

# Artificial Intelligence at Trium: Our Position and Practice

*Trium Analysis Online GmbH — position paper on the use of Artificial Intelligence*

Trium develops software that helps clinicians care for mothers and babies during pregnancy and birth. We are increasingly asked whether, and how, we use Artificial Intelligence. The answer is yes: **Trium uses Artificial Intelligence — both within our software and in how that software is built.** This paper sets out where, and the principle that governs it throughout: **AI supports skilled people; it does not replace their judgement.**

## AI in our product

Trium CTG Online is a CE-marked medical device, regulated under the European Union's Medical Device Regulation (MDR 2017/745) as a Class IIb decision-support system for central fetal monitoring. Within its analysis module, alongside established signal-processing methods, are techniques that go further and **infer structure from the data**: the software fits a parameterised model to each candidate fetal-heart-rate deceleration to characterise its onset, depth, timing, and recovery, and it fits a model to detect rhythmic (sinusoidal) patterns in the heart-rate signal.

Assessed against the EU AI Act — which defines an "AI system" as a machine-based system that infers, from the input it receives, how to generate outputs such as recommendations (Article 3) — these techniques meet that definition: in the terms of the Act, Trium CTG Online is an AI system. They exist to **support** the clinician's interpretation of the cardiogram, never to replace it: the software analyses, classifies, and alerts, but it remains a decision-support tool, not an automated diagnosis system, and the clinician always makes the final clinical decision.

## AI in how we develop our software

The role of AI in software engineering is genuinely contested, and we think it worth saying plainly where we stand. The field runs between two poles: engineers such as Andrew Kelley, creator of the Zig programming language, who have kept AI out of their craft, and voices such as Andrej Karpathy — who coined the term "vibe coding" — who embrace letting AI lead. Trium takes a considered middle path. We treat modern AI tools as **accelerators in the hands of our engineers, not a replacement for them.** How much they assist varies from task to task; what does not vary is that a qualified engineer **directs the work, reviews and understands every contribution, and remains accountable for it** — nothing reaches our products unchecked. We apply the same discipline wherever these tools help us, from research to the documentation of our software.

This discipline matters most where the stakes are highest. The methods at the heart of our analysis — how the software characterises the fetal heart-rate signal — are **conceived and owned by our engineers, not by a tool**; where AI has helped, it has done so in building

out, refining, documenting, and checking that work, on a basis our engineers defined and under their review.

Our use of AI in development is auditable. As the manufacturer of a regulated medical device, we build our software under established verification, validation, and review disciplines, and as we enter regulatory dialogue our practices — including where AI has assisted — are open to examination.

## Looking ahead

Across both what we build and how we build it, one principle holds: **AI assists; accountable people decide**. We treat the human's place in this not as a limitation but as a commitment — to safety, to quality, and to the trust on which medical care depends. We see AI as an increasingly important part of medical software, and we will continue to adopt it responsibly as the technology and its regulation mature: with meaningful human oversight, careful evaluation of every capability we introduce, and an unwavering place for the clinician at the centre of care.

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*Trium Analysis Online GmbH, Munich. This document states Trium's general position on AI and does not modify the intended purpose, instructions for use, or regulatory status of any Trium product.*