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# Evaluating Benefit-Risk in Robotic Medical Devices with Autonomous or Remote Teleoperation Capabilities

## Discussion Paper and Request for Feedback

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*This paper is intended for discussion purposes only and does not represent draft or final guidance. This paper is not intended to propose or implement policy changes regarding evaluation of robotic medical devices. This paper is not intended to communicate FDA's proposed or final regulatory expectations, including its expectations for the evaluation of robotic medical devices with autonomous or remote teleoperation capabilities, but is instead meant to seek early input from groups and individuals outside the Agency and to advance a broader discussion among stakeholders on this topic. Finally, this paper is not intended to address whether the approaches discussed below are within FDA's existing legal authorities or whether new legal authorities would be necessary.*

*FDA's Center for Devices and Radiological Health (CDRH) will hold a hybrid public workshop December 2-3, 2026 with the intent to discuss the topics covered in this paper.*
*https://www.fda.gov/news-events/fda-meetings-conferences-and-workshops/public-workshop-evaluating-benefit-risk-robotic-medical-devices-autonomous-or-remote-teleoperation*

# Introduction

FDA is committed to assuring that patients and providers have timely and continued access to safe, effective, and high-quality medical devices and safe radiation-emitting products. As part of providing this assurance, FDA recognizes that innovations in device design and function are critical to address patient needs.

The Federal Food, Drug, and Cosmetic Act (FD&C Act) establishes a comprehensive system for the regulation of medical devices. Section 513 of the FD&C Act establishes three classes of devices reflecting the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. FDA's regulations describe that reasonable assurance of safety and effectiveness is framed around benefits and risks. FDA's regulations also describe the "valid scientific evidence" that can support a determination of reasonable assurance that a device is safe and effective for its

conditions of use, which can encompass human clinical investigations and non-clinical investigations.[1]

FDA has issued a series of guidance documents to provide greater clarity regarding the principal factors FDA considers when making benefit-risk determinations during the premarket review process.[2,3] When assessing benefits of devices, FDA considers the types of benefits, the magnitude of benefits, the probability of patients experiencing one or more benefits, and the duration of effects. When assessing risks of devices, FDA considers severity, types, number, and rate of harmful events associated with use of the device or procedure associated with the device; probability of harmful events and probability of the patient experiencing one or more harmful events; and duration of harmful events. Additional factors considered when assessing the probable benefits and risks of devices include, but are not limited to, uncertainty[4] surrounding the benefit and risk, patient-centric assessments and patient-reported outcomes, characterization of the disease or condition, patient perspectives,[5] availability of alternate treatments, risk mitigation, device-type postmarket data, and novel technology for addressing unmet health needs.[3,4]

Robotic medical devices perform diagnostic, therapeutic, or rehabilitative tasks on human anatomy through an electromechanical system that is activated by deliberate action of a user to perform or aid in the task. Such devices may include robotic components, their related systems, and/or

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[1] Valid scientific evidence is defined in 21 CFR 860.7(c)(2) as "evidence from well-controlled investigations, partially controlled studies, studies and objective trials without matched controls, well-documented case histories conducted by qualified experts, and reports of significant human experience with a marketed device, from which it can fairly and responsibly be concluded by qualified experts that there is reasonable assurance of the safety and effectiveness of a device under its conditions of use." Pursuant to 21 CFR 860.7(d)(1), a reasonable assurance of safety occurs when "it can be determined, based upon valid scientific evidence, that the probable benefits ... outweigh any probable risks," and can be demonstrated by establishing "the absence of unreasonable risk of illness or injury associated with the use of the device for its intended uses and conditions of use." Similarly, pursuant to 21 CFR 860.7(e)(1), a reasonable assurance of effectiveness occurs when "it can be determined, based upon valid scientific evidence ... the use of the device for its intended uses ... will provide clinically significant results," the evidence of which is demonstrated principally through "well-controlled investigations" (see 21 CFR 860.7(e)(2)), as defined in 21 CFR 860.7(f).

[2] See FDA guidance entitled "Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and De Novo Classifications", available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/factors-consider-when-making-benefit-risk-determinations-medical-device-premarket-approval-and-de

[3] See FDA guidance entitled "Benefit-Risk Factors to Consider When Determining Substantial Equivalence in Premarket Notifications (510(k)) with Different Technological Characteristics", available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/benefit-risk-factors-consider-when-determining-substantial-equivalence-premarket-notifications-510k

[4] See FDA guidance entitled "Consideration of Uncertainty in Making Benefit-Risk Determinations in Medical Device Premarket Approvals, De Novo Classifications, and Humanitarian Device Exemptions", available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/consideration-uncertainty-making-benefit-risk-determinations-medical-device-premarket-approvals-de

[5] See FDA guidance entitled "Incorporating Voluntary Patient Preference Information over the Total Product Life Cycle", available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/incorporating-voluntary-patient-preference-information-over-total-product-life-cycle

robotic accessories. We collectively refer to these devices as "robotic device systems" throughout this document, as discussed further in the Terminology section below. Robotic device systems include, but are not limited to, robotically-assisted surgical devices (also known as RASDs),[6] as described in the Scope section below. Innovations in robotic device systems, such as technological advances in artificial intelligence (AI), machine learning (ML), and connectivity, are transforming the landscape of modern healthcare and expanding potential robotics applications across a wide range of clinical settings. Autonomous and remote teleoperation capabilities are two examples of rapidly emerging areas of innovation in robotic device systems. These specific capabilities may introduce increasingly complex considerations when evaluating overall benefits and risks. This discussion paper and request for feedback, as well as the associated public workshop, aim to promote conversation on several topics concerning robotic device systems with autonomous and/or remote teleoperation capabilities, including: terminology and technical considerations for robotic device systems with autonomous and/or remote teleoperation capabilities; potential benefits and risks of robotic device systems with autonomous and/or remote teleoperation capabilities; and considerations to help inform future policy development responsive to innovation while maintaining device safety and effectiveness.

## Scope

The scope of this discussion paper focuses on robotic device systems intended to perform diagnostic, therapeutic, or rehabilitative tasks on human anatomy through an electromechanical system that uses actuated mechanisms to perform or aid in the task with some level of autonomy and/or through remote teleoperation, as discussed further in the Terminology section below. The scope of this discussion paper is not limited to robotic device systems intended for surgical procedures: these robotic device systems may be designed to assist healthcare providers with various functions (such as positioning and/or controlling instruments and/or imaging tools) to safely and effectively perform specific tasks. Such tasks may include, among others, open, minimally invasive, non-invasive, or endoluminal surgical or interventional procedures.

The incorporation of robotics in medicine spans a wide range of medical devices. RASDs are often the most commonly thought of robotic device system when thinking of robotics in medicine because currently authorized RASDs help surgeons perform various procedures through robotic arms controlled from a console in the room with the patient. However, robotic device systems

[6] For the purposes of this paper, *robotically-assisted surgical devices (RASDs)* are teleoperated, software-controlled systems that integrate robotic technologies and subassemblies that are designed to assist qualified practitioners in precisely positioning and controlling one or more surgical instruments to safely and effectively perform open, minimally invasive, or endoluminal procedures. RASDs are used under direct control or supervision of a qualified practitioner. RASDs utilize robotic technologies comprised of a leader/follower control system architecture and may contain some level of automated functions to enhance and augment user capabilities.

include various types of other medical devices including stereotactic navigation systems[7], imaging devices[8], and endoluminal navigation devices[9], reflecting the breadth of clinical applications these technologies support. Therefore, users of robotic device systems may include multiple types of healthcare providers, ranging from imaging technicians to surgeons and beyond. For the purposes of this discussion paper, "user" refers to an individual who controls or operates the robotic device system during a task or procedure. For autonomous actions, the user is the individual that has directed the robotic device system to perform the task or procedure. In remote teleoperation, the user controls the robotic device system and performs the task or procedure while remotely located.

Medical device manufacturers are exploring ways to utilize autonomous and/or remote teleoperation capabilities in robotic device systems in new healthcare applications. For example, some manufacturers are utilizing remote teleoperation to develop devices that enable ultrasound technicians to remotely perform ultrasounds. Other manufacturers are exploring the ability to perform remote teleoperation using RASDs. Manufacturers are also employing autonomous capabilities to develop ways to autonomously obtain a peripheral blood draw without a phlebotomist[10] and to develop robotic device systems with the capability to autonomously find and stop life-threatening bleeding inside the body.[11] This discussion paper is meant to spark dialogue on the incorporation of autonomous and/or remote teleoperation capabilities across these and other robotic device systems. Such dialogue may include, but is not limited to, discussion of shared terminology and nomenclature for the identification and description of robotic device systems, potential benefits and risks specific to autonomy and/or remote teleoperation capabilities, and potential risk mitigations/risk control measures (e.g., labeling, training, validation practices, and clinical and non-clinical evaluations) to address risks associated with autonomous and/or remote teleoperation capabilities for robotic device systems.

For the purposes of this discussion paper:

- A robotic device system is considered to have a degree of *autonomy* when, based on current state and sensing, the robotic device system performs a task and/or makes

[7] For the purposes of this paper, *stereotactic navigation systems* are software-controlled devices that use patient imaging (e.g., computed tomography (CT), magnetic resonance imaging (MRI)) or anatomical landmarks to guide instrument and implant placement. Some systems include a robotic component to position an instrument guide or to compensate for patient/tissue movement.

[8] For the purposes of this paper, *imaging devices* include modalities such as X-ray, CT, MRI, or ultrasound. Robotic device systems may assist in positioning and controlling imaging equipment for treatment planning, targeting, and delivery.

[9] For the purposes of this paper, *endoluminal navigation devices* are software-controlled systems designed to assist practitioners with navigating and placing intraluminal devices (e.g., guidewires, catheters, stents, endoscopes). A robotic component may be included to assist with steering and implant deployment.

[10] https://www.fda.gov/news-events/press-announcements/fda-authorizes-first-its-kind-robotic-blood-draw-device

[11] https://www.darpa.mil/research/programs/medics-autonomously-stopping-hemorrhage

decisions without user intervention. Autonomy for robotic device systems may exist on a spectrum, ranging from no autonomy to full autonomy as further described below.

- A *remote teleoperated* robotic device system is remotely accessed and controlled in real-time without the user being physically present in the room with the patient. Remote teleoperation can encompass a spectrum ranging from the remote performance of specific tasks to the remote performance of entire procedures. These systems may have variable physical distances between the user console and the patient as further described below.

# Background

Since the early 1990s, robotic device systems have been an integral part of medical innovation, assisting healthcare providers across a wide range of procedures, from surgery and diagnostics to radiotherapy and interventional care. These systems have enhanced instrument control, tool placement, and visualization. FDA has authorized a range of robotic device systems, including RASDs, stereotactic navigation systems, imaging devices, and endoluminal navigation devices, reflecting the breadth of clinical applications these technologies support.

Robotic device systems have a well-established history in clinical practice, and their capabilities have continued to evolve in parallel with broader technological progress. As technology advances, so has the sophistication of robotic device systems, enabling new and expanded clinical applications. Two particularly notable areas of advancement that are key topics of this discussion paper are autonomy and remote teleoperation. Both have seen substantial developments in recent years and are poised for further advancement.[12,13,14,15]

Robotic device systems with autonomous capabilities have been available in the United States market for years.[16] Advances in computer technology, including increases in processing power, data storage, and computational efficiency, are serving as key enablers of progress in robotic device systems with autonomous capabilities. These technological developments support the increasingly feasible design and development of robotic device systems with greater degrees of autonomy, capable of performing more complex actions.[16]

While the first transatlantic remote robotic healthcare procedures were completed in the early 2000s, technological limitations, particularly network latency[17], have historically hindered

[12] Wang, Y, Buehler, M, Farritor S, et al. Expert Consensus-Based Technical Guidelines for Remote Robotic-Assisted Surgery and Procedures. *World J Surg*. 2025;49: 1708-1721. https://doi.org/10.1002/wjs.12653
[13] Ashar BS, Al Kalaa MO, Dohler M, et al. A readiness framework for tele-robotic surgery deployment in rural hospitals. *J Robotic Surg*. 2026;20, 223. https://doi.org/10.1007/s11701-026-03163-5
[14] Rivero-Moreno Y, Rodriguez M, Losada-Muñoz P, et al. Autonomous Robotic Surgery: Has the Future Arrived? *Cureus*. 2024;16(1): e52243. https://doi.org/10.7759/cureus.52243
[15] Rosen J. Robot performs first realistic surgery without human help. Johns Hopkins University, Jul 9 2025, https://hub.jhu.edu/2025/07/09/robot-performs-first-realistic-surgery-without-human-help/
[16] Lee A, Baker TS, Bederson JB, et al. Levels of autonomy in FDA-cleared surgical robots: a systematic review. *npj Digit Med*. 2024;7(103). https://doi.org/10.1038/s41746-024-01102-y
[17] For the purposes of this paper, *latency* refers to the time it takes for a unit of information to cross a wireless link or network connection from sender to receiver, which is also known as transfer delay.

widespread adoption.[18] Advancements in network connectivity and telemedicine have since minimized latency and improved communication, accelerating the growth of remote teleoperation. In June 2025, manufacturers of robotic device systems published a paper relating to technical considerations and guidelines for the network and facility requirements to enable remote robotic-assisted surgery and procedures.[12] Remote teleoperation requires coordination among different locations, and FDA recognizes that technical considerations to enable this coordination are important to the advancement of the innovation of robotic device systems.[19] As of July 2026, no remotely teleoperated or fully autonomous robotic device systems have been granted marketing authorization in the United States.

# Terminology

Advancing the innovation, safety, and effectiveness of robotic device systems regulated by FDA involves a multi-stakeholder approach that could be facilitated by using common language to describe terminology associated with robotic device systems with autonomous and remote teleoperation capabilities. For purposes of this discussion paper, we will use the following terms:

> **Robotic Device System:** An electromechanical system that is activated by deliberate action of a user to perform or aid in diagnostic, therapeutic, or rehabilitative tasks on human anatomy. These devices may include robotic components, their related systems, and/or robotic accessories.
>
> **User:** An individual who controls or operates the robotic device system during a task or procedure.

This discussion paper and request for feedback seeks input from stakeholders on the following terms and potential definitions, specifically in the context of robotic device systems:

> **Autonomy:** The ability of a robotic device system to perform tasks and make decisions based on current state and sensing without user intervention.
>
> **Levels of Autonomy**: Autonomy for robotic device systems exists on a spectrum reflecting the degree to which control is transferred from the user to the robotic device system, ranging from no autonomy to full autonomy.
>
> **Remote Teleoperation**: When a robotic device system is remotely accessed and controlled in real-time without the user being physically present in the room with the patient. Remote

[18] Marescaux J, Leroy J, Rubino F, et al. Transcontinental Robot-Assisted Remote Telesurgery: Feasibility and Potential Applications. *Ann Surg*. 2002;235(4): 487-492. https://doi.org/10.1097/00000658-200204000-00005

[19] Past FDA engagement activities on robotic device systems include, but are not limited to, the 2015 Robotically-Assisted Surgical Devices: Challenges and Opportunities public workshop, 2023 Extended Reality in Orthopedic Surgical Devices public workshop, participation in the Robotics, Telesurgery, and Surgical AI Collaborative Community, and industry engagement with the Medical Device Manufacturers Association (MDMA) and the Advanced Medical Technology Association (AdvaMed).

teleoperation can encompass a spectrum ranging from the remote performance of specific tasks to the remote performance of entire procedures.

*Discussion Question*

1. Does the terminology used in this discussion paper capture the current and anticipated future state of the ecosystem for robotic device systems with autonomous and/or remote teleoperation capabilities? Can the terminology be refined to facilitate multi-stakeholder discussion and innovation in this space? Please provide details and examples.

# Autonomy

As described in the Terminology section above, for purposes of this discussion paper, autonomy can be considered as the ability of a robotic device system to perform tasks and make decisions based on current state and sensing, without user intervention.[20,21] For this discussion, autonomy should be distinguished from automaticity. Automatic behaviors are completely predictable and follow well-established deterministic or probabilistic rules or programming, whereas autonomous behaviors involve the capacity to make large adaptations to changing external conditions through planning, drawing on broader domain knowledge and cognitive tools.[20] This discussion paper and request for feedback focus on autonomous, not automatic, functions.

For robotic device systems, autonomy may exist on a spectrum with the user role shifting from active performance to oversight and supervision as autonomy increases.[22,23] While not yet FDA-authorized, in the future, fully autonomous robotic device systems might perform all aspects of a healthcare procedure independently with the task performance and/or decision making transferred from the user to the robotic device system. Robotic device systems may also have autonomy to perform discrete tasks while the user retains overall control, or a robotic device system may generate and execute a medical plan subject to user approval.[16,24] All of these capabilities are on the spectrum of autonomy as that term is used in this discussion paper.

Several stakeholders have proposed frameworks to define the level of autonomy in robotic device systems. No single, universally agreed-upon framework exists. Each approach may offer distinct advantages depending on the context in which it is applied. The most widely adopted framework for autonomy related to robotic device systems, proposed by Yang, et al. in 2017, defines six discrete levels of autonomy based on the degree of user involvement in a surgical procedure, ranging from

[20] Attanasio A, Scaglioni B, De Momi E, Fiorini P, Valdastri P. Autonomy in surgical robotics. *Annu Rev Control Robot Auton Syst*. 2021;4:651–679. https://doi.org/10.1146/annurev-control-062420-090543
[21] Beer JM, Fisk AD, Rogers WA. Toward a framework for levels of robot autonomy in human-robot interaction. *J Hum-Robot Interact*. 2014;3(2):74–99. https://doi.org/10.5898/JHRI.3.2.Beer
[22] Fosch-Villaronga E, Khanna P, Drukarch H, et al. The Role of Humans in Surgery Automation. *Int J of Soc Robot*. 2023;15:563-580. https://doi.org/10.1007/s12369-022-00875-0
[23] Fiorini P, Goldberg KY, Liu Y, Taylor RH. Concepts and Trends in Autonomy for Robot-Assisted Surgery. *Proc IEEE*. 2022;110(7):993-1011. https://doi.org/10.1109/JPROC.2022.3176828
[24] Haidegger T. Autonomy for Surgical Robots: Concepts and Paradigms. *IEEE Trans Med Robot Bionics*. 2019;1(2):65-76. https://doi.org/10.1109/TMRB.2019.2913282

Level 0 (full surgeon control) to Level 5 (fully autonomous surgery with no user input).[25] This framework classifies autonomy at the level of the overall procedure, so it is less granular than some alternative frameworks that are intended to better capture the complexity of user-robot interaction across different tasks and environments. These alternative frameworks include, but are not limited to:

- International Electrotechnical Commission (IEC/TR 60601-4-1)[26]: Establishes a Degree of Autonomy (DoA) framework for medical electrical equipment.
- Haidegger[24]: Introduces a Level of Autonomy (LoA) scale for use with current and future surgical robots.
- Schmidgall et al.[27]: Proposes an integrated framework for characterizing surgical robot autonomy.

Unlike the Yang, et al. framework, these frameworks break down autonomy into four fundamental cognitive functions (monitor, generate, select, execute) and assess the degree to which each function is performed by the user versus the robotic device system. This produces a more granular characterization of autonomy, though the multidimensional structure may make these frameworks less practical as a high-level grouping tool.

## A. Benefits and Risks

This discussion paper and request for feedback seeks stakeholder experiences and perspectives on the benefits and risks associated with increasingly autonomous robotic device systems, and potential evidence and approaches that may be considered to reasonably assure their safety and effectiveness throughout their total product life cycle. The incorporation of autonomy into robotic device systems has potential benefits, such as enhancing procedural accuracy, reproducibility, or workflow efficiency in healthcare, thereby offering potential improvement in clinical outcomes. However, the potential benefits of a robotic device system with autonomous capabilities may be accompanied by new and distinct risks, such as incorrect autonomous execution, reduced user vigilance, and limited adaptability to intra- and inter-procedural variability, which may impact the robotic device system's overall risk profile. Depending on the nature and degree of autonomous function, autonomy-related risks may influence the device classification and regulatory controls necessary to provide reasonable assurance of safety and effectiveness. Careful characterization of the nature and magnitude of the potential benefits and potential risks of robotic device systems with autonomous capabilities may help to support a thorough evaluation of safety and effectiveness. Autonomy is

[25] Yang G-Z, Cambias J, Cleary K, et al. Medical robotics—regulatory, ethical, and legal considerations for increasing levels of autonomy. *Sci Robot*. 2017;2:eaam8638. https://doi.org/10.1126/scirobotics.aam8638
[26] International Electrotechnical Commission. IEC/TR 60601-4-1: Medical electrical equipment — Part 4-1: Guidance and interpretation — Medical electrical equipment and medical electrical systems employing a degree of autonomy. Geneva: IEC; 2017.
[27] Schmidgall S, Opfermann JD, Kim JW, Krieger A. Will your next surgeon be a robot? Autonomy and AI in robotic surgery. *Sci Robot*. 2025;10:eadt0187. https://doi.org/10.1126/scirobotics.adt0187

one of several risk factors that FDA weighs when determining overall risk and identifying appropriate regulatory controls and risk mitigations.

### *a. Benefit Considerations: Autonomy*

Autonomous robotic device systems may offer several possible clinical benefits, broadly categorized as improved consistency of task execution and improved access to healthcare procedures. Specifically, by executing predefined movements with accuracy, autonomous robotic device systems may improve the consistency and repeatability of procedures even during lengthy or technically demanding interventions. Improved consistency of task execution may improve patient outcomes by reducing adverse events associated with human imprecision or lack of experience. Additionally, integration of pre-procedure imaging with autonomy may enhance procedural planning and execution, improving procedural accuracy. In some cases, autonomy may also allow for increased patient access to care by reducing the need for skilled healthcare providers. While not a direct patient benefit, autonomous functions may also reduce the cognitive and physical burden on users through improved workflows.

The integration of AI and ML algorithms such as real-time image recognition, intraprocedural decision support, and adaptive planning into autonomous robotic medical systems has the potential to amplify these benefits. AI/ML-enabled capabilities may enhance a robotic device system's ability to respond to complex or variable anatomical conditions in ways that rule-based automation cannot and may support more personalized procedural approaches by incorporating patient-specific data into autonomous execution.

Potential factors that may be part of a benefit-risk consideration may include procedural complexity, the importance of repeatability, the degree of clinical expertise across care settings, and the impact on patient outcomes when characterizing and weighing the benefits of autonomous functionality against associated risks.

### *b. Risk Considerations: Autonomy*

An important consideration for autonomous robotic device systems is how the level of autonomy may impact the potential for patient harm. As decision-making authority and task execution shift from the user to the robotic device system, the robotic device system's capacity to independently act upon unanticipated conditions (unexpected tissue deformation, hemorrhage, anomalous anatomy, etc.) may increase. At higher levels of autonomy, device-generated errors may be initiated and executed before a supervising user can meaningfully evaluate or interrupt them.[21,28]

The scope and complexity of autonomous functionality may also be considerations when evaluating the overall risk profile of these devices. For example, a robotic device system that autonomously performs a discrete, well-bounded surgical subtask within a surgeon-controlled

[28] Bernhard L, Schwingenschlögl P, Hofmann J, Wilhelm D, Knoll A. Boosting the hospital by integrating mobile robotic assistance systems: A comprehensive classification of the risks to be addressed. *Auton Robot*. 2024;48(1). https://doi.org/10.1007/s10514-023-10154-0

procedure may introduce less risk than one that autonomously generates, selects, and executes a complete patient-specific operative plan with only supervisory oversight by the user. The specific clinical consequences of autonomous system failure also factor into the evaluation of overall risk.

One potential risk is that autonomous robotic device systems may not adequately adapt to dynamic conditions that could render the device ineffective or unsafe. Continued autonomous actions under these conditions may result in patient harm, including misdiagnosis, uncontrolled bleeding, injury to adjacent tissues or organs, or failure to achieve the intended outcome. Limited adaptability, or delays in transitioning control from the robotic device system to the user, may further impede timely response during critical moments. Software or communication failures may compromise control of the robotic device system and prevent a user from safely interrupting or overriding autonomous actions.

Human factors may also introduce risk. Automation bias (the tendency of users to defer to robotic device system direction over their own clinical judgment) and automation rejection (when the user overrides or disables the robotic device system's actions in favor of their own judgment) may erode the independent oversight that serves as a critical safeguard against robotic device system error or negatively impact technical performance. Additionally, some users may lack the expertise to complete a procedure manually if the autonomous system fails or may be more likely to defer to the robotic device system rather than their own judgment. User training requirements and any associated learning curve may be important to consider, as patient outcomes may be poorer during this period. As autonomy level and procedural complexity increase, more specific use guidelines like well-defined target populations and clinical indications may be considerations.

Connected devices, including those with autonomous capabilities, qualify as "cyber devices" under Section 524B of the FD&C Act, introducing a cybersecurity threat surface. Users may not have sufficient bandwidth to address potential cybersecurity vulnerabilities while actively performing a procedure. A cybersecurity threat could compromise the robotic device system’s functionality, availability, data integrity, or the security of connected networks, with direct implications for patient safety.

Autonomous functionality driven by complex algorithms, often utilizing AI and/or ML, may introduce unique risk considerations. AI/ML-based autonomous systems may perform unpredictably when encountering intraprocedural conditions outside the scope of their training data. Algorithm performance may also vary across patient subgroups if training data are not representative of the intended use population, potentially introducing or exacerbating disparities in clinical outcomes. Unlike rule-based automation, some AI/ML-driven decision making may lack transparency, potentially making it difficult for users to evaluate or meaningfully override autonomous actions. Additionally, algorithm performance may degrade over time as clinical environments, patient populations, or configurations of the robotic device system evolve.

The potential risks associated with autonomous robotic device systems are multifactorial and may vary across robotic device system types, autonomy levels, and clinical indications. As described above, reduction in user actions or decision-making may lead to improvements in patient safety.

However, patient safety concerns may also vary with the degree to which autonomous functionality displaces user actions or decision-making, with higher levels of autonomy potentially increasing machine-generated errors before a healthcare provider can intervene. Additional risk factors may include limited intraprocedural adaptability, delays in control transition and override, and automation bias.

*Discussion Questions*

2. What benefits and risks associated with autonomous capabilities in robotic device systems might be important considerations for FDA? Please comment on benefits and risks mentioned in this discussion paper as well as any additional benefits or risks that may not have been mentioned.
3. Are the potential benefit-risk consideration factors identified in this section (procedural complexity, the importance of repeatability, the degree of clinical expertise across care settings, and the impact on patient outcomes) appropriate factors to consider when characterizing and weighing the benefits of autonomous functionality against associated risks? What other factors should be considered, if any?
4. How may varying levels of autonomous function affect the overall risks associated with a robotic device system, including the nature and severity of potential patient harm and impact on effectiveness?
5. What evidence, including but not limited to clinical and non-clinical evidence, can help characterize the benefits and risks of autonomous robotic functions across typical and worst-case scenarios?
6. How might FDA consider factors such as automation bias, delays in override and control transition, and intraprocedural adaptability in the context of the specific tasks being automated, the intended patient population, and the clinical consequences of autonomous robotic device systems?

# Remote Teleoperation

As discussed in the Terminology section, for purposes of this paper, remote teleoperation refers to a robotic device system that is remotely accessed and controlled in real-time without the user being physically present in the room with the patient. The physical distance between the user console and the patient may vary considerably, ranging from a different room within the same facility to a different hospital system within the same geographic region to an entirely different geographic region or country, and may involve wired (e.g., fiber optic) or wireless (e.g., Wi-Fi, 5G, satellite) connection types. For the purposes of this discussion paper, remote teleoperation could encompass a spectrum ranging from the remote performance of specific tasks to the remote performance of entire procedures.

Remote teleoperation may improve patient access to specialized healthcare by enabling remote clinical expertise in underserved or difficult-to-access areas, supporting remote mentoring and proctoring, and improving procedural workflow with a potential benefit in life-threatening and time-

sensitive conditions (e.g., ischemic stroke, myocardial infarction) where timely specialist access is critical to patient outcomes.[12] On the other hand, risks related to intraprocedural adverse event management, connectivity loss, and reduced sensory perception and awareness for the remote provider might scale with the degree of separation between user and patient. These risks may occur in time-sensitive procedures where delays or system failures are more likely to result in serious patient harm. All of these risk factors can contribute to the robotic device system's overall risk profile. As with autonomy, remote teleoperation may be one of several factors for FDA to weigh when determining overall robotic device system risk.

Remote teleoperation is an emerging capability where the associated benefits and risks are actively being explored. In the questions below, this discussion paper solicits feedback on these benefit and risk considerations and the evidence needed to reasonably assure that remote teleoperated robotic device systems are safe and effective throughout their total product life cycle.

## B. Benefits and Risks

### *a. Benefit Considerations: Remote Teleoperation*

When assessing the benefits of robotic device systems with remote teleoperation capabilities, considerations include the severity of the medical condition for which the device is intended to be used and the context of use of the robotic device system. For time-sensitive patient needs (e.g., endovascular stroke treatment), where earlier intervention can be critical to achieving better patient outcomes, remote teleoperation may offer the potential benefit of connecting patients with remote users who can perform a time-sensitive task or procedure. Even when patient needs are less time-sensitive, remote teleoperation may provide an option for patients to connect with specialized healthcare providers to perform a task or procedure remotely. In such cases, a remote user with specialized expertise may control the actions of a robotic device system, enabling the patient to receive specialized care which may not otherwise be available. Additionally, with remote teleoperation capabilities, a remote specialist may be able to perform certain tasks to address complex clinical scenarios, anatomical variants, or challenging procedural steps during a procedure otherwise conducted by healthcare providers in the room with the patient.

### *b. Risk Considerations: Remote Teleoperation*

An important risk consideration for remote teleoperation is the management of intraprocedural adverse events, where risk may scale in some cases as the distance between qualified healthcare provider and the patient increases due to potentially longer time delay between the onset of the adverse event and the arrival of a qualified healthcare provider. Risks such as bleeding, tissue trauma, and connectivity loss that necessitate conversion from remote teleoperation to local procedural intervention could require extensive evaluation and mitigation and in extreme cases may lead to patient death. Use of robotic device systems for certain procedures, such as those in the ophthalmic space or during endovascular treatment of stroke, may entail risks requiring local management, such as patient movement or psychological distress in awake patients or those under conscious sedation. Ensuring that local healthcare providers are available in a patient's room

may be a straightforward risk mitigation strategy, but this may not be feasible when the level of expertise necessary to address adverse events is not locally available. Moreover, dedicating two qualified specialists to a single procedure when a robotic device system is used, one acting remotely and one on standby locally, may reduce the overall availability of specialized care from a broader public health perspective. This presents a question as to whether benefit-risk analysis for robotic device systems ought to include condition-specific and/or procedure-specific considerations. For example, a system enabling remote coronary stent deployment may carry greater inherent risk than one limited to linear and rotational advancement of a gastrointestinal endoscope.

A robotic device system with teleoperation capabilities that is limited to performing specific, lower-risk tasks within a larger procedure may introduce less risk than a robotic device system with teleoperation capabilities that enables a user to perform an entire procedure or that executes critical steps independently. The specific risks of the procedure and the severity of potential patient harm may also be factors for consideration.

Available communication capabilities and channels between local and remote individuals may also contribute to a robotic device system's overall risk. Bidirectional communication between the remote user, the patient, and the local healthcare team may help maintain procedural workflow and help mitigate risk. Loss of audio-visual communication at different stages of the procedure may contribute to risk. For example, loss of real-time imaging to the user could result in serious adverse events, such as advancement of endoluminal devices into unintended vessels, vessel perforation, or clot dislodgement. FDA recognizes that certain clinically relevant sensory inputs available to an on-site healthcare provider (changes in the pitch of a bone drill, tissue resistance during palpation, procedurally relevant odors, etc.) may be inaccessible to the remote user. Potential considerations are whether built-in boundary conditions (e.g., velocity or force limits) or compensatory features (e.g., haptic feedback, visual alerts) could adequately address these sensory limitations.

Lapses in motion control connectivity, and the measures in place to prevent delayed or degraded signals from reaching the patient console, may also inform the risks of remote teleoperation. Unintended, distorted, or delayed signals may result in procedural errors or interruptions. Delays in audio-visual communication and motion control may not be synchronous, potentially creating coordination challenges during the procedure. Such risks may be higher in potentially life-threatening and time-sensitive procedures like those to treat acute stroke, gastrointestinal bleeding, acute myocardial infarction, or penetrating trauma.

When evaluating risk mitigations, a key consideration might include how quickly a procedure can be transitioned to a manual procedure in the event of an urgent need for local intervention. An additional consideration might include whether the necessary local expertise and personnel must be immediately available to safely use a device if local intervention is indicated. If a co-located specialist is not present, another consideration may be how quickly care can be escalated, including whether patient transfer to another facility would be required to complete the procedure

safely. Locations which may realize the greatest benefits from remote teleoperation may also be the same locations which could present the greatest risks due to the lack of on-site resources.

*Discussion Questions*

7. What benefits and risks associated with remote teleoperation capabilities in robotic device systems might be important considerations for FDA? Please comment on the potential benefits and risks discussed above as well as any benefits or risks that are not discussed in this discussion paper. Additionally, please consider remote teleoperation requiring real-time intraprocedural decision making (e.g., device selection during ischemic stroke intervention).
8. How might the overall risk of a robotic device system change as the level of remote teleoperation changes? Please include specific examples.
9. How might expectations for emergency management and conversion to a manual procedure, including the potential need for patient transfer, factor into the benefit-risk considerations of a robotic device system with remote teleoperation capabilities? Please include specific examples.
10. What evidence may help characterize the benefits and risks of robotic device systems with remote teleoperation capabilities across different procedure types, clinical settings, and patient populations?

# Additional Risk Considerations for Autonomy and Remote Teleoperation

Autonomous and remote teleoperation capabilities may each independently introduce distinct risks, as discussed above. Additional risks may arise when both capabilities are present in the same robotic device system and used simultaneously. One potential example of these additional risks is latency challenges when user intervention is needed if a robotic device system's autonomous capabilities fail during remote teleoperation, potentially delaying a timely response to an intraprocedural adverse event, thus resulting in a device-related adverse event. Another example is inconsistent or unreliable handoffs of control between autonomous and remote teleoperation modes, which may introduce unanticipated failure modes that neither capability would present independently.

There are also risks that may be shared by robotic device systems with either autonomous or remote teleoperation capabilities, regardless of whether both capabilities are present in the device. These risks may include sensor and imaging dependency, where both autonomous decision making and remote user awareness rely heavily on the quality and continuity of imaging and sensor data. Software and hardware failure modes may be a shared risk, as failures in either domain may compromise control of the robotic device system or patient safety regardless of whether the system is operating autonomously or under remote teleoperation. Gaps in clinical team training may present a similar shared risk, as personnel may need to be adequately prepared to manage robotic

device system failures, execute manual overrides, and respond to intraprocedural adverse events whether the procedure is being performed autonomously or remotely.

Cybersecurity warrants attention with regard to the connected nature of robotic device systems with autonomous and remote teleoperation capabilities. When both capabilities are present in the same robotic device system, cybersecurity vulnerabilities may simultaneously compromise autonomous decision making and remote user control, compounding the potential for patient harm. A cybersecurity breach compromising the integrity of sensor or imaging data in a robotic device system could undermine the safety of either an autonomous or remote teleoperated procedure independently. Key cybersecurity considerations previously identified in FDA guidance[29] include, but are not limited to:

- **Network performance:** Network performance may be compromised by cybersecurity incidents, design vulnerabilities exposed through user error, or physical phenomena affecting signal propagation which could cause serious patient harm. Robotic device systems that rely on network connectivity, such as those connecting via a local area network, may become non-functional if vulnerabilities are exploited, whether intentionally or unintentionally.
- **System-level threats**: An end-to-end system perspective rather than examination of isolated individual components is an important aspect of evaluating cybersecurity risks. A vulnerability in any single element can cascade across the entire system, expanding the threat surface and undermining the integrity, availability, or safety of the system as a whole.
- **Integrity and non-repudiation:** Without robust authentication, integrity, and non-repudiation controls, the accuracy of commands transmitted to the robotic device system cannot be guaranteed, potentially resulting in unintended behavior of the robotic device system and patient harm.
- **Availability:** System availability encompasses both the control end and the procedural end, such that the network remains fully functional and the robotic device system continues to operate throughout the procedure.
- **Reliance on users:** Users may be unable to independently identify and address cybersecurity threats on both ends of the system. For example, a cybersecurity issue affecting the integrity of the video feed may not be apparent to a user at the patient's bedside.

[29] See FDA guidance entitled "Cybersecurity in medical devices: Quality management system considerations and content of premarket submissions," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cybersecurity-medical-devices-quality-management-system-considerations-and-content-premarket

*Discussion Questions*

11. How might risks that arise when a robotic device system has autonomous and remote teleoperation capabilities factor into the establishment and testing of connectivity standards, engineering controls, facility capabilities, personnel qualifications, etc.?
12. What evidence might be used to demonstrate a robotic device system's ability to withstand unexpected degradations in connectivity or cybersecurity breaches? What safety controls may be needed (velocity limits, force safety stops, positional monitoring, etc.) to address the risks of hardware and software failure when a robotic device system has autonomous and remote teleoperation capabilities?

# Risk Mitigation

Risks identified for robotic device systems with autonomous and/or remote teleoperation capabilities may potentially be mitigated through a variety of different approaches including, but not limited to, system design, performance testing, labeling, training, verification and validation testing, user oversight, human factors and usability engineering, and postmarket oversight, such as described below. FDA has issued guidance documents that discuss risk mitigation methods for devices such as those listed here, which may be located using the guidance search function found on FDA's website.[30] Well-designed systems and controls may help reduce risk by enforcing safety constraints (e.g., haptic boundaries), accuracy requirements, and incorporating redundant safety mechanisms and fail-safes. For robotic device systems with autonomous and remote teleoperation capabilities specifically, the final overall benefit-risk profile may vary based on factors including anatomic location, clinical condition, the scope of tasks performed remotely, and connection quality.

**Verification and Validation:** FDA is considering how autonomous and remote teleoperation capabilities in robotic device systems may be verified and validated through a range of methods, including, but not limited to, nonclinical (e.g., bench testing, in silico testing, cadaver studies) and clinical studies. Such verification and validation testing is intended to confirm that the robotic device system performs as intended across a variety of scenarios, including worst-case conditions.

**User Oversight:** In robotic device systems with autonomous and/or remote teleoperation capabilities, user oversight may remain critical in clinical settings. FDA is considering whether or how the healthcare team in the room with the patient may need to be trained to become a user of the robotic device system to perform manual overrides or initiate an emergency stop for safe and effective use of the robotic device system. Another consideration is the potential role of the healthcare team in the room with the patient (e.g., nursing staff, operating room staff) who are knowledgeable in how to properly prepare

[30] https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products

patients, robotic device systems, and procedural spaces to be used for remotely teleoperated and/or autonomous robotic device systems.

**Human Factors:** While human factors may introduce risk, they may also contribute to risk mitigations. FDA is considering how user interfaces, control transitions, instructions for use, defined indications, and limitations may be conveyed through a user training program for autonomous and/or remote teleoperated robotic device systems. Human factors and usability engineering may potentially help improve the safety and effectiveness of robotic device systems for patients and users alike.

**Postmarket Oversight:** Following marketing authorization, postmarket oversight can play a role in monitoring performance of the robotic device system and adverse events. Real-world data and Medical Device Reporting (MDR) may identify and potentially help correct issues with autonomous and/or remote teleoperated functions and prevent recurrence.

*Discussion Questions*

13. What risk mitigations might be appropriate for robotic device systems with autonomous and/or remote teleoperation capabilities as the role of the on-site user shifts from active performance to assistance, oversight, and/or supervision?
14. What benchmarks for verification and validation, user oversight, human factors, safety features, or other risk mitigations might help mitigate the risks of autonomous and/or remote teleoperation capabilities?
15. How might postmarket oversight activities help mitigate safety risks associated with autonomous and/or remote teleoperated capabilities in robotic device systems? Please include specific examples.

# Conclusion

Robotic device systems incorporating autonomous and/or remote teleoperation capabilities represent a rapidly evolving frontier in medical device technology with potential to help improve patient outcomes and expand access to care. At the same time, these capabilities may introduce multifactorial risks related to autonomous decision making, adaptability, connectivity, sensory limitations of remote users, human factors, and cybersecurity, among other factors.

As robotic device systems continue to evolve, engagement between FDA and stakeholders in the medical device ecosystem can help FDA ensure that regulatory approaches remain adaptive, science-based, and supportive of innovation while upholding rigorous standards for safety and effectiveness. FDA intends for this discussion paper to prompt feedback from industry, healthcare providers, patients, and other stakeholders as FDA continues to consider potential benefits and risks of robotic device systems with autonomous and/or remote teleoperation capabilities, and potentially appropriate risk mitigations for such devices within a framework grounded in device safety and effectiveness. The questions posed throughout this paper are intended to solicit the perspectives, expertise, and practical experience of the broader stakeholder community. FDA is

seeking to develop a regulatory approach that would rigorously and appropriately mitigate risks while championing the meaningful benefits these technologies offer.

FDA encourages all interested parties to submit comments to the public docket and to participate in the associated public workshop. The feedback received will help inform the development of future policies related to robotic device systems with autonomous and/or remote teleoperation capabilities, to advance the goal of assuring that patients and providers have timely access to safe, effective, and innovative medical technologies.