HIPAA Compliance Statement

Last updated 28th of June 2026

Overview

In the United States, the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), as amended, and its implementing regulations set forth requirements for the privacy and security of "protected health information" ("PHI"). Bioxtreme Ltd. ("Bioxtreme") performs certain services involving the use, disclosure access or storage of PHI from "covered entities" or their business associates. As such, we are a HIPAA-regulated "business associate" subject to HIPAA's privacy, security and breach reporting requirements, among others. Bioxtreme is committed to maintaining compliance with applicable HIPAA requirements and has implemented policies, procedures, and safeguards designed to protect Protected Health Information in accordance with HIPAA.

Privacy

Bioxtreme maintains written policies and procedures required by HIPAA's Privacy Rule to protect PHI from any use, disclosure or access prohibited by law. We train our workforce regarding these policies and procedures, and we monitor, audit, and enforce compliance with HIPAA.

We use, disclose and access PHI only to the extent necessary to provide our services to covered entities and only as permitted by our written business associate agreements, unless otherwise required by law. We limit our use, disclosure and access to PHI to that which is minimally necessary to provide our services. Bioxtreme does not extract or download patient data for device evaluation or product development. Any system logs or performance metrics collected during service are strictly technical in nature and contain no patient-identifiable information.

Security

Bioxtreme has implemented administrative, physical, and technical safeguards to protect the privacy, confidentiality, integrity and availability of PHI. This means Bioxtreme maintains policies and procedures to: implement and maintain adequate security measures; protect information systems and related buildings and equipment; and adequately control access to PHI. We also ensure that any agent or subcontractor engaged in supporting our technical services, who may have incidental access to systems containing PHI, agrees to implement similar safeguards to protect it. Bioxtreme conducts regular risk analyses intended to evaluate and address risks to PHI, and we regularly update our policies and procedures.

Specifically, we have taken the following steps to protect the confidentiality, integrity and availability of PHI:

- Designated a security officer responsible for overseeing the development and implementation of all HIPAA security compliance measures;

- Implemented security awareness and training programs for all members of our workforce;
- Perform regular evaluations of environmental or operational changes that may affect the security of electronic PHI;
- Implemented policies and procedures to:
  - prevent, detect, contain and correct security violations;
  - address security incidents;
  - respond to an emergency, system failure or natural disaster;
  - limit physical access to electronic information systems and physical facilities;
  - manage and secure the workstations and software access rights of our workforce to ensure technicians only utilize connection tools and system privileges when expressly authorized for device maintenance;
  - govern the receipt and removal of hardware and electronic media that contain electronic PHI maintain strict policies governing the receipt, tracking, and secure return shipment of customer hardware sent to our facility for upgrades or repairs, ensuring the physical protection of the device while any electronic PHI remains stored on the system; and
  - record, authenticate and review all remote connection logs and workstation activity utilized during technical service sessions to monitor access and protect against any unauthorized interaction with the supported systems

Breach Notification

We report any breach of unsecured protected health information to covered entities in accordance with HIPAA and our business associate agreements. Additionally, we take steps to mitigate, to the fullest extent practicable, any harmful effect known to Bioxtreme of any use or disclosure of PHI by in violation of HIPAA.