

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION					
DISTRICT ADDRESS AND PHONE NUMBER 109 Holton Street Winchester, MA 01890 (781) 587-7500 Fax: (781) 587-7556		DATE(S) OF INSPECTION 2/3/2026-2/9/2026* FBI NUMBER 3010331770			
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Ashkan Vaziri , Ashkan Vaziri; CEO/Owner					
FIRM NAME BioSensics LLC		STREET ADDRESS 57 Chapel St Ste 200			
CITY, STATE, ZIP CODE, COUNTRY Newton, MA 02458-1080		TYPE ESTABLISHMENT INSPECTED Manufacturer			
This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above. <i>The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.</i>					
DURING AN INSPECTION OF YOUR FIRM I OBSERVED: OBSERVATION 1 Design and development procedures were not adequately documented. Specifically, your firm was unable to provide information required by your firm's design control procedure BS-02-0025 "Product Development & Design Controls" Version 3, regarding the LEGSys system, a Class II exempt wireless wearable system intended for measuring spatiotemporal parameters of gait and assessing fall risk in patients aged 70 and older. A. Your firm was unable to provide a Design and Development Plan for the LEGSys device. Section 6.2.2 of procedure BS-02-0025 requires that "The Project Manager shall create a DDP at the start of the project" and Section 6.2.1 lists the Design Development Plan as a Phase 1 deliverable. C. Your firm was unable to provide records of design and development reviews for the LEGSys device. Section 6.1.1 of procedure states, "A design review shall be conducted at the completion of each phase" and Section 6.1.3 requires that meeting minutes be recorded using FM-0025-A and FM-0025-B templates. Your firm could not provide records of design reviews conducted at the completion of Phase 1, Phase 2, Phase 3, or Phase 4 for the LEGSys device.					
OBSERVATION 2					
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Corrective action was not adequately taken to eliminate the cause of nonconformities in order to prevent recurrence. Specifically, your firm failed to initiate corrective action for recurring LEGSys connectivity failures despite documented evidence of trending nonconformities. Your complaint records document recurring connectivity failures including CF-21 dated October 25, 2023, where LEGSys System BDP-105 would not deploy because sensors would not connect to the tablet, and CF-27 dated February 6, 2024, which explicitly states "A known issue (as reported in CF-21) occurred again at the JHU site. System BDP-108 would not deploy as the paired LEGSys sensors would not connect to the system." Both complaints identified the same root cause of incorrect MAC address codes preventing sensor connection. CF-100 dated January 14, 2026, documents the same connectivity issue where LEGSys sensors paired but would not connect for exercise initiation. Your firm's complaint management procedure BS-02-0007 Version 7, Section 6.4.4, states "If a trend in complaints is identified, then a CAPA may be opened," yet no corrective action was initiated despite your own documentation acknowledging this as a "known issue" that "occurred again."					
OBSERVATION 3 Product which does not conform to product requirements was not adequately identified and controlled to prevent its unintended use or delivery. Specifically, during the inspection of the firm's incoming inspection and storage area, two unlabeled boxes containing nonconforming product were observed, one stored on a shelf adjacent to boxes labeled as accepted product, and a second stored on top of a metal cabinet. Neither of these were identified as rejected with a (b) (4) or in an identified quarantined area, as is required by Section 6.11.5 of your firm's BS-02-0005 Nonconformances, Version 4 procedures, as well as Section 5.4.2 of BS-02-0020 Preservation of Product, Version 4.					
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2/03/2026(Tue), 2/04/2026(Wed), 2/05/2026(Thu), 2/06/2026(Fri), 2/09/2026(Mon)			
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Annotations to Observations Observation 1: Promised to correct Observation 2: Promised to correct Observation 3: Promised to correct			
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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."