# Medtronic
Engineering the extraordinary

# Artificial Intelligence (AI) Compass for responsible use of AI

Since 1949, Medtronic has been engineering the extraordinary. As the global leader in healthcare technology, we have deep clinical knowledge and experience developing new lifesaving and life-sustaining medical technologies. Our journey of innovation continues with advances in the application of artificial intelligence (AI) to our medical technologies. The AI Compass represents the principles we will use to guide our journey and the commitments we make to the users of our technologies, including patients and healthcare providers.

While these technologies have great potential to improve patient care and further the Medtronic Mission to alleviate pain, restore health, and extend life, we also recognize that AI-enabled technologies raise new and important considerations. This AI Compass affirms our commitments to apply AI ethically and where it will make contributions to improve patient health outcomes and the conditions of patient care delivery.

As we continue on our journey of AI innovation, we commit to a continuous learning and improvement mindset, recognizing that the state of our knowledge as well as that of user and public expectations will continue to evolve.

## Guiding Principles

### Principle 1: Beneficial use

We develop AI-enabled technologies that further the Medtronic Mission of alleviating pain, restoring health, and extending life.

Commitments:

- We take a patient-centered approach to the design, development, and deployment of our AI-enabled technologies. Our goal is to incorporate AI in our products and therapies where the application of AI meaningfully improves patient health outcomes or the conditions of patient care delivery.

### Principle 2: Safety and effectiveness

We apply best practices and scientific evidence to design AI-enabled technologies that are secure, safe, and effective.

Commitments:

- We leverage our extensive medical device and clinical knowledge to design safe and effective AI-enabled technologies.

- We employ good machine learning practices (GMLP) that are consistent with current best-in-class industry standards to develop AI-enabled technologies and to improve our AI solutions over time.

- We apply appropriate methodologies to assess the robustness of our AI systems for performance, reliability, safety, and security.

- We use a total product lifecycle approach to our AI-enabled technologies to adapt and improve our technologies based on real-world performance data.

- We comply with applicable laws, regulations, and standards for safety and effectiveness in the research, design, manufacturing, distribution, and monitoring of our AI-enabled technologies.

## Principle 3: Fairness and non-discrimination

We develop, validate, and monitor solutions using high-quality, robust, and clinically relevant data of target patient groups with the goal of identifying and eliminating potential bias and discrimination in our AI- enabled technology.

Commitments:

- We strive to identify and address any unwarranted bias and discriminatory patterns in our AI.

- We engage with external stakeholders to foster a healthcare data ecosystem that makes robust and representative data available to enable us to mitigate bias, while still protecting patient privacy.

## Principle 4: Quality and accountability

Consistent with the Medtronic Mission, a commitment to quality is our top priority. This same philosophy guides our creation and use of AI-enabled technologies.

Commitments:

- We strive to prevent issues before they arise, and we diligently review to discover and assess potential quality or safety issues. We act swiftly and boldly to address any issues we may discover, putting the patient's interest first in all decisions.

- We maintain accountability with robust data and algorithm governance, testing, and validation procedures.

- We design AI-enabled technologies with opportunities for users to provide feedback and report any issues in accordance with our complaint handling policies and applicable regulations.

- We apply our Quality Management Systems to AI-enabled medical device technologies throughout the total product lifecycle.

## Principle 5: Human control and oversight

We develop and design AI-enabled technologies to empower users, including patients and healthcare providers, with appropriate human control and oversight.

Commitments:

- We ensure that the AI-enabled technologies are designed with appropriate human interaction and oversight depending on the context of use.

- We ensure that AI-enabled technologies are designed following usability and human factors principles to prioritize the user's safe and effective interaction with the technology.

- We ensure that the appropriate level of human control and oversight is identified, assessed, and clearly communicated in our labeling and instructions for use.

- We provide appropriate materials and tools to enable users to make informed decisions regarding their use of, and interaction with, our AI-enabled systems, and to reasonably assess and challenge information and capabilities provided by the system.

## Principle 6: Privacy and security

Medtronic protects the personal data and privacy of users, patients, healthcare providers, and partners throughout the total product lifecycle.

Commitments:

- We work with patients, healthcare providers, and other partners to provide clear notice and seek appropriate authorization for intended data uses.

- We use privacy-by-design methodologies and privacy-preserving techniques to safeguard the privacy of patients.

- We leverage security-by-design methodologies to identify and mitigate cybersecurity risks and vulnerabilities, including those unique to AI-enabled technologies.

- We value the personal and sensitive information entrusted to our care and ensure that we meet or exceed industry privacy and security standards and comply with applicable laws and regulations.

## Principle 7: Transparency

We are transparent about whether our medical technologies are AI-enabled, the intended use of the system, the algorithms that produce AI-enabled outcomes, and the responsibility for ultimate decision-making.

Commitments:

- In order to provide optimal transparency, we use language appropriate to the intended audience, e.g., patients, regulatory bodies, healthcare providers, or researchers.

- We communicate how and why we are leveraging AI in our medical technologies, as well as the limitations of the AI.

- We provide the users of our AI-enabled technologies with meaningful information to enable them to make informed decisions regarding their use of, and interaction with, our AI systems.