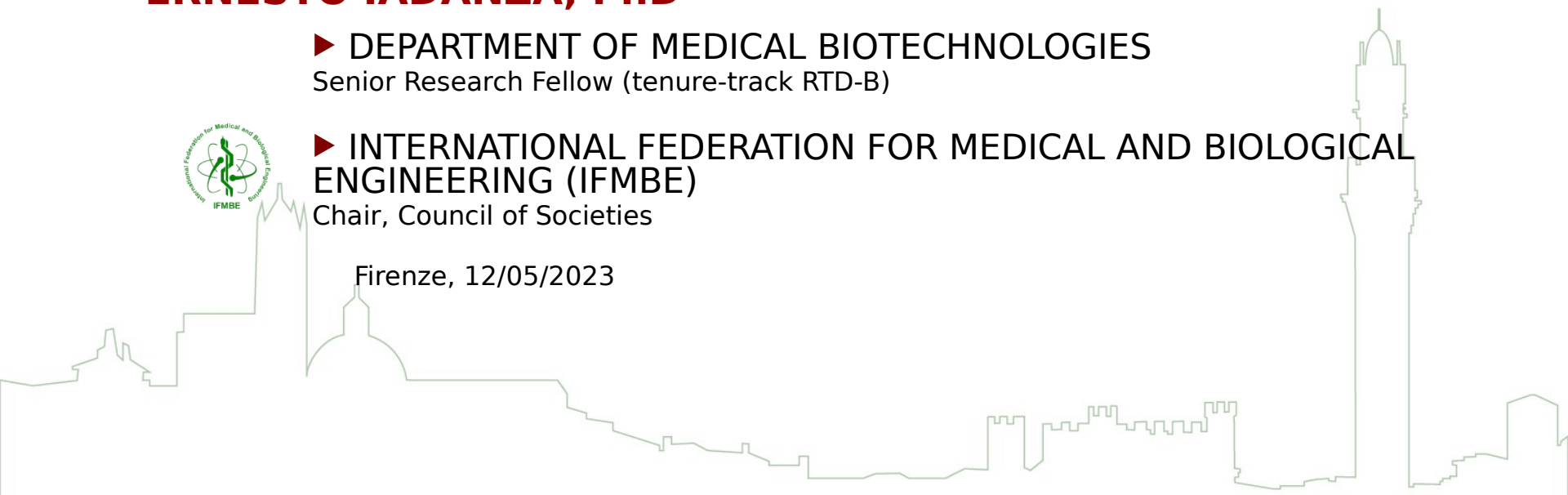
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Chair, Council of Societies

Firenze, 12/05/2023





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# Brief biography

Nationally qualified as **Associate Professor in Bioengineering (ASN)**

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**Chair**, International Federation for Medical and Biological Engineering (IFMBE) Council of Societies

IBM Faculty **Award**, IFMBE/CED **Awards** 2019-22, IEEE **Senior Member**

**Editor in Chief**, “Clinical Engineering Handbook 2nd Edition”, Academic Press, Elsevier, 2020

**20+ years** consultant, researcher and Professor in Clinical Engineering

**Associate Editor** for many BME journals. Supervisor in 200+ theses. Author of 190+ publications on international books, scientific journals, volumes and conference proceedings.

EDITOR-IN-CHIEF  
**ERNESTO IADANZA**

# CLINICAL ENGINEERING HANDBOOK

SECOND EDITION

## Dedication

This Handbook is dedicated to the memory of my first mentor,  
Professor Silvano Dubini.



- Section 1** Clinical Engineering
- Section 2** Worldwide Clinical Engineering Practice
- Section 3** Health Technology Management
- Section 4** Management
- Section 5** Safety
- Section 6** Professionalism, Education and Ethics
- Section 7** Medical Devices: Design, Manufacturing, Evaluation, and Control
- Section 8** Medical Devices: Utilization and Service
- Section 9** Information Technology and Mobile Apps
- Section 10** Engineering the Clinical Environment
- Section 11** Medical Device Regulations, and the Law
- Section 12** Health Technology Assessment
- Section 13** Introduction to Factors

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• eBook ISBN: 9780128134688



**ELSEVIER**





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Italian universities rankings 2022:

- #1 place (medium-sized Universities)
- #2 place (among statal Universities)





## WHY UNISI? - The University of Siena in numbers

[www.unisi.it/perche-unisi](http://www.unisi.it/perche-unisi)

Degree courses

69

Degree courses  
in english

18

Scholarships

3454

Double  
degrees

12

PhD  
programmes

23

Exchange  
partnership

780

Number of  
students

17000

### RIGHT TO STUDIES

- | 11 residence halls
- | 1438 bed places
- | 9 university restaurants
- | 30,6% of students have received scholarships (national percentage 22,9%)

### ADVISING

- | 1 study choice guidance and support
- | 1 job orientation service
- | 1 life coaching and psychological support
- | 1 diversity and inclusion advising

### SERVICES

- | Wireless internet service in all University locations
- | 5 area libraries with 10 service desks
- | 2 study rooms open till midnight seven days a week
- | 127 workstations, some devoted to students with disabilities

- | 45,5% of students have given positive feedback to library and technology services (32,6% national data)
- | 55% of students evaluated "available and adequate" the spaces dedicated to individual study (36,7% national percentage)

### PLACEMENT & CAREER SERVICE

- | 33 contracts of high apprenticeship activated
- | 1852 active conventions with companies for internship
- | 1002 vacancies published
- | 250 users of the CV check service
- | 450 individual career orientation
- | 120 seminars held in the University by employment experts and companies counselors
- | 11 business selection sessions in the University
- | 25 sector job days

### INTERNATIONAL

- | 399 Erasmus and overseas scholarships for study abroad
- | 125 Erasmus scholarships for internship activities abroad
- | 9% of international students enrolled at Unisi courses
- | 534 international students in European and International exchange programs

## WHY UNISI?

The University of Siena  
in numbers



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## 2019 NATIONAL AND INTERNATIONAL RANKINGS

The University of Siena is well ranked in the most important national and international Higher Education Institutions classifications, like CENSIS (national), U-Multirank, QS WUR, Times Higher Education (THE), CWUR, ARWU



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**IFMBE**

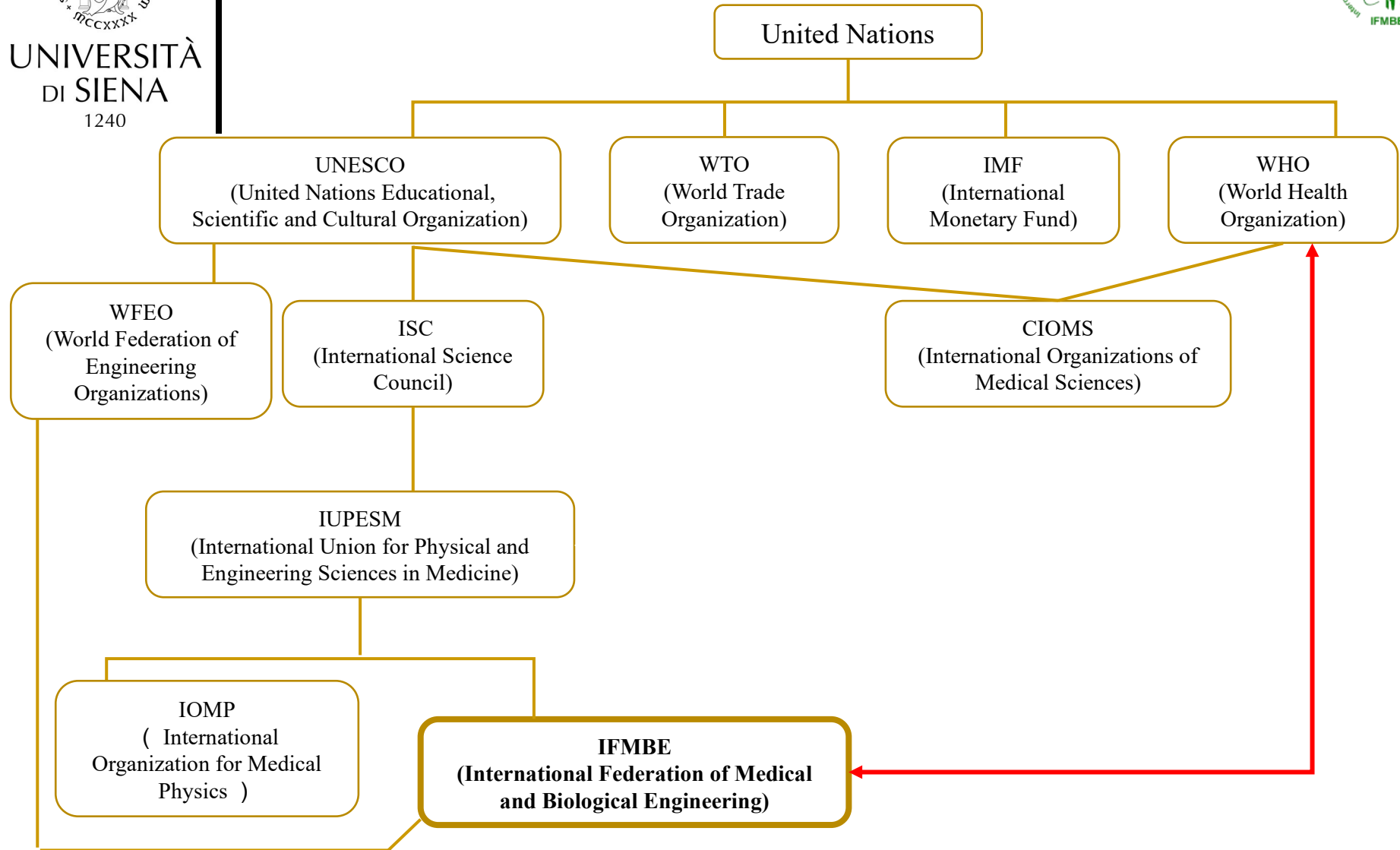


# The International Federation for Medical and Biological Engineering

International Federation for Medical and Biological  
Engineering / IFMBE



# IFMBE Liaisons



# Council of Societies

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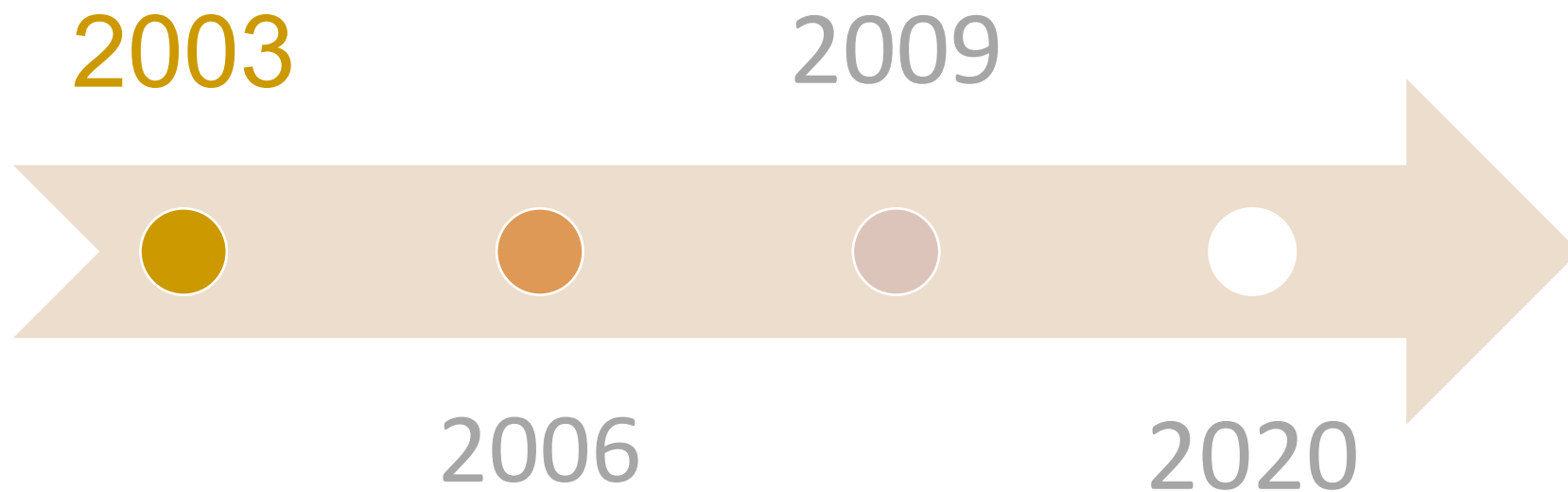
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- IEEE/EMBS





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# Measuring performances through Key Performance Indicators (KPIs)





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2003

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ADVANC



Conferences > Proceedings of the 25th Annual... ?

## A new proposal of quality indicators for clinical engineering

Publisher: IEEE

Cite This

PDF

E. Rodriguez; A. Miguel; M.C. Sanchez; F. Tolkmitt; E. Pozo All Authors

2  
Paper  
Citations

165  
Full  
Text Views



### Abstract

#### Document Sections

- I. INTRODUCTION
- II. METHODOLOGY
- III. RESULTS
- IV. DISCUSSION
- V. CONCLUSIONS

### Abstract:

As we know from Stiefels paper "...we want to do our work right the first time and better the next time. But we really don't know whether we have done it right, or are doing it better, unless we have a measurement system for quality." Unfortunately, there is little agreement in the standardization of indicators used for evaluation of organizations related to medical equipment management. And those that do the first steps, always walk on thin ice. With this paper, we suggest a set of five quality indicators for the control and the evaluation of management for medical equipment maintenance. The indicators proposed allow the organization, that applies them, to easily correct and adjust their management programs, with a strive for improvement in results and quality and broadening their experiences. The selection of the indicators was executed according to those that are most used among leading health care organizations. Sometimes the indicators are labeled differently but the basic idea is the same, and therefore the results can be compared competitively and the potential of an organization can be displayed.

E. Rodriguez, A. Miguel, M. C. Sanchez, F. Tolkmitt and E. Pozo, "A new proposal of quality indicators for clinical engineering," Proceedings of the 25th Annual International Conference of the IEEE Engineering in Medicine and Biology Society (IEEE Cat. No.03CH37439), Cancun, 2003, pp. 3598-3601 Vol.4, doi:

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E. Rodriguez, A. Miguel, M. C. Sanchez, F. Tolkmitt and E. Pozo, "A new proposal of quality indicators for clinical engineering," Proceedings of the 25th Annual International Conference of the IEEE Engineering in Medicine and Biology Society (IEEE Cat. No.03CH37439), Cancun, 2003, pp. 3598-3601 Vol.4, doi: 10.1109/IEMBS.2003.1280931.

In this paper, we propose **a set of five indicators** which are used to control and evaluate the management of **maintenance in clinical engineering**.

The indicators allow comparison among equal institutions and open the doors to have active effects on the quality of management and make necessary changes to adjust a program.

They also permit to improve the results, broaden the experience in the use of quality indicators and to calculate to the potential of an organization.





## 1.- Availability

The availability of medical equipment is based on the time each medical equipment in a hospital should be available, and its relation to the time, it is available.

$$I_A [\%] = \frac{T_A}{T_{PA}} * 100$$

For example, if a clinical laboratory usually uses a medical equipment from **8:00am to 11:00am** every workday, the equipment should be available **15h** per week, and therefore  $15h \times 52 = 780$  hours per year.

In case the equipment is **down from Friday 10:00am to the following Monday 9:00am**, the non-availability of the equipment is 5 hours and the indicator is calculated to be:  $I_A [\%] = 775 / 780 * 100 = 99\%$ .

An availability of medical equipment of over 90% is considered good.

E. Rodriguez, A. Miguel, M. C. Sanchez, F. Tolkmitt and E. Pozo, "A new proposal of quality indicators for clinical engineering," Proceedings of the 25th Annual International Conference of the IEEE Engineering in Medicine and Biology Society (IEEE Cat. No.03CH37439), Cancun, 2003, pp. 3598-3601 Vol.4, doi: 10.1109/IEMBS.2003.1280931.



## 2.- Compliance with the Plan of Preventive Maintenance

This indicator refers to the compliance with the planned maintenance for one year.  
It is calculated for

1) the **hours spent on preventive maintenance** vs. the hours planned for preventive maintenance

and

2) the **number of preventive maintenance interventions** vs. the number of planned interventions.

This quality indicator is also displayed as a percentage, whereas a percentage of **95% is considered to be good.**

$$I_{CtP}^h [\%] = \frac{T_{TM}}{T_{TM\_plan}} * 100$$

$$I_{CtP}^l [\%] = \frac{N_{TI}}{N_{PI}} * 100$$



### 3.- Effectiveness and the use of Time

This indicator refers to the **effectiveness of productiveness** of a department. It reflects the use of time for corrective and preventive maintenance. The effectiveness should be over 70%, in order to be competitive.

$$I_{EoP} [\%] = \frac{T_{TM}}{T_H} * 100$$

According to the definition, the term effectiveness describes the ability of achieving a goal, reaching a consequence or accomplishing an objective. In our case, this means that **the majority (more than 70%) of time available should be used for preventive and corrective maintenance activities.**

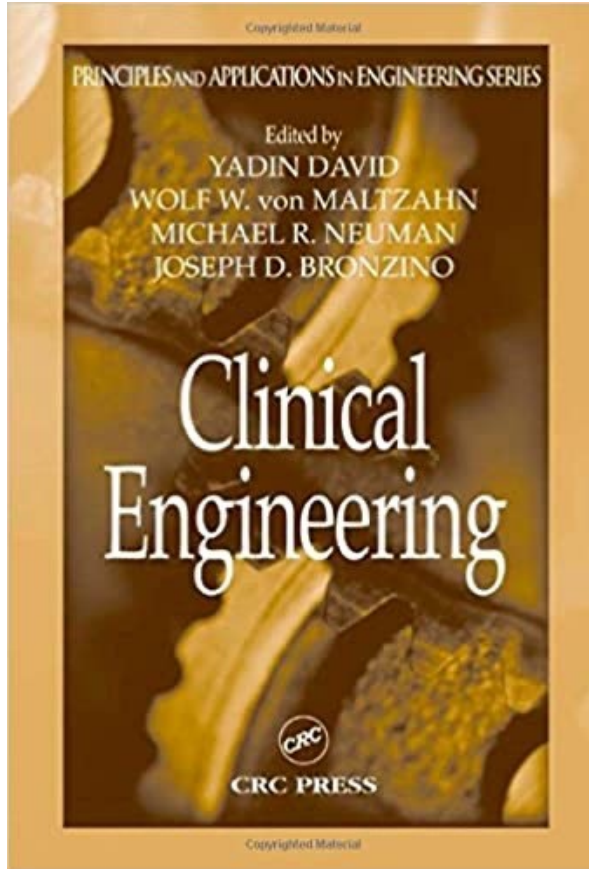
**Back in 2003 clinical engineering  
was still a matter of screwdrivers...**





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2003



# 4

## Clinical Engineering Program Indicators

4.1 Department Philosophy.....	4-2
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Dennis D. Autio  
*Dybonics, Inc.*

Robert L. Morris  
*Dybonics, Inc.*

The role, organization, and structure of clinical engineering departments in the modern health care environment continue to evolve. During the past 10 years, the rate of change has increased considerably faster than mere evolution due to fundamental changes in the management and organization of health care. Rapid, significant changes in the health care sector are occurring in the United States and in nearly every country. The underlying drive is primarily economic, the recognition that resources are finite.

Indicators are essential for survival of organizations and are absolutely necessary for effective management of change. Clinical engineering departments are not exceptions to this rule. In the past, most clinical engineering departments were task-driven and their existence justified by the tasks performed. Perhaps the most significant change occurring in clinical engineering practice today is the philosophical shift to a more business-oriented, cost-justified, bottom-line-focused approach than has been generally the case in the past.

Changes in the health care delivery system will dictate that clinical engineering departments justify their performance and existence on the same basis as any business, the performance of specific functions at a high-quality level and at a competitive cost. Clinical engineering management philosophy must change from a purely task-driven methodology to one that includes the economics of department performance. Indicators need to be developed to measure this performance. Indicator data will need to be collected and analyzed. The data and indicators must be objective and defensible. If it cannot be measured, it cannot be managed effectively.

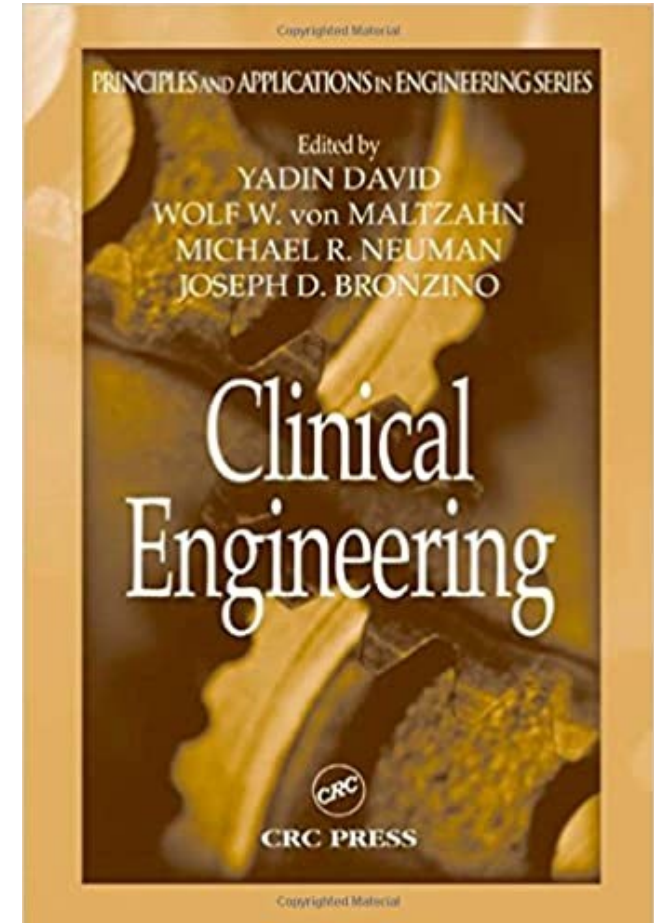


## 4.2 Standard Database

In God we trust...all others bring data!

Florida Power and Light

Evaluation of indicators requires the collection, storage, and analysis of data from which the indicators can be derived. A standard set of data elements must be defined. Fortunately, one only has to look at commercially available equipment management systems to determine the most common data elements used. Indeed, most of the high-end software systems have more data elements than many clinical engineering departments are willing to collect. These standard data elements must be carefully defined and understood. This is especially important if the data will later be used for comparisons with other organizations. Different departments often have different definitions for the same data element. It is crucial that the data collected be accurate and complete. The members of the clinical engineering department must be trained to properly gather, document, and enter the data into the database. It makes no conceptual difference if the database is maintained on paper or using computers. Computers and their databases are ubiquitous and so much easier to use that usually more data elements are collected when computerized systems are used. The effort required for analysis is less and the level of sophistication of the analytical tools that can be used is higher with computerized systems.



# How can I define an indicator?

## 4.5 Indicator Example 1: Productivity Monitors

**Defines Indicators.** Monitor the productivity of technical personnel, teams, and the department. Productivity is defined as the total number of documented service support hours compared with the total number of hours available. This is a desirable rate-based outcome indicator. Provide feedback to technical staff and hospital administration regarding utilization of available time for department support activities.

**Establish Thresholds.** At least 50% of available technician time will be spent providing equipment maintenance support services (revolving equipment problems and scheduled IPMs). At least 25% of available technician time will be spent providing equipment management support services (installations, acceptance testing, incoming inspections, equipment inventory database management, hazard notification review).

**Monitor Indicator.** Data will be gathered every 4 weeks from the equipment work-order history database. A trend analysis will be performed with data available from previously monitored 4-week intervals. These data will consist of hours worked on completed and uncompleted jobs during the past 4-week interval.

Technical staff available hours is calculated for the 4-week interval. The base time available is 160 hours (40 hours/week × 4 weeks) per individual. Add to this any overtime worked during the interval. Then subtract any holidays, sick days, and vacation days within the interval.

CJHOURS: Hours worked on completed jobs during the interval

UJHOURS: Hours worked on uncompleted jobs during the interval

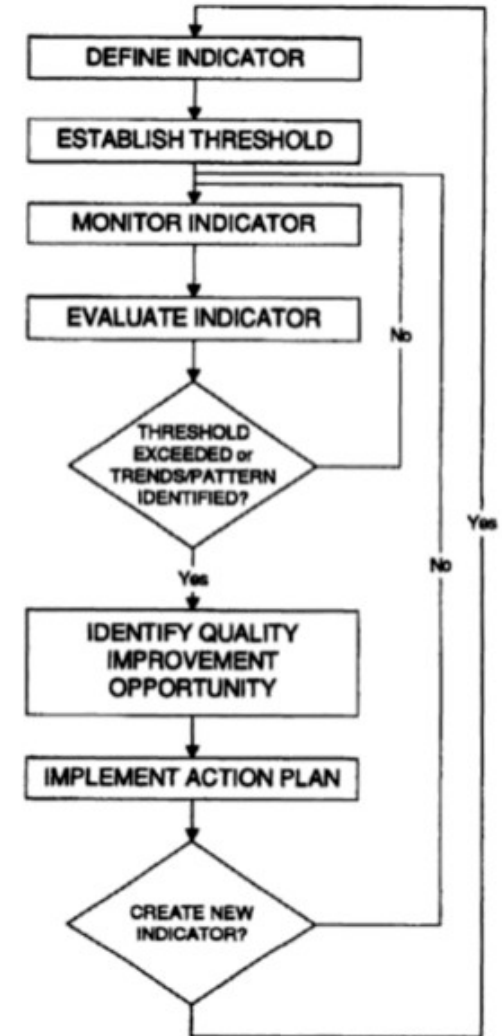
AHOURS: Total hours available during the 4-week interval

Productivity = (CJHOURS + UJHOURS)/AHOURS

**Evaluate Indicator.** The indicator will be compared with the threshold, and the information will be provided to the individual. The individual team member data can be summed for team review. The data from multiple teams can be summed and reviewed by the department. Historical indicator information will be utilized to determine trends and patterns.

**Quality-Improvement Process.** If the threshold is not met, a trend is identified, or a pattern is observed, a quality-improvement opportunity exists. A team could be formed to review the indicator, examine the process that the indicator measured, define the problem encountered, identify ways to solve the problem, and select a solution. An action plan will then be developed to implement this solution.

**Implement Action Plan.** During implementation of the action plan, appropriate indicators will be used to monitored the effectiveness of the action plan.

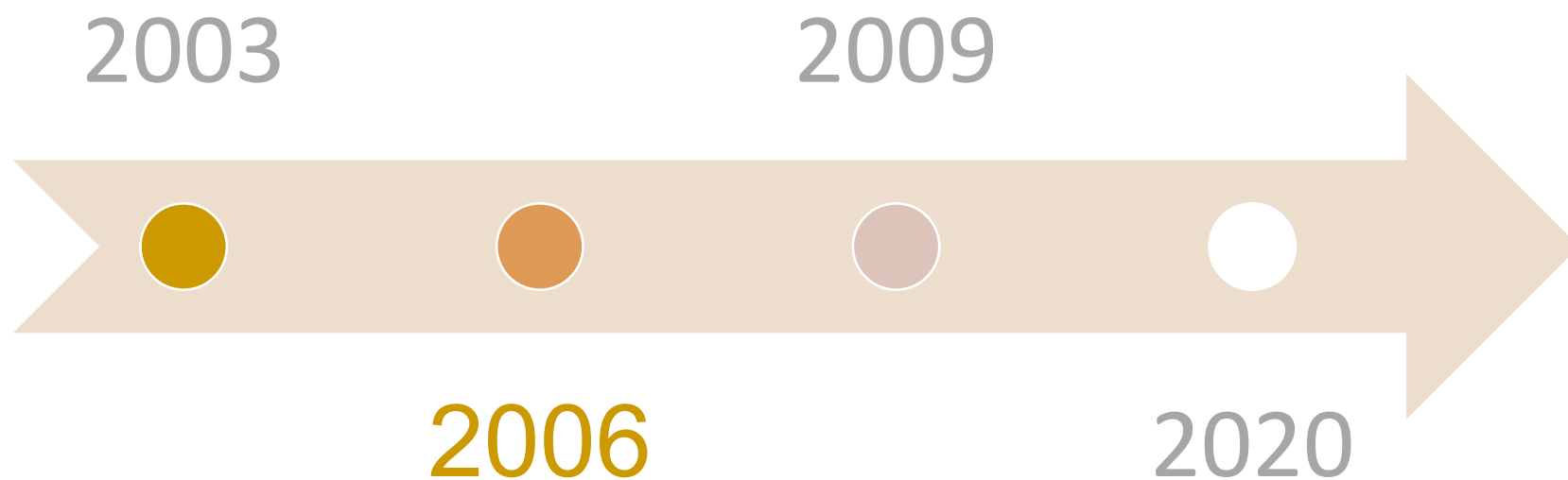






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# Evolution of the discipline: KPIs and evidence





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2006



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ADVANCED SEARCH

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## Benchmarking Performance Improvement Indicators for the Clinical Engineering Department

Publisher: IEEE

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P. Kitcher **All Authors**

2  
Paper  
Citations

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### Abstract

#### Document Sections

- » Introduction
- » Method
- » Results
- » Conclusion

#### Authors

### Abstract:

Performance measurement and Benchmarking have become an integral component of all sectors and the Clinical Engineering (CE) department can not be overlooked. The optimum goal of Benchmarking Performance indicators in the CE department is to continuously strive to improve the quality of the CE department's services upstream, which will consequently lead to a better financial performance downstream. To be successful in this work, I identified mainstream performance indicators essential in making the adjustments needed for improvement of the department's performance. As to the selection of these indicators, an in-depth survey was sent out to over sixty CE directors. The response was analyzed to reveal the top three mainstream performance indicators to be: (a) CE service cost as a percentage of CE inventory value; (b) Total number of preventive maintenance (PMs) completed per month versus total number of PMs scheduled in a month; (c) CE service cost over the last fiscal year versus the total productive (worked) staff hours in that fiscal year. Upon further mathematical analysis of CE department

P. Kitcher, "Benchmarking Performance Improvement Indicators for the Clinical Engineering Department," Proceedings of the IEEE 32nd Annual Northeast Biomedical Engineering Conference, Easton, PA, USA, 2006, pp. 137-138, doi: 10.1109/NEBC.2006.1629790.

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Review > Biomed Instrum Technol. 2007 Jul-Aug;41(4):267-77.

doi: 10.2345/0899-8205(2007)41[267:DBFCEA]2.0.CO;2.



## Measure for measure: developing benchmarks for clinical engineering activities: a methodology

Jonathan A Gaev <sup>1</sup>

Affiliations + expand

PMID: 17849749 DOI: 10.2345/0899-8205(2007)41[267:DBFCEA]2.0.CO;2

2006

### Measure for Measure



Developing Benchmarks for Clinical Engineering Activities: A Methodology

Jonathan A. Gaev

### The Indicators

- **% repairs completed in one working day** = [number of CM events completed in one work- ing day / total number of CM events] \* 100%

- **Total CE cost / device serviced** = total cost for all CE activities / total number of devices receiving service

- **% PM complete** = [# PM events completed / # PM events scheduled] \* 100%

- **% Technician time spent on maintenance** = 100% \* [Time spent on inspection, incoming testing, PM, and corrective main- tenance] / [2,080 hours \* number of technicians]

- **Customer satisfaction** (5-point scale)

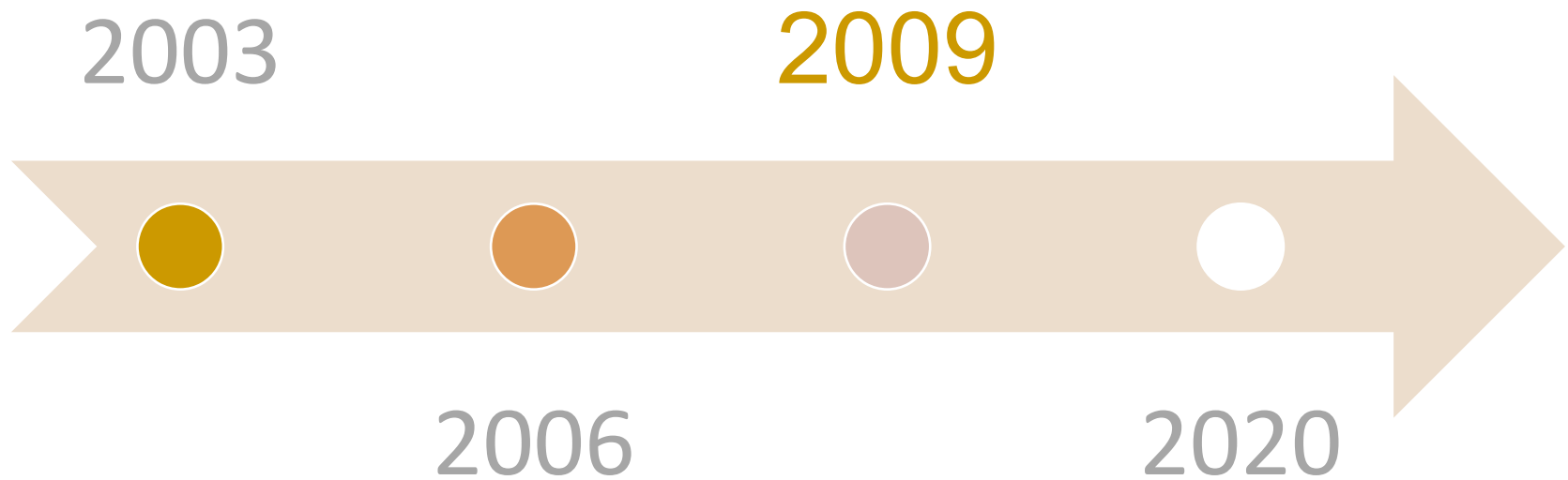
- **CE department development** = hours spent on development activities per year / [# of BMETs + Clinical Engineers + CE department Managers]

- **Technology Management Intensity:** [# hours spent on these activities in one year / Total number of working hours for all CE depart- ment employees in one year] \* 100%



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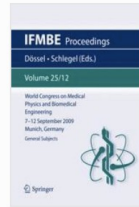


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2009



Joachim H. Nagel



[World Congress on Medical Physics and Biomedical Engineering, September 7 - 12, 2009, Munich, Germany](#) pp 397-400  
| [Cite as](#)

## Indicators for Evaluating and Measuring the Impact of Healthcare Infrastructure and Technology Management on Investments, Service Delivery and Quality of Care

Authors [Authors and affiliations](#)

J. H. Nagel, M. Nagel

Conference paper

445

Downloads

Part of the [IFMBE Proceedings](#) book series (IFMBE, volume 25/12)

### Abstract

Modern health care heavily relies on a whole range of health technologies that should be efficient, safe, cost effective and available to all people without causing a financial burden to the health care systems that would make them unachievable or unsustainable. Resources are often wasted on investments in health technologies that do not meet priority needs or are too complex, incompatible with the existing infrastructure and services, or too costly to maintain.

Nagel J.H., Nagel M. (2009) Indicators for Evaluating and Measuring the Impact of Healthcare Infrastructure and Technology Management on Investments, Service Delivery and Quality of Care. In: Dössel O., Schlegel W.C. (eds) World Congress on Medical Physics and Biomedical Engineering, September 7 - 12, 2009, Munich, Germany. IFMBE Proceedings, vol 25/12. Springer, Berlin, Heidelberg. <https://doi.org/10.1007/978->



## INDICATORS

There are different motivations and goals to use indicators in a study and, consequently, the indicators being used must be optimized to achieve the specific aims of the study. In this project we have three different questions to be answered:

1. the degree to which health care infrastructure and health technology management have been established on **local, regional and country levels**,
2. what the **impact is of healthcare infrastructure and technology management on investments, service delivery, quality of care and patient safety**, and
3. **how the functioning** of healthcare infrastructure and technology management as well as their impact on the quality of care **can be measured and improved**.

# EVIDENCE!

Nagel J.H., Nagel M. (2009) Indicators for Evaluating and Measuring the Impact of Healthcare Infrastructure and Technology Management on Investments, Service Delivery and Quality of Care. In: Dössel O., Schlegel W.C. (eds) World Congress on Medical Physics and Biomedical Engineering, September 7 - 12, 2009, Munich, Germany. IFMBE Proceedings, vol 25/12. Springer, Berlin, Heidelberg. [https://doi.org/10.1007/978-3-642-03893-8\\_115](https://doi.org/10.1007/978-3-642-03893-8_115)



## Indicator Development Process

A **literature search** for published, commonly cited and accepted indicators for evaluating and measuring the impact of healthcare infrastructure and technology management on investments, service delivery and quality of care was **done without much success**.

Thus, **a whole new set of indicators was developed** by the authors.

Looking at the aims and goals of this project it becomes obvious that there should be four different baskets of indicators for:

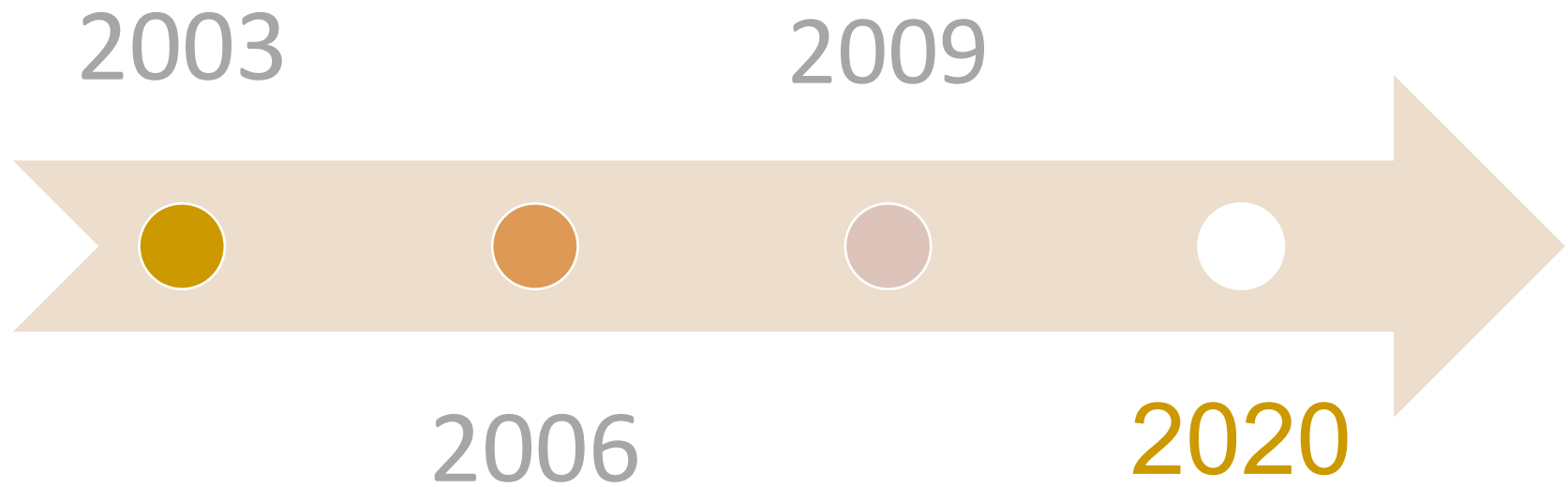
1. the implementation of HTM,
2. the quality of HTM,
3. the impact of HTM on the investment / use of resources, and
4. the impact of HTM on the quality of care and patient safety.

Nagel J.H., Nagel M. (2009) Indicators for Evaluating and Measuring the Impact of Healthcare Infrastructure and Technology Management on Investments, Service Delivery and Quality of Care. In: Dössel O., Schlegel W.C. (eds) World Congress on Medical Physics and Biomedical Engineering, September 7 - 12, 2009, Munich, Germany. IFMBE Proceedings, vol 25/12. Springer, Berlin, Heidelberg. [https://doi.org/10.1007/978-3-642-03893-8\\_115](https://doi.org/10.1007/978-3-642-03893-8_115)



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# Evolution of the discipline: KPIs and evidence





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# CLINICAL ENGINEERING HANDBOOK

SECOND EDITION



## Chapter 41

# CE-HTM indicators

Thomas M. Judd<sup>a</sup>, Antonio Hernandez<sup>b,\*</sup>

<sup>a</sup>Clinical Engineering Division, IFMBE, Marietta, GA, United States, <sup>b</sup>PAHO Health Technology Regional Adviser



### Update

The 2004 first edition clinical engineering (CE) handbook focused on individual CE department performance improvement indicators or measures of performance, as are utilized in a typical first world country. The second edition focuses on CE-health technology management (HTM) indicators used by developing countries at the national Ministry of Health (MoH), central, and local facility levels. This update is primarily based on a World Health Organization (WHO)-The Pan American Health Organization (PAHO) study in 2009.

### Background (Nagel et al., 2009)

There are ways to measure positive effects on the availability, access, capability, and perceived quality of healthcare services.

- These physical advances have often not been matched by an equal advancement of
- related policies, institutional capacities, planning, managerial and technical aptitudes, and recurrent operating budget
- This undermines major capital investments and technical contributions at country level.
- This is one of the most critical system-wide barriers to scaling up priority health interventions and achieving the WHO's Millennium Development Goals (MDGs).

- Recommend and implement system changes and operational improvements including
  - institutional and technical capacity development,
  - ongoing support to healthcare infrastructure and technology policy implementation,
  - institutionalization of HTM seamlessly integrated into the overall health system and services policy, planning, and management.

### Objective (Nagel et al., 2009)

The objective is to define and develop models to assess and predict the impact of healthcare infrastructure, technology allocation, and investments at local and country levels. Indicators:

- Implementation of CE and HTM process indicators.
- Quality of CE-HTM outcome indicators

### Definitions (Health Technologies Resource, 2016)

#### Health technology (HT)

Application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures, and systems is developed to solve a health problem and improve the quality of lives ([https://www.who.int/healthsystems/WHA60\\_29.pdf](https://www.who.int/healthsystems/WHA60_29.pdf)).

2020

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Chapter 41

## CE-HTM indicators

Thomas M. Judd<sup>a</sup>, Antonio Hernandez<sup>b,\*</sup>

<sup>a</sup>Clinical Engineering Division, IFMBE, Marietta, GA, United States, <sup>b</sup>PAHO Health Technology Regional Adviser



### Rationale of indicators (Nagel et al., 2009)

1. Relationship between the indicator and process or outcome.
1. Benchmark or comparison.
2. Definition of each indicator.
3. Results of empirical testing.

### Group of indicators (Nagel et al., 2009)

1. Implementation of CE-HTM infrastructure
2. Quality of CE-HTM services
3. Impact of CE-HTM on the investment/use of resources
4. Impact of CE-HTM on the quality of care and patient safety





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Chapter 41

## CE-HTM indicators

Thomas M. Judd<sup>a</sup>, Antonio Hernandez<sup>b,\*</sup>

<sup>a</sup>Clinical Engineering Division, IFMBE, Marietta, GA, United States, <sup>b</sup>PAHO Health Technology Regional Adviser



Unfortunately, the indicators provided from this 2009 study were not validated in pilot studies in various selected countries after their development. Perhaps leading CE societies such as Association for Clinical Engineering (AIIC) in Italy, Clinical Engineering Association of South Africa (CEASA) in South Africa, Association of Chamber of Commerce Executives (ACCE) in the United States, the International Federation of Medical and Biological Engineering (IFMBE) CE division (globally), and others could assist in using and refining these indicators through various MoH CE-HTM unit or department leaders in the coming years. This could help continue to drive improvements in healthcare delivery processes and outcomes for which CE-HTM around the world is already demonstrating (David and Judd, 2018).

# Evidence Based Maintenance (EBM)

EBM proposed definition by Binseng Wang (2010):

“A continual improvement process that analyses the effectiveness of maintenance resource deployed in comparison to outcomes achieved previously or elsewhere, and makes necessary adjustments to maintenance planning and implementation”







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# A set of indicators for management and maintenance of medical technologies



*Evidence-based medical equipment management: a convenient implementation*

**Ernesto Iadanza, Valentina Gonnelli, Francesca Satta & Monica Gherardelli**

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<https://doi.org/10.1007/s11517-019-02021-x>

ORIGINAL ARTICLE



## Evidence-based medical equipment management: a convenient implementation

Ernesto Iadanza<sup>1</sup> · Valentina Gonnelli<sup>1</sup> · Francesca Satta<sup>2</sup> · Monica Gherardelli<sup>1</sup>

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### Abstract

Maintenance is a crucial subject in medical equipment life cycle management. Evidence-based maintenance consists of the continuous performance monitoring of equipment, starting from the evidence—the current state in terms of failure history—and improvement of its effectiveness by making the required changes. This process is very important for optimizing the use and allocation of the available resources by clinical engineering departments. Medical equipment maintenance is composed of two basic activities: scheduled maintenance and corrective maintenance. Both are needed for the management of the entire set of medical equipment in a hospital. Because the classification of maintenance service work orders reveals specific issues related to frequent problems and failures, specific codes have been applied to classify the corrective and scheduled maintenance work orders at Careggi University Hospital (Florence, Italy). In this study, a novel set of key performance indicators is also proposed for evaluating medical equipment maintenance performance. The purpose of this research is to combine these two evidence-based methods to assess every aspect of the maintenance process and provide an objective and standardized approach that will support and enhance clinical engineering activities. Starting from the evidence (i.e. failures), the results show that the combination of these two methods can provide a periodical cross-analysis of maintenance performance that indicates the most appropriate procedures.

**Keywords** Evidence-based maintenance · Health technology management · Key performance indicators · Medical equipment · Clinical engineering

### 1 Introduction

Today's rapid and continuous technological evolution, which affects most production sectors, also involves healthcare. Indeed, healthcare technologies have become an essential part of the provided services, as they play increasingly significant roles in the diagnosis and treatment of patients.

The complexity of the technological assets found in healthcare facilities, in terms of number and diversity, is reflected in the complexity of technology management, which must be efficient so that the equipment can always be used safely and appropriately. From this perspective, maintenance

is a key process throughout the life cycle of every medical device. Maintenance planning requires the assessment of a number of parameters, including how a piece of equipment is used, how often it is used, its intended use, risk associated with its usage and its failure rates.

There are two main types of maintenance required for medical equipment in all hospitals: scheduled maintenance (SM) and corrective maintenance (CM). SM, in compliance with the manufacturer's instructions, includes the operations performed at scheduled times to reduce deterioration from use (often referred to as "preventive maintenance") or the occurrence of functional failures. CM comprises the repair of the equipment's functions (i.e. its restoration) as well as its replacement when repair is not feasible due to costs or obsolescence [15].

Maintenance is also a crucial aspect of the activities in a hospital's clinical engineering (CE) department because it involves significant human and financial resources. Therefore, the assessment of the effectiveness of any maintenance programmes is strictly linked to the optimization of the use of available resources in CE departments [20].

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Published online: 10 August 2019

Springer

We needed data  
(evidence!) for proving  
the EBM approach

---

- *University Hospital of CAREGGI  
(Florence)*
- 1500 beds
- **16200 pieces of equipment**
- 5600 employees
- 54000 hospital admissions
- 128000 access to the emergency  
room





# Data analysis

**13 classes** of medical equipment analysed

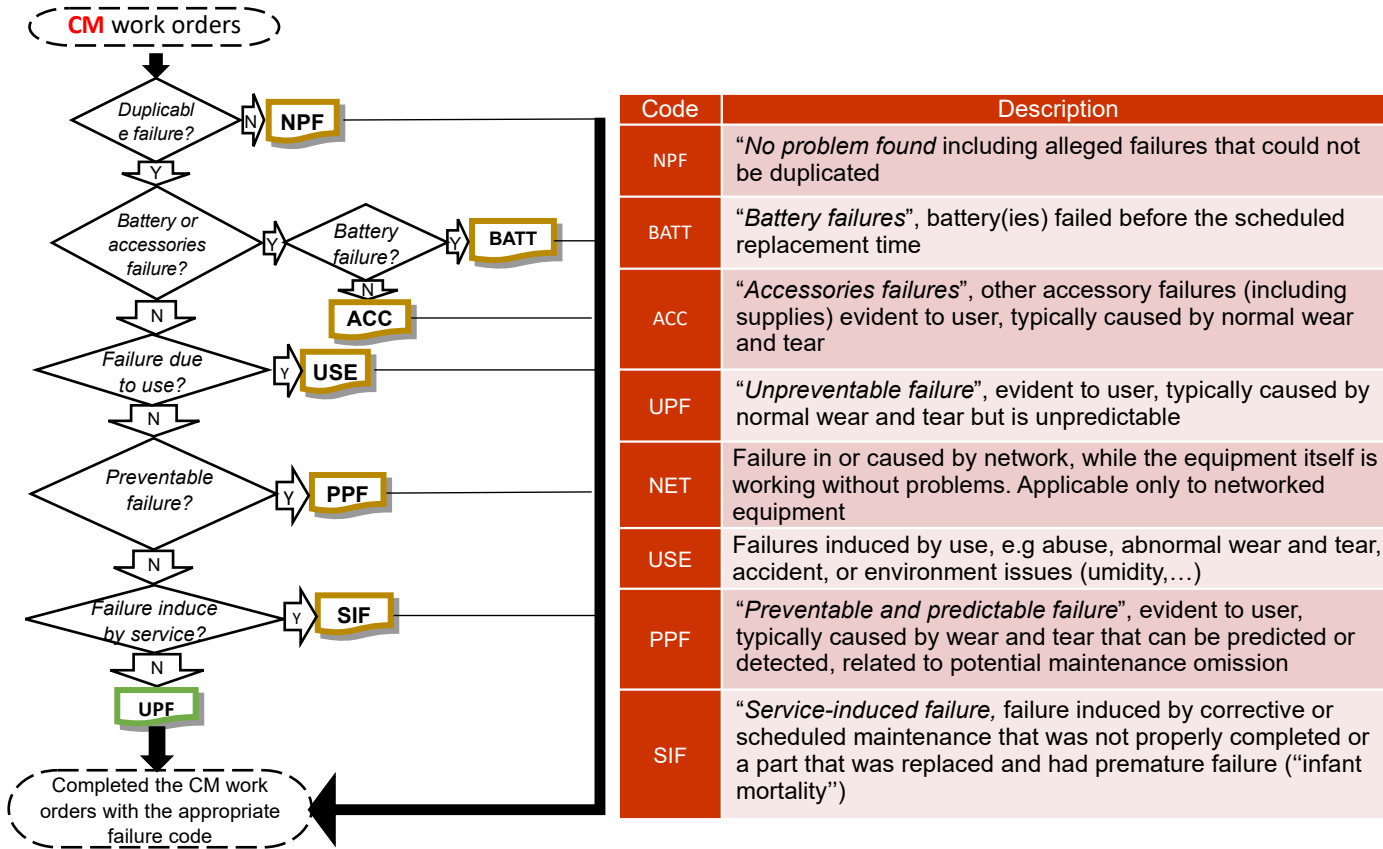
2 critical areas: Operating Room (**OR**) and Intensive Care Unit (**ICU**)

Time span: 5 years

Medical equipment	CIVAB class	Units	Total CM work orders	Total SM work orders	OR & IC work orders (CM)	OR & IC work orders (SM)	CM work orders coded	% of CM eliminated
Anesthesia machine	ANS	87	802	491	668	444	593	11,23%
Aspirator	ACH	183	160	287	25	42	20	20,00%
Monitoring central	CMO	44	212	147	120	87	114	5,00%
Defibrillator	DEF	282	1.463	2.036	559	709	438	21,65%
Electrosurgery unit	ELB	109	287	408	219	342	181	17,35%
Electrocardiograph	ECG	236	1.384	947	170	148	155	8,82%
Surgical lamp	LSC	241	411	1.222	264	987	239	9,47%
Monitor	MON	669	1.294	3.337	599	1.794	547	8,68%
Ceiling mounted unit	PSO	291	284	522	242	386	165	31,82%
Pulse Oximeter	OOR	445	557	1.120	120	297	110	8,33%
Surgical table	TOP	65	520	382	435	211	349	19,77%
Telemetry	UTC	78	99	142	61	51	59	3,28%
Ventilator	VPO	142	796	831	685	748	611	10,80%
<b>TOT</b>		<b>2872</b>	<b>8269</b>	<b>11872</b>	<b>4167</b>	<b>6246</b>	<b>3581</b>	<b>14,06%</b>

# Classification of maintenance work orders: Assigning Failure Codes

[Wang B, Fedele J et al. (2010) Evidence-based maintenance: part I-measuring maintenance effectiveness with failure codes. Journal of Clinical Engineering]





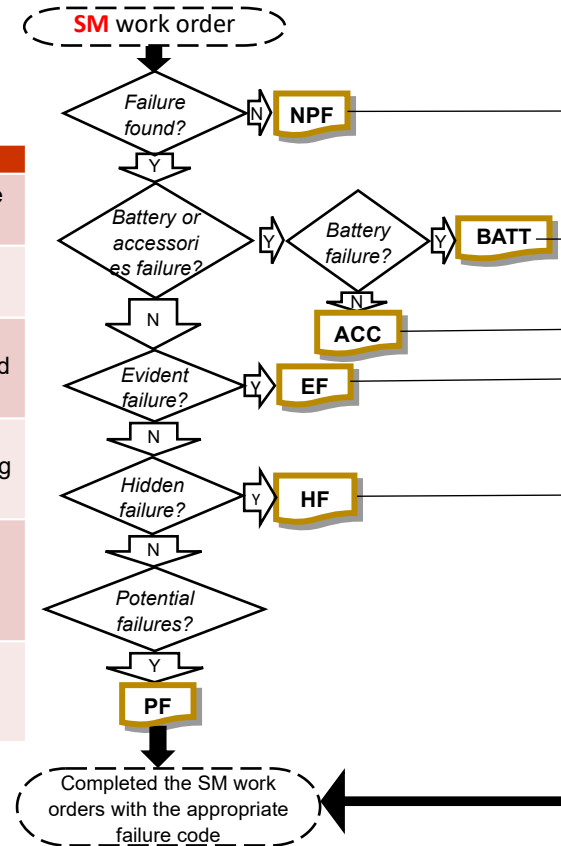


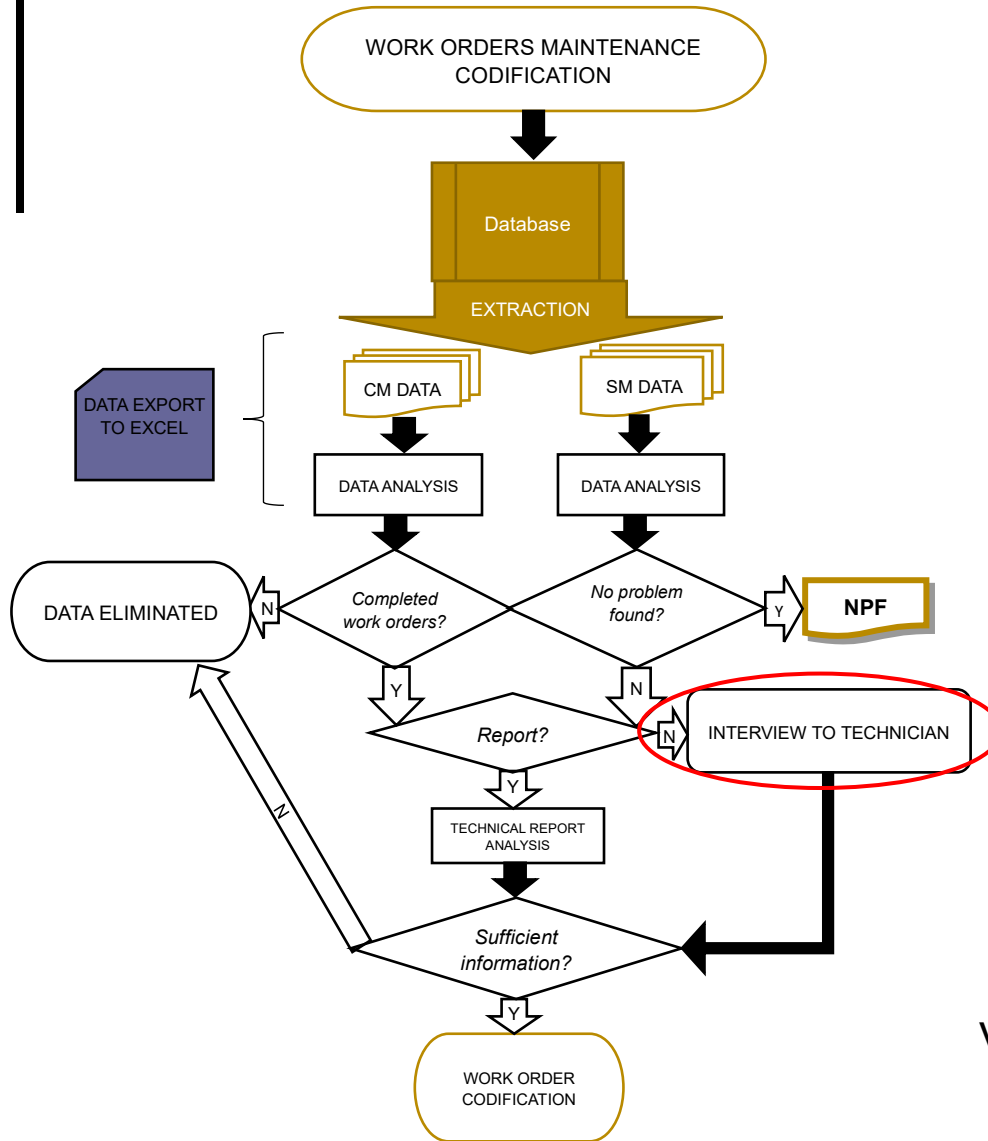
# Classification of maintenance work orders: Assigning Failure Codes

[Wang B, Fedele J et al. (2010) Evidence-based maintenance: part I-measuring maintenance effectiveness with failure codes. Journal of Clinical Engineering]



Code	Description
NPF	"No problem found" including alleged failures that could not be duplicated
BATT	"Battery failures", battery(ies) failed before the scheduled replacement time
ACC	"Accessories failures", other accessory failures (including supplies) evident to user, typically caused by normal wear and tear
EF	"Evident failure", a problem that can be detected but was not reported by the user without running any special tests or using specialized test/measurement equipment
PF	"Potential failure", failure is either about to occur or in the process of occurring but has not yet caused equipment to stop working or problems to patients or users (frayed power cord)
HF	"Hidden failure", a problem that could not be detected by the user unless running a special test or using specialized test/measurement equipment (out of calibration, failed EST)





Valentina Gonnelli, MSc,





# A set of 20 KPIs was defined (Financial, Technological, Organizational)



Original Article | [Open Access](#) | [Published: 10 August 2019](#)

## Evidence-based medical equipment management: a convenient implementation

[Ernesto Iadanza](#) ✉, [Valentina Gonnelli](#), [Francesca Satta](#) & [Monica Gherardelli](#)

*Medical & Biological Engineering & Computing* 57, 2215–2230 (2019) | [Cite this article](#)

KPI 1 DOWNTIME	KPI 3 MTTR	KPI 5 CLASS FR	KPI 8 NEGLIGENT WO	KPI 9 1 DAY WO	KPI 10 SM WITH PROBLEM	KPI 15 COSR	KPI 16 IN HOUSE MAINT	KPI 17 EXT MAINT
KPI 2 UPTIME	KPI 4 MTBF	KPI 6 GFR	KPI 11 COVERAGE RATE OF SM	KPI 12 FALSE FAILURES	KPI 13 N° DEVICES PER TEC	KPI 18 CM COST	KPI 19 SM COST	KPI 20 SPARE PARTS COST
	KPI 7 AFR			KPI 14 CM HOURS VS SM HOURS				



# Evidence-based medical equipment management: a convenient implementation

[Ernesto Iadanza](#) , [Valentina Gonnelli](#), [Francesca Satta](#) & [Monica Gherardelli](#)

*Medical & Biological Engineering & Computing* 57, 2215–2230 (2019) | [Cite this article](#)



CM SM

KPI	Category	Formula/Description	Operational efficiency, actual equipment availability compared with requirements.	CM	SM
KPI 1 Downtime (%) (non-availability time)	T	$T_{down}(\%) = \frac{T_{nd}}{RT}100$ with: $T_{nd}$ = non-availability time per year; $RT$ = Required Time per year.	Operational efficiency, actual equipment availability compared with requirements.	X	X
KPI 2 Uptime (%) (availability time)	T	$T_{up}(\%) = \frac{T_d}{RT}100$ with: $T_d = RT - T_{nd}$	Operational efficiency, actual equipment availability compared with requirements.	X	
KPI 3 MTTR (mean time to restoration)	T	$MTTR = \frac{T_f}{N_{CM}}$ $T_f$ is the off-duty time for failure; $N_{CM}$ is the total number of corrective actions.	Parameter of reliability, availability.	X	
KPI 4 MTBF (mean time between failures)	T	$MTBF = \frac{T_d}{N_{CM}}$ $T_d$ is the availability time; $N_{CM}$ is the total number of corrective actions.	Parameter of reliability, availability.	X	
KPI 5 Class failure ratio (fails per class)	T	$Class\ Failure\ Ratio = \frac{N_{CMi}}{N_{CM}}$ $N_{CMi}$ is the number of corrective actions per year applied to the $i$ th equipment class; $N_{CM}$ is the total number of corrective actions in the same year.	Failure rate of each class of equipment	X	
KPI 6 Global failure rate (defectiveness)	T	$GFR = \frac{N_{CM}}{N_{dev}}$ $N_{CM}$ is the total number of corrective actions per year; $N_{dev}$ is the number of devices in the inventory at the end of the year.	Fault occurrences related to the number of devices	X	
KPI 7 AFR: age failure rate	T	$AFR = \frac{N_{CMlog_{age\_class}}}{N_{devlog_{age\_class}}}$ $N_{CM}$ is the total number of corrective actions per year; $N_{dev}$ is the device number. Age classes: 0–2 years, 3–5 years, 6–9 years, $\geq 10$ years	Device obsolescence	X	
KPI 8 “Negligent” actions (%)	O	$Negligent\ Actions(\%) = \left(\frac{N_{negl}}{N_{CM}}\right)100$ $N_{negl}$ is the number of corrective actions per year, that have not been completed within 30 days (“negligent” actions); $N_{CM}$ is the number of corrective actions per year.	Operational performance of maintenance process	X	
KPI 9 “1 day” actions	O	$1day\ actions(\%) = \left(\frac{N_{1day}}{N_{CM}}\right)100$ $N_{1day}$ is the number of corrective actions per year, that have been completed within 24 h; $N_{CM}$ is the number of corrective actions per year.	Operational performance of maintenance process	X	
KPI 10 SM with failure (%)	O	$SM\ with\ failure(\%) = \left(\frac{N_{SM\ failure}}{N_{SM}}\right)100$ $N_{SM\ failure}$ is the number of scheduled maintenance actions per year with code $\neq$ NPF; $N_{SM}$ is the number of scheduled maintenance actions per year.	Scheduled maintenance intervention with fault occurred		X
KPI 11 SM coverage rate (scheduled maintenance)	O	$SM\ Coverage\ Rate(\%) = \left(\frac{N_{SM}}{N_{dev}}\right)100$ SM coverage rate	Scheduled Maintenance conformity to the requirements		X



# Evidence-based medical equipment management: a convenient implementation

[Ernesto Iadanza](#) , [Valentina Gonnelli](#), [Francesca Satta](#) & [Monica Gherardelli](#)



				CM	SM
		$N_{SM}$ is the number of scheduled actions per year; $N_{dev}$ is the number of devices available in that year.			
KPI 12	O	$N^{\circ}NPF(\%) = \left(\frac{N^{\circ}NPF}{N_{CM}}\right) 100$	No fault found during the corrective maintenance work order	X	
No problem found (fake faults) (%)		$N_{CM}$ is the number of corrective actions per year.			
KPI 13	O	$\left(\frac{\text{No device}}{\text{No technicians}}\right)$	Maintenance workload	X	X
No. devices per technician (internal)					
KPI 14	O	Working hours spent on corrective maintenance vs working hours spent on scheduled maintenance	Maintenance-workload comparison between corrective and scheduled maintenance	X	X
Time cost of the workforce					
KPI 15	F	$COSR(\%) = \left(\frac{\text{Global Maintenance Cost}}{\text{Acquisition Cost}}\right) 100$	Maintenance service: financial performance (cost-effectiveness).	X	X
COSR (cost of service ratio = global maintenance to acquisition cost) (%)					
KPI 16	F	$\left(\frac{\text{External Maintenance Cost}}{\text{Total Maintenance Cost}}\right) 100$	Impact of external maintenance on the total cost of the maintenance service		
External maintenance Cost (% with respect to total maintenance cost)		where external maintenance cost = scheduled and corrective external maintenance costs			
KPI 17	F	$\left(\frac{\text{Internal Maintenance Cost}}{\text{Total Maintenance Cost}}\right) 100$	Impact of internal maintenance on the total cost of the maintenance service		
Internal maintenance cost (% with respect to total maintenance cost)		where internal maintenance cost = scheduled and corrective internal maintenance costs			
KPI 18	F	$\left(\frac{\text{Corrective Maintenance Cost}}{\text{Total Maintenance Cost}}\right) 100$	Maintenance type: impact of corrective maintenance on the total cost of the maintenance service.	X	
Corrective maintenance cost (CM) (% with respect to total maintenance cost)		where corrective maintenance cost = internal CM cost + external CM cost			
KPI 19	F	$\left(\frac{\text{Scheduled Maintenance Cost}}{\text{Total Maintenance Cost}}\right) 100$ where scheduled maintenance cost = internal SM cost + external SM cost	Maintenance type: impact of scheduled maintenance on the total cost of the maintenance service.		X
Scheduled maintenance cost (SM) (% with respect to total maintenance cost)					
KPI 20	F	$\left(\frac{\text{Cost of Spare Parts}}{\text{Total Maintenance Cost}}\right) 100$	Maintenance: Spare Parts and consumables.	X	X
Cost of spare parts (+ consumables) (% with respect to total maintenance cost)					





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# EBM starts to be proposed in CE public tenders for global services



## 1. Metodologia di EVIDENCE BASED MAINTENANCE (EBM)

Al fine di implementare un metodo di lavoro che consenta di monitorare costantemente e di fornire alla stazione appaltante una completa fotografia in *real-time* delle prestazioni di manutenzione preventiva e correttiva, il RTI adotterà l'approccio denominato *EVIDENCE BASED MAINTENANCE* (EBM).

[...]

Questo approccio, proposto a livello mondiale da Wang et al. nel 2010 e riproposto con una applicazione pratica in Italia nel 2019 da Iadanza et al. consiste nella raccolta di evidenze durante le operazioni di manutenzione preventiva e correttiva e nella successiva analisi di un set di indicatori di prestazione, o *Key Performance Indicators* (KPI) al fine di mantenere sempre sotto controllo il processo, ma anche di pianificare eventuali azioni correttive quali per esempio il progetto e realizzazione di interventi formativi mirati o l'approfondimento di situazioni critiche insieme il SIC, agli utilizzatori ed eventualmente ai fabbricanti.

Il RTI propone l'implementazione di tale metodologia con un doppio approccio:

Wang, B., Fedele, J., Pridgen, B., Williams, A., Rui, T., Barnett, L., ... & Poplin, B. (2010). Evidence-based maintenance: part I: measuring maintenance effectiveness with failure codes. *Journal of Clinical Engineering*, 35(3), 132-144.

Iadanza, E., Gonnelli, V., Satta, F., & Gherardelli, M. (2019). Evidence-based medical equipment management: a convenient implementation. *Medical & biological engineering & computing*, 57(10), 2215-2230.





# EBM starts to be proposed in CE public tenders for global services

Integration of CMMS features with the ability for technician to troubleshoot fault classification in accordance with the following international coding scheme, where with SM the preventive maintenance is indicated (Scheduled Maintenance) and with CM the corrective (Corrective Maintenance):

Code	Description	CM/SM
NPF	No problem found	both
BATT	Battery failure	both
ACC	Accessory failure (including supplies)	both
NET	Failure related to network	CM
USE	Failure induced by use (i.e. abuse, accident, environment conditions)	CM
UPF	Unpreventable failure caused by normal wear and tear	CM
PPF	Predictable and preventable failure	CM
SIF	Induced by service (i.e. caused by a technical intervention not properly completed or premature failure of a part just replaced)	CM
EF	Evident failure (i.e. evident to user but not reported)	SM
PF	Potential failure (i.e. in process of occurring)	SM
HF	Hidden failure (i.e. not detectable by the user unless special test or measurement equipment)	SM



## Optimizing the CMMS Failure Code Field

Matthew F. Baretich, PE, PhD, AAMIF  
 Carol Davis-Smith, CCE, FACCE, AAMIF



**Table 5.** Failure Code Field Options

Option	Definition	Examples
Accessory or Disposable Failure ✓	Failure of device accessory or disposable, not a failure of the device itself.	ESU footswitch. Infusion pump cassette.
Calibration Failure ✓	Failure of a device to meet calibration parameters, requiring recalibration.	Need to adjust low-battery alarm trigger point.
Component Failure (Battery) ✓	Failure of the battery that provides power for device operation.	Battery fails to hold a charge. Battery reconditioning fails.
Component Failure (Not Battery) ✓	Failure of a device component other than the battery.	Infusion pump pressure sensor. Device power cord. Device display.
Failure Caused by Maintenance ✓	Failure of a device resulting from maintenance activities.	Physical damage during maintenance. Overvoltage during testing.
Failure Caused by Abuse or Negligence	Failure of a device resulting from damage caused by intentional misuse or negligent use.	User drops defibrillator. Patient damages infusion pump.
Network or Connectivity Failure	Functional failure external to device from failure of network or connectivity.	Network connection not accessible. Infusion pump library not updated.
Software Failure	Functional failure of a device resulting from malfunctioning software.	Infusion pump software malfunctions. Physiological monitor required rebooting.
Use Error (Use Failure)	Failure of a device to support achievement of a clinical objective.	User error. Infusion pump programming error.
Failure Caused by Utility System	Functional failure of a device resulting from failure of or access to a utility system.	Electrical power. Medical gas or vacuum. Ventilation.
Failure Cause by Environmental Factor	Functional failure of a device resulting from an environmental factor.	Excessive ambient temperature. Excessive relative humidity.
Failure Could Not Be Identified	Reported failure could not be reproduced or identified by testing.	Inaccurate or incomplete report of failure. Intermittent device failure.
Failure Not Diagnosed—Device Not Repaired	Reported failure indicated that testing or repair was unwarranted.	Device replacement was more cost-effective than testing or repair.
No Failure Associated with the WO	There was no failure associated with the work order (included for completeness).	PM work order completed normally. PM work order could not be completed.

✓ = PM-related failure

WO = work order





Smart Hospitals

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Leveraging AI based technology to transform the future of the health care delivery in Leading Hospitals in Europe.

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement N° 101017331

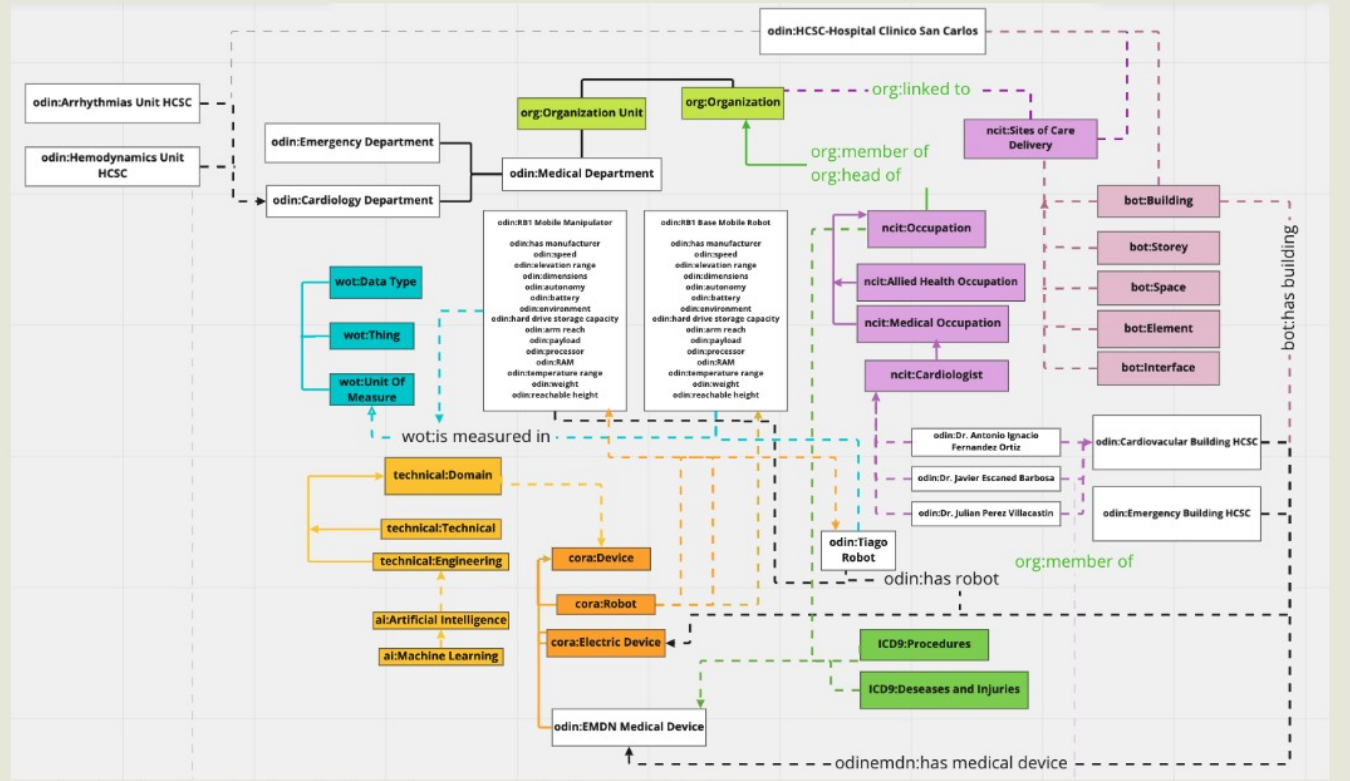


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# odin Ontology

This ontology has been created using the information gathered from the projects partners, informations which allows to create a network of relevant (semantic) wise data. In order to achieve the best flexibility of the system the Ontology, accordingly to the Linked Open Data paradigm, reuse a set of widely adopted ontologies.







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Ontology Specification Draft

**This version:** <https://odin-smarthospitals.eu/odinemdn> language [en](#)

**Latest version:** <https://odin-smarthospitals.eu/odinemdn>

**Download serialization:**  
[Format: JSON LD](#) [Format: RDF/XML](#) [Format: N Triples](#) [Format: TTL](#)

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[Visualize with: WebVowl](#)

**Cite as:**  
 Retrieved from: <https://odin-smarthospitals.eu/odinemdn>

**Abstract**

This ontology is implemented to describe all the existing Medical Devices-MD. This has been done in according with European Medical Device Nomenclature (EMDN) term description.

**1. Introduction** [back to ToC](#)

This is a place holder text for the introduction. The introduction should briefly describe the ontology, its motivation, state of the art and goals.

**1.1. Namespace declarations**

Table 1: Namespaces used in the document

<b>odinemdn</b>	<https://odin-smarthospitals.eu/odinemdn>
<b>odinemdn</b>	<https://odin-smarthospitals.eu/odinMD>
<b>owl</b>	<http://www.w3.org/2002/07/owl>
<b>rdf</b>	<http://www.w3.org/1999/02/22-rdf-syntax-ns>
<b>xml</b>	<http://www.w3.org/XML/1998/namespace>
<b>xsd</b>	<http://www.w3.org/2001/XMLSchema>
<b>rdfs</b>	<http://www.w3.org/2000/01/rdf-schema>

**2. OdinEMDN Ontology: Overview** [back to ToC](#)

This ontology has the following classes and properties.

# European Medical Devices Nomenclature (EMDN) ontology provided by ODIN

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement N° 101017331



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# OHIO - Odin Hospital Indoor cOmpass

## General information

Acronym	OHIO
Addressed challenge	Challenge #2: New pilot
Area	IoT + WebApps
Solution TRL level	7/8
Type of integration with ODIN	ODIN platform deployed locally and integrated as detailed in the following
Pilot deployment site	Hospital "Le Scotte", AOUS, Siena, Italy
RUC or SUBCASE	RUC B2 - Clinical Engineering

## Coordinator

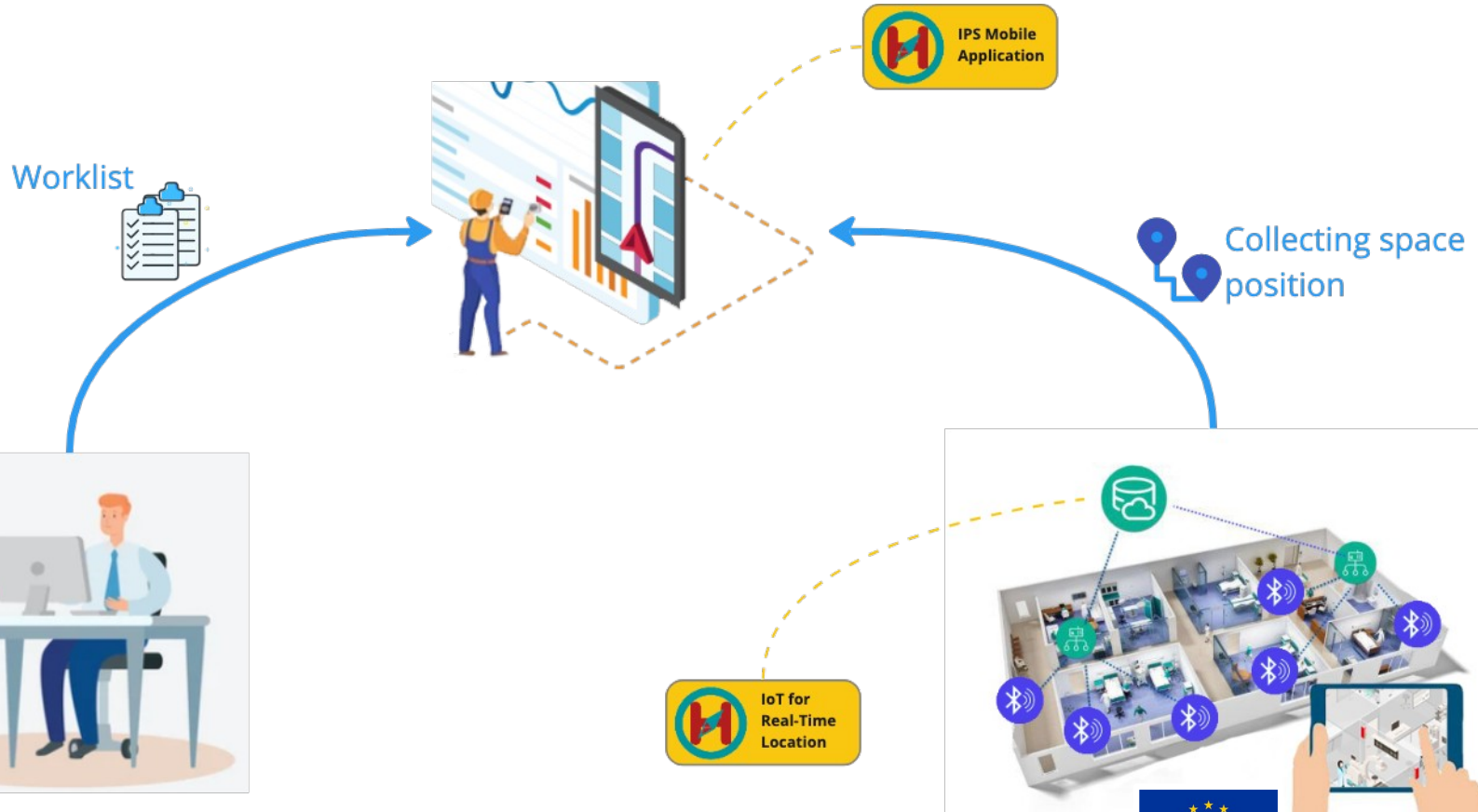
Organization name	Department of Medical Biotechnologies of the University of Siena
Consortium entities (if applicable)	Department of Medical Biotechnologies of the University of Siena (UNISI-DBM), Azienda Ospedaliero-Universitaria Senese (AOUS)
Type of organization(s)	University Department + University Hospital
Country	ITALY
Contact person name	Ernesto Iadanza, PhD
Contact person e-mail address	ernesto.iadanza@unisi.it



The OHIO project has indirectly received funding from the European Union's Horizon 2020 research and innovation action programme, via the ODIN – Open Call issued and executed under the ODIN project (Grant Agreement no. 101017331).



# OHIO SOLUTION



# OK, KPIs. BUT TO MEASURE WHAT?

## MAINTENANCE

## HTM

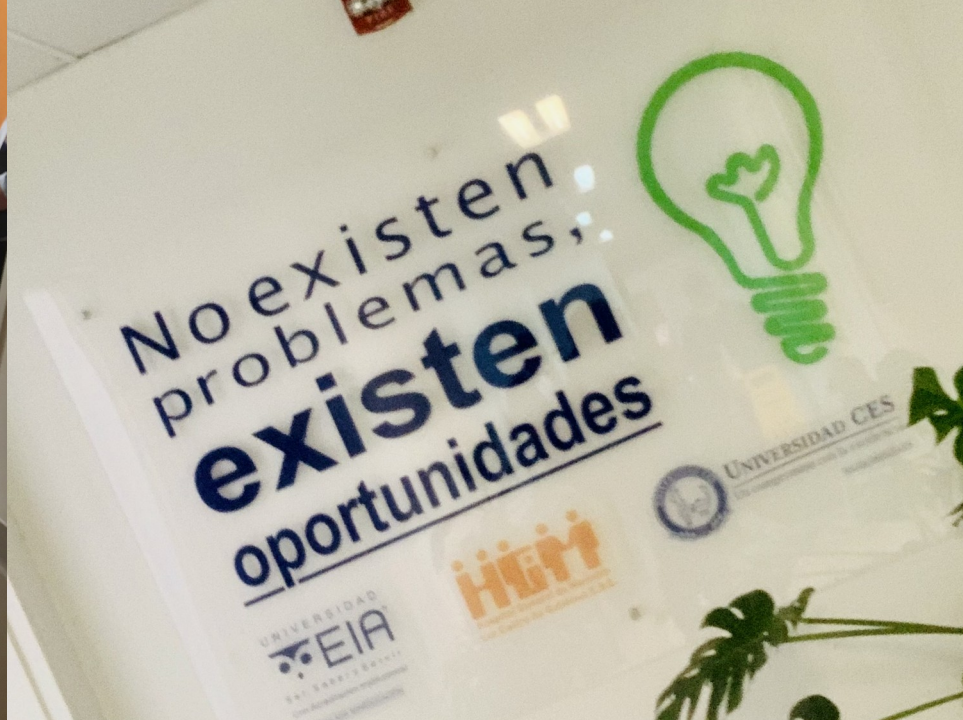
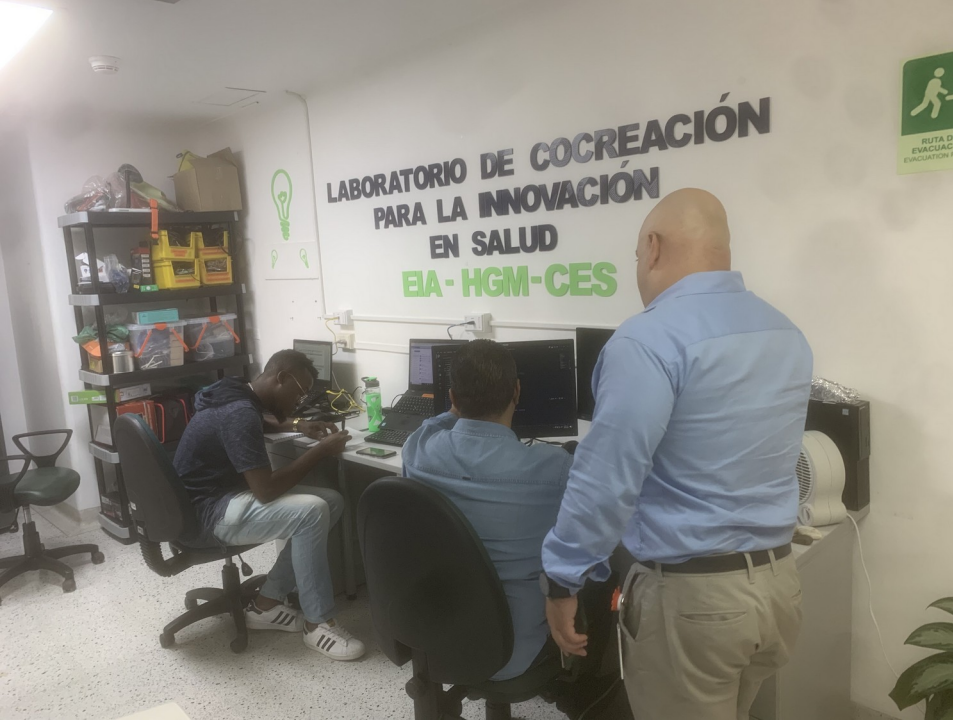
## IMPACT

- PLANNING
- DECISIONS
- FACILITIES
- HTA
- TRAINING

## INNOVATION

- DESIGN
- RESEARCH PROJECTS
- PUBLICATIONS
  - BOOKS
  - JOURNALS
  - PROCEEDINGS









# NEED FOR STANDARDIZATION

---

- STANDARD NOMENCLATURES
- ONTOLOGIES
- DICTIONARIES
- CONCEPTS
  - e.g.: “we want the global service to intervene in x hours for CRITICAL EQUIPMENT”.
  - OK, BUT WHAT IS DEEMED CRITICAL TO YOUR STRUCTURE?



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# Benchmark delle attività di IC, una panoramica degli indicatori presenti in letteratura

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ENGINEERING (IFMBE)  
Chair, Council of Societies



Firenze, 6/05/2023