Safe(?) Interoperability

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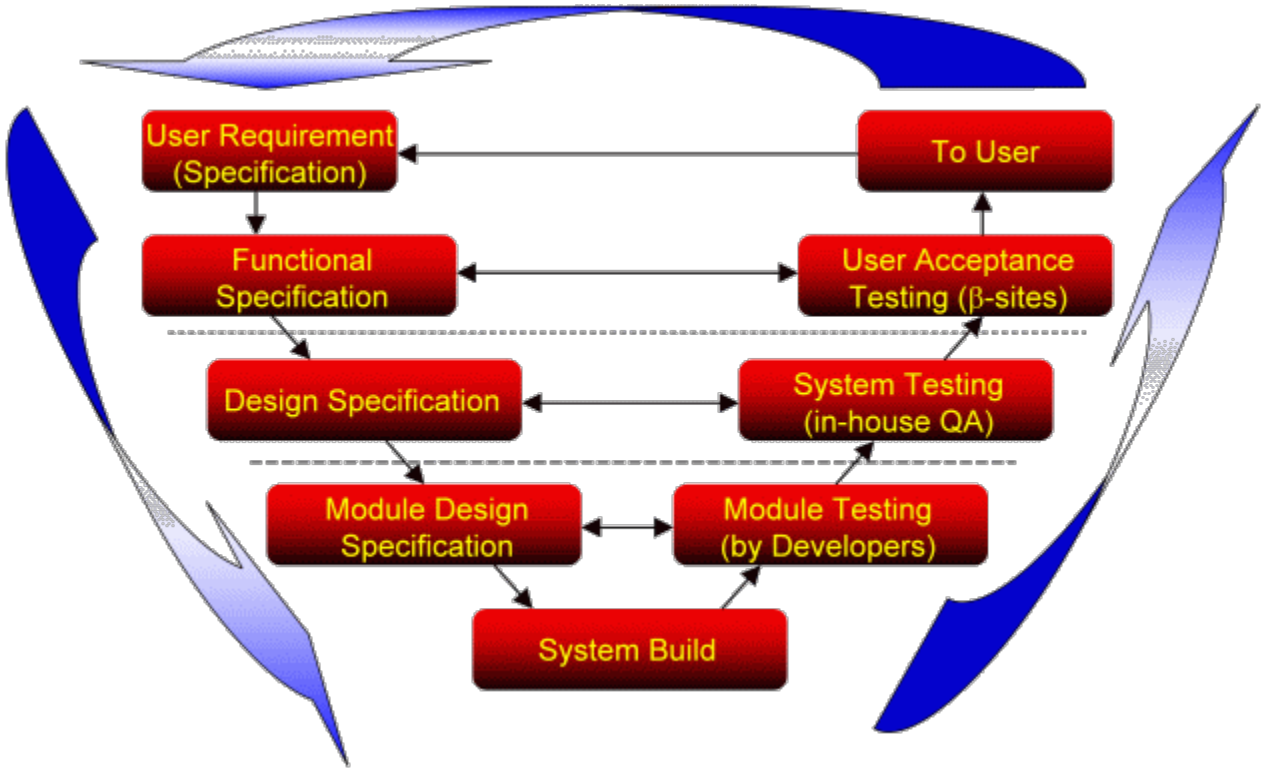
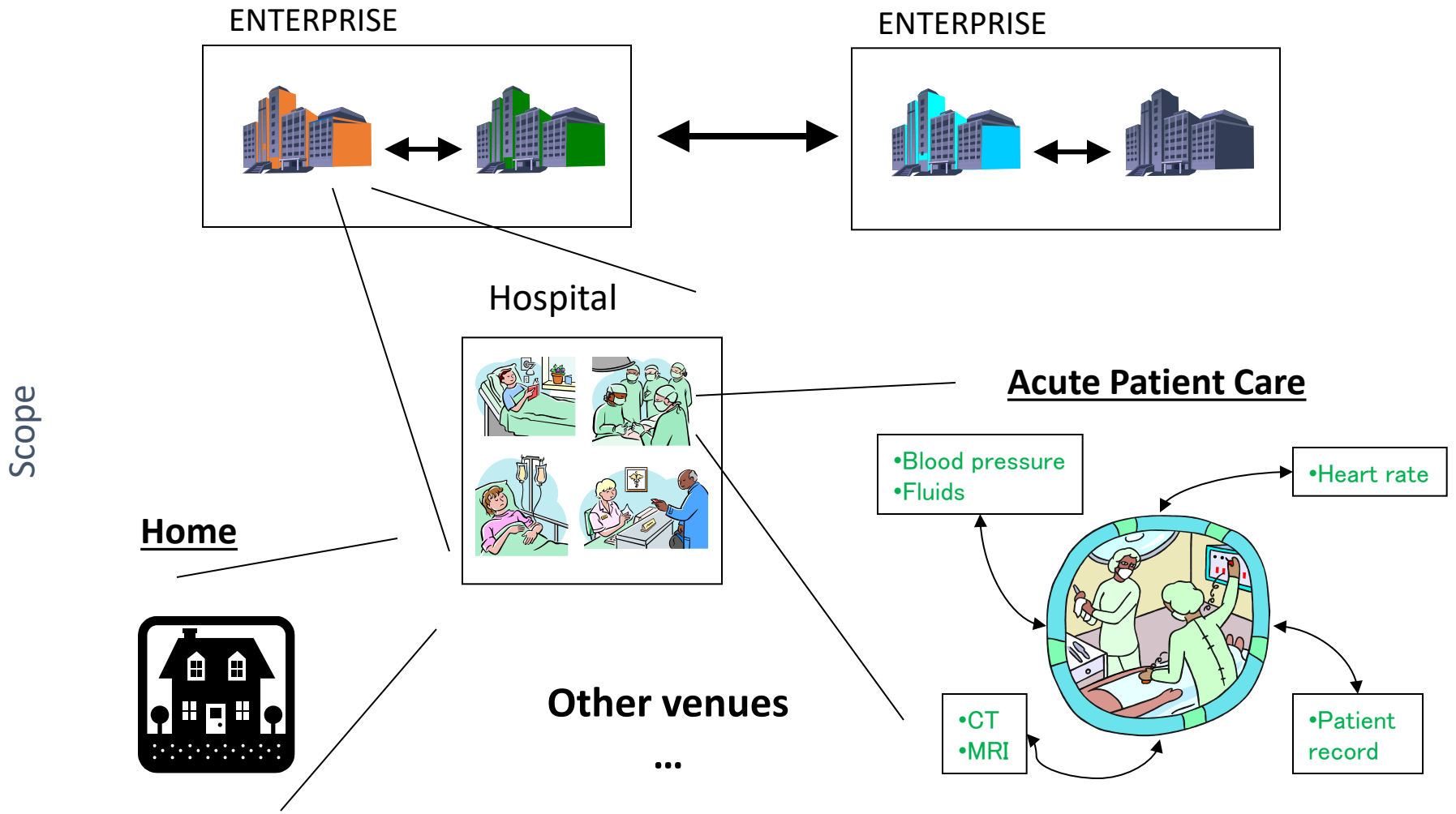
US FDA

IMAG Interagency Modeling and Analysis Group

Systems engineering



Interoperability roles/responsibilities



Physical and Virtual Assets and Their Interaction

What is the physical asset? What is the virtual asset?

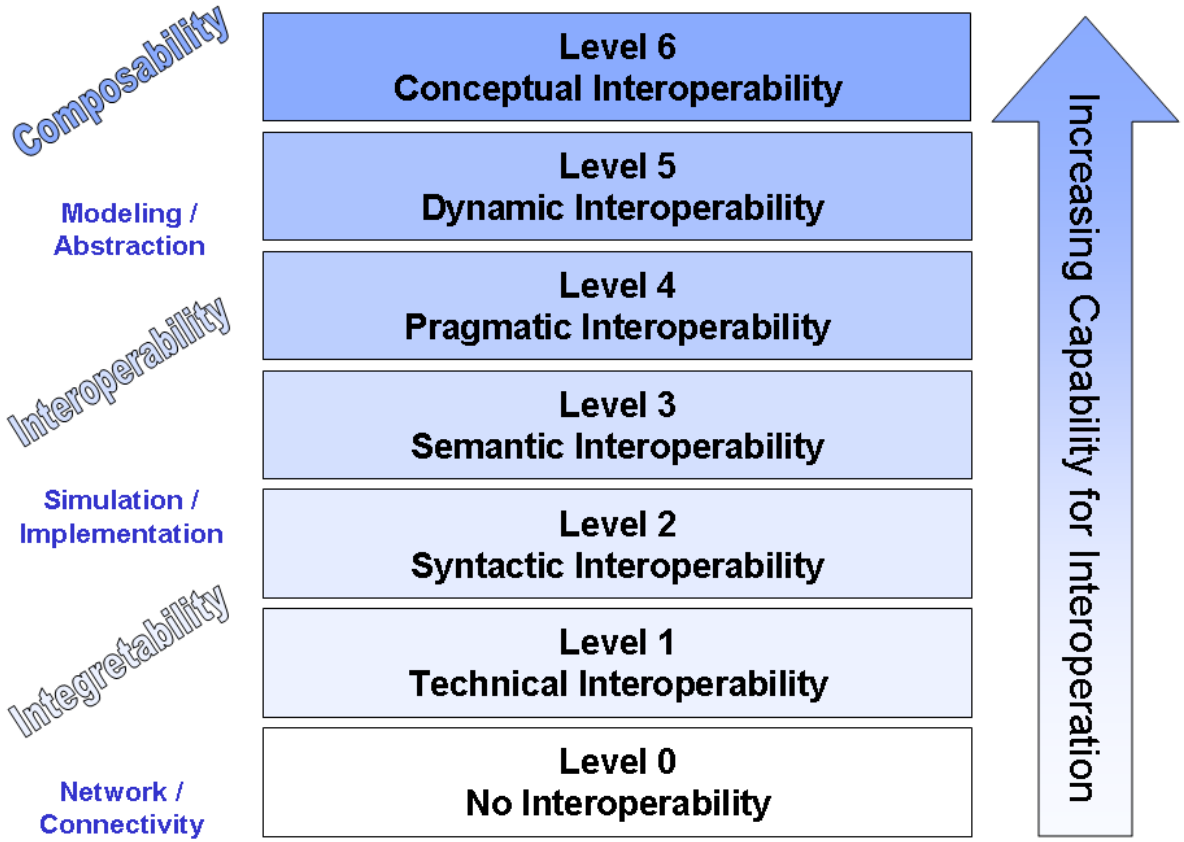
What is the system?

what are the actors, interactions, and system boundaries

What intended use are you claiming?

What information is passed between the physical and virtual assets in real time?

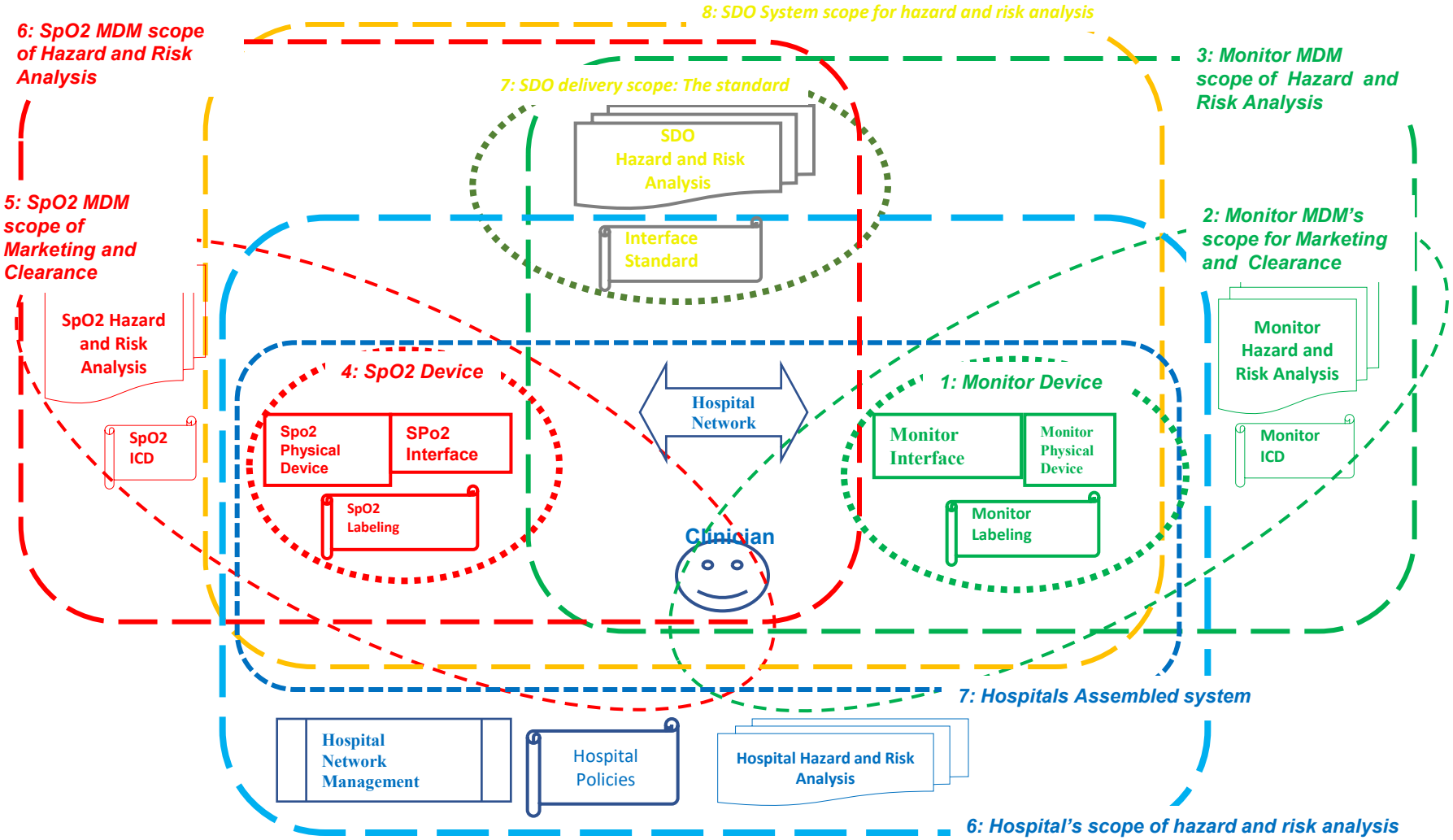
Levels of Interoperability - Turnista

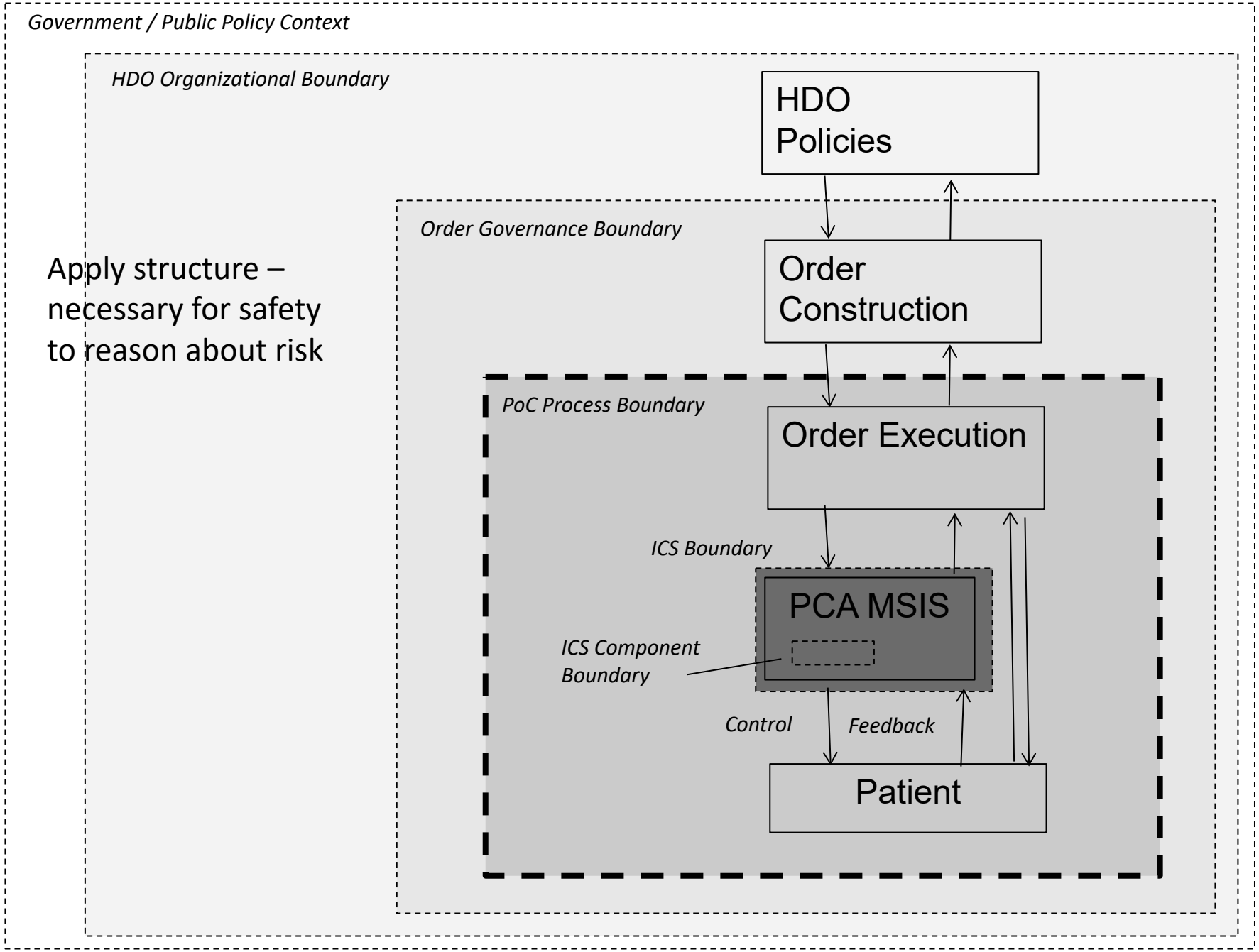


Turnitsa, C.D. (2005). Extending the Levels of Conceptual Interoperability Model. Proceedings IEEE Summer Computer Simulation Conference, IEEE CS Press

What is the System?

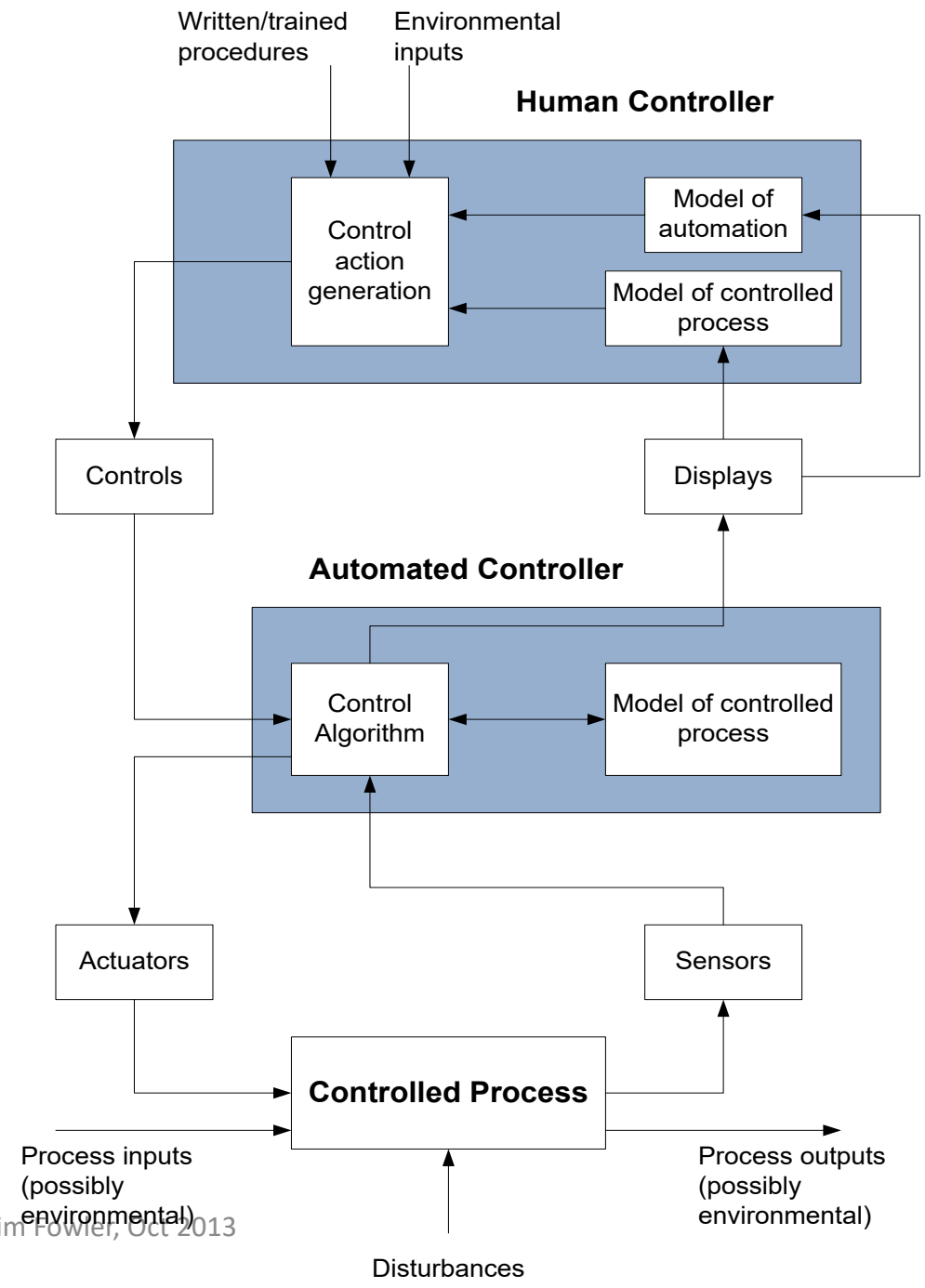
1: Monitor Instantiation in the hospital
2: Monitor MDMs Scope of Labeling, Marketing Claims, User Manuals, and Intended Use
3: Monitor MDM's system for the scope of hazard and risk analysis8:
4: SpO2 Device instantiation in the hospital
5: Spo2 MDM's scope for Labeling, Marketing Claims, User Manuals, and Intended Use
6: Spo2 MDM's scope for hazard and risk analysis
7 : SDO scope of delivered standard
8: SDO's scope for hazard and risk analysis for the standard
9: Hospital's scope of the assembled system
10: Hospital's cope of hazard and risk analysis, quality assurance, and non-FDA regulatory compliance





Apply structure – necessary for safety to reason about risk

Higher Level Diagram



Template configuration for a higher-level system view for use in STPA, modified Fig. 8.8 from Leveson. (©2011 by Nancy G. Leveson. All rights reserved. Used with permission.)

Highest Level Diagram

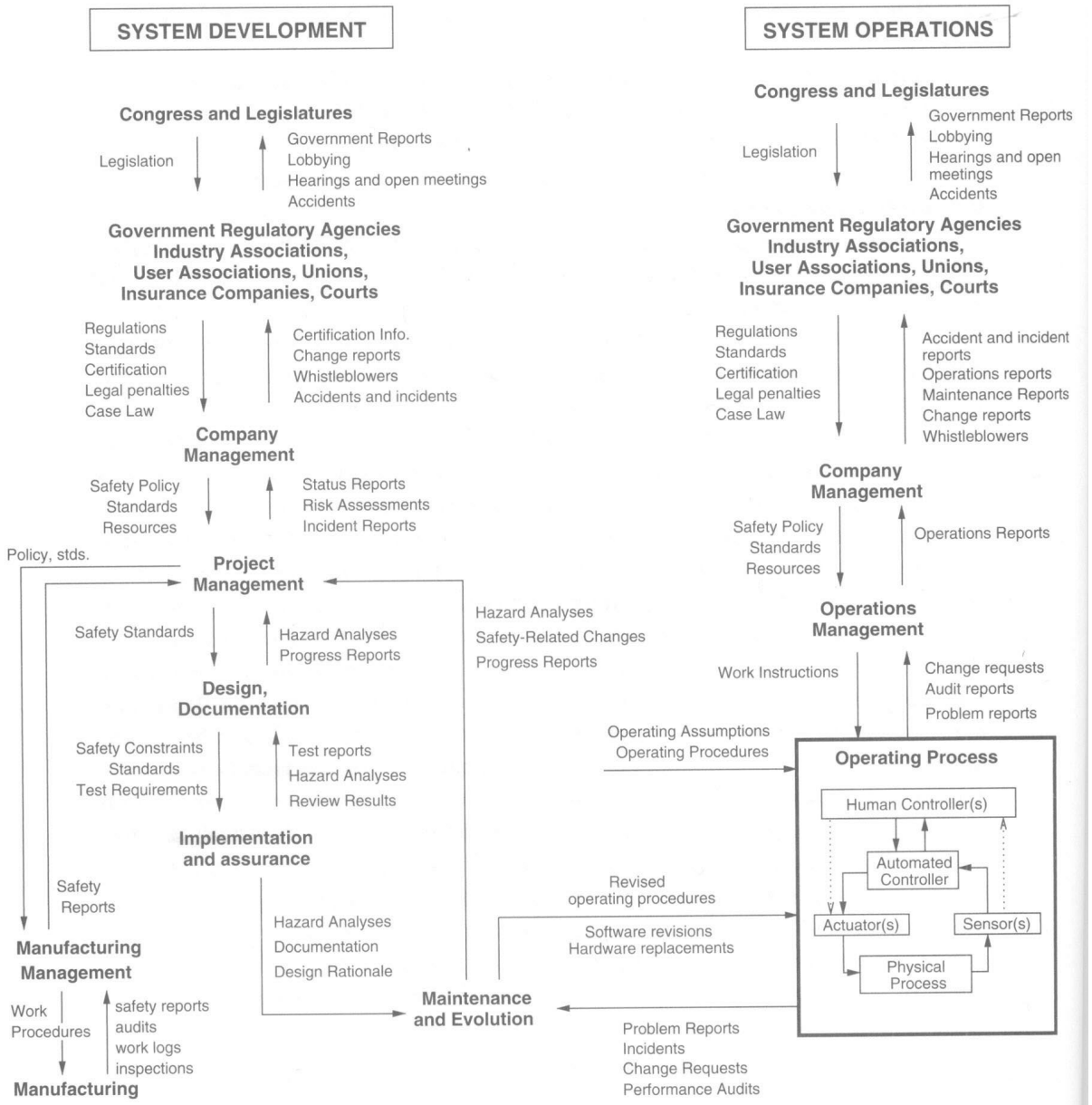
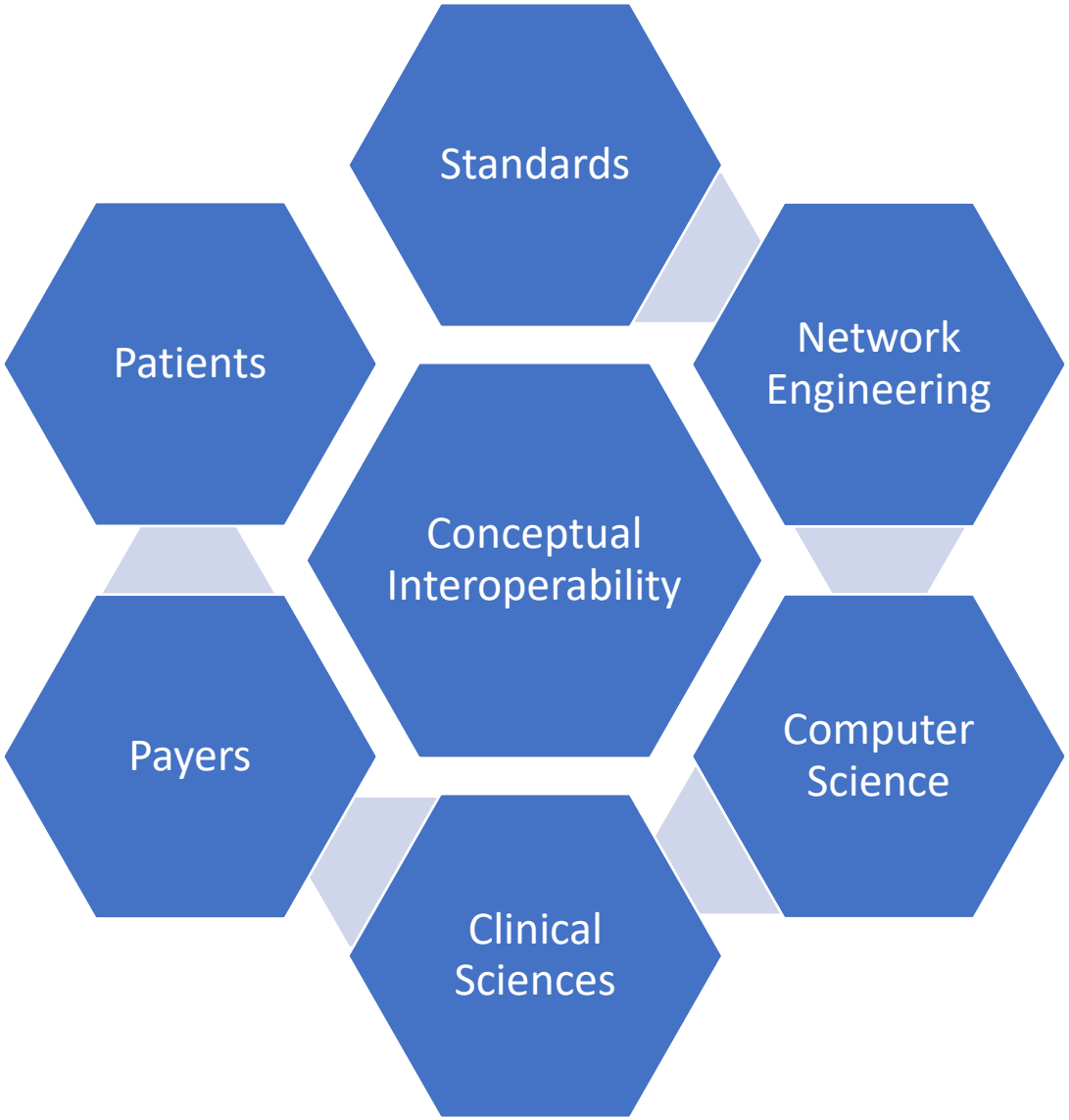


Figure 4.4
General form of a model of sociotechnical control.

Fig. 4.4 from Leveson. (©2011 by Nancy G. Leveson. All rights reserved. Used with permission.)

quilt

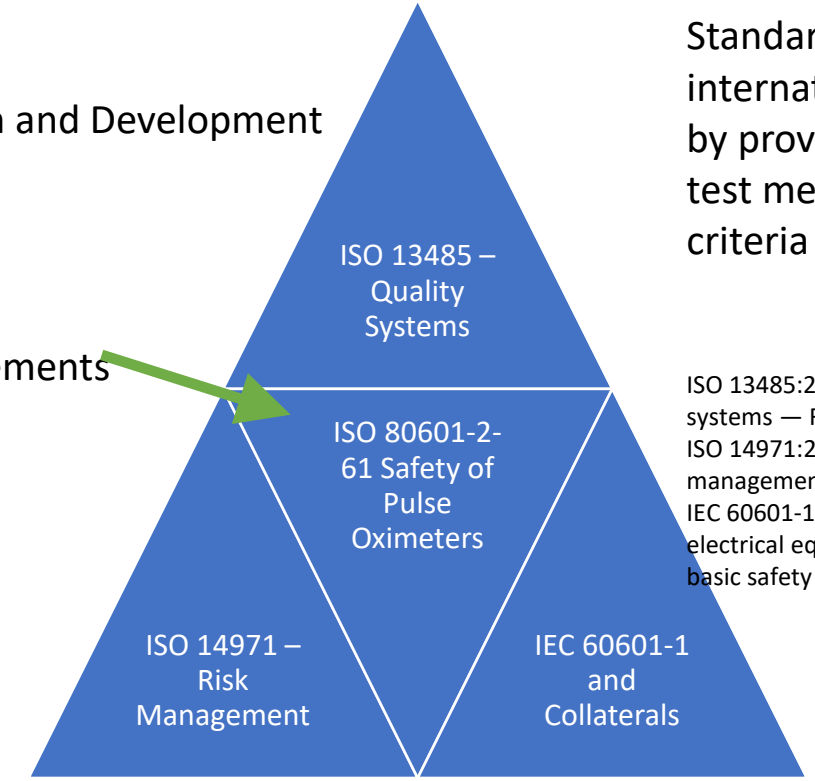

Standards
Patients
Network Engineering
Conceptual Interoperability
Payers
Computer Science
Clinical Sciences

Medical Device (Pulse Oximeter) Safety Standards

Process for Design and Development

Specific Safety and performance requirements for pulse oximeters

Process for Identification of unsafe situations



Standards – establish a minimum internationally accepted safety floor by providing consensus objective test methods and acceptance criteria

ISO 13485:2016 Medical devices — Quality management systems — Requirements for regulatory purposes
ISO 14971:2007 Medical devices — Application of risk management to medical devices
IEC 60601-1:2005+AMD1:2012+AMD2:2020 — Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

Safety requirements – e.g. electrical, thermal, mechanical, biocompatibility

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CORRESPONDENCE

Racial Bias in Pulse Oximetry Measurement

In the multicenter cohort, the unadjusted analyses involving patients with an oxygen saturation of 92 to 96% on pulse oximetry showed an arterial blood gas oxygen saturation of less than 88% in 160 of 939 measurements in Black patients (17.0%; 95% CI, 12.2 to 23.3) and in 546 of 8795 measurements in White patients (6.2%; 95% CI, 5.4 to 7.1).

In device applications, the Food and Drug Administration requires reporting of demographic subgroups to mitigate risk. However, our findings highlight an ongoing need to understand and correct racial bias in pulse oximetry and other forms of medical technology.

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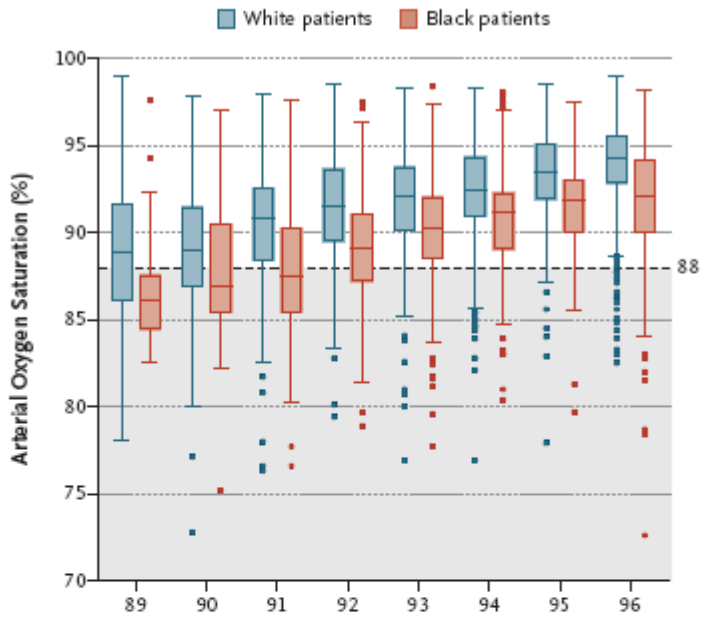

No. of Paired Measurements								
White patients	92	178	231	314	438	556	653	817
Black patients	20	52	59	83	127	126	188	225

Figure 1. Accuracy of Pulse Oximetry in Measuring Arterial Oxygen Saturation, According to Race.

Shown is a comparison of paired measurements of pulse oximetry readings of oxygen saturation and time-matched directly measured arterial oxygen saturation among hospitalized patients who were stratified according to race. The shaded area indicates an arterial oxygen saturation of less than 88%. In the box plot, the horizontal line within each box represents the median, the top and bottom of each box represent the upper and lower limits of the interquartile range, and the whiskers represent 1.5 times the interquartile range. Outliers outside this range are indicated by data points.

Questions

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