

TR 108:2022
(ICS 25.040.30)

TECHNICAL REFERENCE

Safe deployment of robot systems in the healthcare sector



TR 108:2022
(ICS 25.040.30)

TECHNICAL REFERENCE

**Safe deployment of robot systems in the
healthcare sector**

Published by Enterprise Singapore

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilised in any form or by any means, electronic or mechanical, including photocopying and microfilming, without permission in writing from Enterprise Singapore. Request for permission can be sent to: standards@enterprisesg.gov.sg.

© Enterprise Singapore 2022

ISBN 978-981-5073-28-7

Contents

	Page
Foreword _____	4
0 Introduction _____	6
1 Scope _____	6
2 Normative references _____	7
3 Terms and definitions _____	7
4 Abbreviated terms _____	8
5 Use of robot systems in the healthcare sector _____	9
6 Service development process _____	12
7 Safety considerations relating to infection control in a healthcare environment _____	20
8 Risk assessment for deployment of robot systems in healthcare _____	26
9 Robot systems development _____	45
10 Continued safety of deployed robot systems _____	53

Annexes

A	Requirements for managing outsourced cleaning operations involving robots _____	56
B	Examples of deliverables or documentation requirements _____	59

Tables

1	Sample checklist for assessing the performance and viability of robots _____	15
2	Sample checklist for safety assessments _____	16
3	Type of robot and its use in logistical and general services _____	18
4	Type of robot and its use in rehabilitative services _____	18
5	Types of robots and their uses in nursing and patient care services _____	18
6	Type of robot and its use in cleaning services _____	19
7	Zone types and their characteristics _____	22
8	Protocols for ad hoc robot cleaning _____	23
9	Example risk scores _____	24
10	Frequency of cleaning based on risk stratification matrix _____	25
11	Hazards relating to hospital codes or emergencies _____	27
12	Hazards for logistical and delivery robots _____	28
13	Hazards for rehabilitative robots _____	33
14	Hazards with nursing and patient care robots _____	36
15	Hazards relating to cleaning robots _____	38
16	Classification and treatment of data used by robots _____	46

	Page
Figures	
1 System-level safety assessment supported by relevant standards _____	10
2 Milestones in the system life cycle _____	11
3 Overview of the role of this TR among stakeholder groups _____	12
4 Stages in the service development process _____	13
5 Service decomposition process _____	20
6 Components in the chain of infection _____	21
7 Robot movement and deployment across different zone types _____	22
8 Four-step process of risk management applied to the robot's service life cycle _____	27
9 Hierarchy of controls _____	44
10 Robot service ecosystem _____	45
Bibliography _____	60

Foreword

This Technical Reference (TR) was prepared by the Working Group on Safe Deployment of Robots in Healthcare set up by the Technical Committee on Robotics and Automation under the purview of the Manufacturing Standards Committee.

The TR covers safety in the planning, commissioning, and ongoing operations of robot services in healthcare environments. It describes the activities to be undertaken by various stakeholders in order to meet safety requirements and contextualises them against existing applicable standards and regulations specific to the healthcare sector.

This TR is a provisional standard made available for application over a period of three years. The aim is to use the experience gained to update the TR so that it can be adopted as a Singapore Standard. Users of the TR are invited to provide feedback on its technical content, clarity and ease of use. Feedback can be submitted using the form provided in the TR. At the end of the three years, the TR will be reviewed, taking into account any feedback or other considerations, to further its development into a Singapore Standard if found suitable.

It is presupposed that in the course of their work, users will comply with all relevant regulatory and statutory requirements. Some examples of relevant regulations and acts are listed in the Bibliography. The Singapore Standards Council and Enterprise Singapore shall not be responsible for identifying all of such legal obligations.

In preparing this TR, reference was made to the following publications:

1. IEC 60601-1-2:2014 – Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests
2. ISO 12100:2010 – Safety of machinery – General principles for design – Risk assessment and risk reduction
3. ISO 13482:2014 – Robots and robotic devices – Safety requirements for personal care robots
4. ISO/IEC/IEEE 15288:2015 – Systems and software engineering – System life cycle processes
5. ISO/TR 23482-2:2019 – Robotics – Application of ISO 13482 – Part 2: Application guidelines
6. ISO/TR 23482-1:2020 – Robotics – Application of ISO 13482 – Part 1: Safety-related test methods
7. SS 485:2011 – Specification for slip resistance classification of pedestrian surface materials.
8. TR 42:2015 – Technical Reference for facility design guidelines for acute general hospitals.
9. TR 64:2018 – Guidelines for IoT security for smart nation
10. TR 67:2018 – Connected medical device security
11. Building and Construction Authority, Universal Design Guide for Public Spaces
12. National Infection and Prevention Control Guidelines for Acute Healthcare Facilities
13. World Health Organization – 5 moments of health hygiene

Permission has also been sought from the Ministry of Health for the reproduction of materials from “The National Infection Prevention and Control Guidelines for Acute Healthcare Facilities 2017 – 1.1 Six Elements to the Chain of Infection” into this standard.

Acknowledgement is made for the use of information from the above publications.

Attention is drawn to the possibility that some of the elements of this TR may be the subject of patent rights. Enterprise Singapore shall not be held responsible for identifying any or all of such patent rights.

NOTE

1. *Singapore Standards (SSs) and Technical References (TRs) are reviewed periodically to keep abreast of technical changes, technological developments and industry practices. The changes are documented through the issue of either amendments or revisions. Where SSs are deemed to be stable, i.e. no foreseeable changes in them, they will be classified as "mature standards". Mature standards will not be subject to further review unless there are requests to review such standards.*
2. *An SS or TR is voluntary in nature except when it is made mandatory by a regulatory authority. It can also be cited in contracts making its application a business necessity. Users are advised to assess and determine whether the SS or TR is suitable for their intended use or purpose. If required, they should refer to the relevant professionals or experts for advice on the use of the document. Enterprise Singapore and the Singapore Standards Council shall not be liable for any damages whether directly or indirectly suffered by anyone or any organisation as a result of the use of any SS or TR. Although care has been taken to draft this standard, users are also advised to ensure that they apply the information after due diligence.*
3. *Compliance with a SS or TR does not exempt users from any legal obligations.*

Safe deployment of robot systems in the healthcare sector

0 Introduction

The use of robotic systems can help alleviate manpower shortages and allow professional healthcare workers to focus on tasks involving direct patient care. As more hospitals look towards robots for solutions, there is a need to ensure that the solutions rolled out are designed, tested, deployed and can be sustained at a safe level in a dynamic healthcare environment. The purpose of this Technical Reference (TR) is to provide a set of recommendations and requirements for the safe and sustainable deployment of robot systems in a healthcare environment.

Robot safety standards are established at the robot-level for specifications and robot operations, especially in industrial settings. In the healthcare environment, an individual robot is a component of a robot system sharing the same workspace, working collaboratively to perform a series of tasks and with connectivity to IT systems. The robot system interacts with not just able-bodied humans, but also patients with varied health conditions, visitors such as children and elderly people who have varied levels of safety awareness in an environment that is largely uncontrolled. Robot-level safety standard alone is not sufficient to ensure safety of robots deployed at the system-level working in a dynamic healthcare environment.

1 Scope

This TR provides recommendations and requirements at system level for the deployment of robot systems in the healthcare sector. It specifies a safety evaluation framework and the risk assessment requirement for the safe and sustainable deployment of robot systems in dynamic healthcare environments. The guidelines apply to robot systems used for various purposes in the operations of a healthcare facility, including logistics, concierge services, rehabilitation, nursing and caring of patients.

The robots deployed as part of the system can include personal care robots such as mobile servant robots, physical assistant robots and personal carrier robots. These robots can be off-the-shelf industrial units, robots that are collaboratively developed with manufacturers, or robots customised for healthcare. Industrial robots, autonomous guided vehicles (AGV) and autonomous mobile robots (AMR) deployed as service robots in healthcare facilities are also covered in this TR.

Robots (including but not limited to surgical robots and rehabilitative robots) that are classified as medical devices are excluded from this TR if they are used as intended. However, if a robot that is classified as a medical device is repurposed to be used outside of its intended use, such robots are fall within the scope of this TR. For example, an autonomous wheelchair that is repurposed to provide a service to transfer visitors autonomously around the hospital, is considered a personal carrier robot, rather than a medical device.

This TR extends beyond robot-level standards compliance and has considered safety at the service and system level, covering the interactions between humans, robots, facilities and the environment in healthcare settings. The healthcare settings refer to acute hospitals, community hospitals, polyclinics and nursing homes including home care units where elderly people and patients live independently. This TR requires robots deployed at system level to conform to applicable safety standards at a component level, and that the individual robots meet relevant safety requirements.

The content in this TR does not override existing product-level and system certifications for robots actively deployed before the publication of this TR. Safety recommendations pertaining to human-robot interaction covered in existing standards for robotic devices remain applicable.

The referred ISO standards apply to the robots at a device level. This TR focuses on the safety of robots as they are deployed to perform services in a healthcare environment, and covers recommendations that apply to ensure safety at a total system level.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 12100:2010	Safety of machinery – General principles for design – Risk assessment and risk reduction
ISO 13482	Robots and robotic devices – Safety requirements for personal care robots
ISO 13485	Medical devices – Quality management systems – Requirements for regulatory purposes
ISO 14971	Medical devices – Application of risk management to medical devices
ISO/TR 23482-1:2020	Robotics – Application of ISO 13482 – Part 1: Safety-related test methods
ISO/TR 23482-2:2019	Robotics – Application of ISO 13482 – Part 2: Application guidelines
ISO/IEC/IEEE 15288:2015	Systems and software engineering – System life cycle processes