EITAN MEDICAL LTD.

Data Act Transparency Notice

Pursuant to Article 3(2) of Regulation (EU) 2023/2854

Effective Date	22 June 2026
Issued by	Eitan Medical Ltd. – Legal & Compliance

1. Introduction and Purpose

This Transparency Notice is issued by Eitan Medical Ltd. ("**Eitan Medical**", "**we**", "**us**") in accordance with Article 3(2) of Regulation (EU) 2023/2854 of the European Parliament and of the Council of 13 December 2023 on harmonised rules on fair access to and use of data (the "**EU Data Act**"), which has applied across EU Member States since 12 September 2025.

Its purpose is to inform users of Eitan Medical's connected medical device products and related digital services — prior to entering into any contract for the purchase, lease, or use of such products — of the nature of data generated by those products and services, how that data is held, used, and shared, and what rights users have in respect of that data.

This notice applies to all connected product versions of Eitan Medical's infusion pump platform, including the Sapphire® family and Avoset™ family of ambulatory and volumetric infusion pumps where those products incorporate connectivity features (collectively, "**Connected Products**"). It should be read alongside any applicable Privacy Notice issued under the General Data Protection Regulation (EU) 2016/679 ("**GDPR**"), which continues to govern all processing of personal data.

2. Identity of the Data Holder

The Data Holder responsible for data generated by the Connected Products is:

Legal Entity	Eitan Medical Ltd.
Registered Address	29 Yad Haruzim St., P.O.B 8639, Netanya 42505, Israel
EU Representative	Eitan Medical France SAS, 7 place Félix Baret, 13006 Marseille, France
Contact – Data Act Enquiries	DPO@eitanmedical.com
General Website	www.eitanmedical.com

Where a Connected Product is sold, rented, or leased to an end-user through an authorised distributor, that distributor may also constitute a Data Holder in respect of any data it independently collects or processes. Users should consult their distributor's own transparency disclosures accordingly.

3. Description of Data Generated by the Connected Products

3.1. Types of Data

The Connected Products generate and may transmit the following categories of data during normal operation:

- Device operational status data (e.g., power state, alarm status, device mode, battery level, connectivity status)
- Infusion therapy data (e.g., programmed drug/fluid type, dose, rate, volume to be infused, volume infused, infusion start and stop events)
- Device configuration data (e.g., drug library version, device settings, software version, pump serial number)
- Event and alarm log data (e.g., occlusion alarms, air-in-line events, programming confirmations)

Note: The Connected Products are not designed to independently capture or transmit patient identification data. Where infusion therapy data is associated with a patient identifier, such linkage occurs within the

customer information systems operated by the healthcare institution (the user), and is subject to that institution's own data protection obligations and processes. Eitan Medical processes such data as a data processor in accordance with any applicable Data Processing Agreement.

3.2. Format of Data

Data generated by the Connected Products is structured in machine-readable formats, including:

- Proprietary binary or encrypted formats used for on-device storage and direct pump-to-system communication;
- HL7 v2.x and/or FHIR-compliant message formats for integration with healthcare institution information management and EMR/EHR systems;
- JSON and XML formats for API-based data exchange with Eitan Medical's Insight™ clinical data management platform and third-party systems.

Data made available to users upon request will be provided in a commonly used, machine-readable format (e.g., CSV, JSON, or PDF report) to the extent technically and operationally feasible.

3.3. Estimated Volume of Data

The volume of data generated per device varies depending on clinical use intensity, connectivity configuration, and the duration of deployment. As a general indication:

- A single actively used Connected Product may generate between approximately 500 KB and 5 MB of operational and event log data per day under typical hospital deployment conditions.
- Cumulative data over a product lifecycle (typically 7–10 years) may reach several gigabytes per device.
- Data transmitted in real time over network connections constitutes a subset of total generated data and depends on the connectivity and integration configuration selected by the user.

4. Purpose and Use of Data

Data generated by the Connected Products is used for the following purposes:

- **Clinical Therapy Management:** Clinical therapy management: To support healthcare institutions in monitoring and documenting infusion therapy delivery
- **Maintenance & Servicing:** Device maintenance and servicing: To facilitate planned maintenance, remote troubleshooting, and software/firmware updates.
- **Post-Market Surveillance:** Post-market surveillance and vigilance: To fulfil Eitan Medical's obligations under the EU Medical Device Regulation (EU) 2017/745 ("MDR") and applicable national vigilance frameworks, including the monitoring of device performance and safety signals.
- **Product Improvement:** Product improvement and quality: To analyse anonymised or aggregated device performance data for the purpose of improving product design, reliability, and clinical outcomes, subject always to applicable data protection law.
- **Regulatory Compliance:** Regulatory compliance: To respond to lawful requests from competent national or EU authorities.

Eitan Medical does not use data generated by Connected Products for profiling individual end-users for commercial marketing purposes, nor does it sell such data to third parties for their independent commercial purposes.

5. Data Retention

Eitan Medical retains data generated by the Connected Products for the following periods, subject to applicable law and any contractual arrangements with the user:

Data Category	Retention Period	Basis
Device event & alarm logs	10 years from generation	EU MDR post-market obligations; legal limitation periods

Device configuration data	Duration of contract + 5 years	Contractual & regulatory compliance
Aggregated/anonymised performance data	Indefinite (no personal data)	Legitimate interest in product improvement

6. Data Sharing

Eitan Medical may share de-identified data generated by Connected Products with the following categories of recipients, and only to the extent necessary for the stated purposes:

- **Authorised Users:** Healthcare institutions and clinical users: Data is made available to the user (the procuring healthcare institution or authorised clinical staff) in accordance with applicable product integration agreements and the user's own data governance frameworks.
- **Third-Party Integrators:** Third-party system integrators and IT providers: Where the user has configured the Connected Product to integrate with third-party hospital information systems (e.g., EMR/EHR, MDMS), data is transmitted to those systems pursuant to the user's instructions. Eitan Medical is not responsible for those systems' data handling.
- **Group Companies & Service Partners:** Eitan Medical group companies and authorised service partners: For the purpose of providing technical support, maintenance, and warranty services.
- **Regulatory Authorities:** Competent authorities and regulatory bodies: Where required by applicable law, including national market surveillance authorities, notified bodies, and EU institutions.
- **Corporate Successors:** Successor entities: In the context of any merger, acquisition, or corporate restructuring of Eitan Medical, subject to applicable notification obligations.

Eitan Medical does not share data with third parties for their independent commercial purposes, including advertising or data brokering.

7. User Rights under the EU Data Act

As a user of a Connected Product, you have the following rights under the EU Data Act, exercisable at no cost:

- **Right of Access:** Right to access product data: You are entitled to access the data generated by your Connected Product, either directly through the device interface or related digital service, or upon request to Eitan Medical (Article 4).
- **Right to Portability:** Right to data portability: You may request that data generated by the Connected Product be transmitted to a nominated third party (e.g., a third-party clinical analytics provider) on fair, reasonable, and non-discriminatory terms (Article 5).
- **Right to Complain:** Right to lodge a complaint: You have the right to lodge a complaint with the competent national authority designated under the EU Data Act in your Member State if you consider that Eitan Medical has failed to comply with its obligations.

Requests to exercise any of the above rights should be directed to: DPO@eitanmedical.com

We will respond to legitimate requests without undue delay and in any event within 30 days of receipt, unless exceptional technical circumstances apply.

8. Contract Duration and Termination

The duration of Eitan Medical's data-related obligations corresponds to the term of the relevant product purchase, lease, service, or licensing agreement entered into between Eitan Medical (or its authorised distributor) and the user.

Upon expiry or termination of the relevant agreement:

- Users may request export or transfer of all data generated by the Connected Product within 30 days of termination.
- Eitan Medical will delete or anonymise data held solely on the basis of that contract, subject to applicable regulatory retention obligations (see Section 5).
- Data retained for post-market surveillance and regulatory compliance purposes will continue to be held for the periods set out in Section 5, notwithstanding termination.

9. Interaction with GDPR and Other Applicable Law

This notice addresses Eitan Medical's obligations under the EU Data Act in respect of non-personal data and is complementary to — not a substitute for — Eitan Medical's Privacy Notice under the GDPR, which governs the processing of any personal data.

Where data generated by Connected Products constitutes or contains personal data (as defined under the GDPR), all processing by Eitan Medical is subject to the full requirements of the GDPR and any applicable national implementing legislation. In such cases, the relevant legal basis, data subject rights, and controller/processor responsibilities are addressed in Eitan Medical's applicable Data Processing Agreement and Privacy Notice.

This notice should also be read in conjunction with Eitan Medical's obligations under the EU Medical Device Regulation (EU) 2017/745, applicable cybersecurity requirements, and any sector-specific regulatory requirements applicable in the relevant Member State.

10. Changes to this Notice

Eitan Medical will update this notice where the nature, purpose, or recipients of data generated by Connected Products materially change during the lifecycle of the product or the term of the relevant agreement. Users will be informed of material changes by:

- Publication of the updated notice on Eitan Medical's website (www.eitanmedical.com/data-act);
- Direct notification to the contractual counterparty where required by the Data Act or the terms of the relevant agreement.

11. Contact and Complaints

Data Act Enquiries	dpo@eitanmedical.com
Data Protection Officer	Guy Hadar, DPO, EVP, Corporate Development and General Counsel
Postal Address	Eitan Medical Ltd., 29 Yad Haruzim St., P.O.B 8639, Netanya 42505, Israel
EU Representative	Eitan Medical France SAS, 7 place Félix Baret, 13006 Marseille, France
Competent Authority	As Eitan Medical Ltd.'s EU legal representative is established in France, Eitan Medical is under the primary competence of the French authority designated pursuant to Article 37 of the EU Data Act. A register of all competent authorities designated by Member States is maintained by the European Commission at: https://digital-strategy.ec.europa.eu/en/policies/data-act. Users in other Member States may also approach their own national competent authority.

Changes Schedule

The 22 June 2026 is the updated version.

No changes were made from the previous version.