Manufacturer report: Injury

[redacted]

reporter occupation:
MAUDE link: XXXXXXXXXXXXXXXXXXXXXX

dates

Report Date: [redacted]
Event Date: [redacted]
Mfr Rec'd Date: [redacted]
FDA Rec'd Date: [redacted]
Date Added: [redacted]
Date Changed: [redacted]

device

- **product code:** OYC
- **device name:** Pump, Infusion, Insulin, To Be Used With Invasive Glucose Sensor
- **brand:** [redacted]
- **generic:** [redacted]
- **operator:** 0LP LAY USER/PATIENT
- **model #:** [redacted]
- **catalog #:** [redacted]
- **lot #:**
- **other ID #:**
- **evaluated by manufacturer:** N
- **available:** R
- **expires:**
- **PMA/510K #:**

description

IT WAS REPORTED VIA PHONE CALL THAT INSULIN PUMP EXPERIENCED DISPLAY ANOMALY. IT WAS REPORTED THAT THERE WAS MISSING SEGMENTS ON DISPLAY SCREEN. CUSTOMER'S BLOOD GLUCOSE WAS BETWEEN 400 MG/DL AND 500 MG/DL. CALLER WAS ADVISED THAT INSULIN PUMP WOULD NEED TO BE REPLACED.

other elements

- mdr-report-key: [redacted]
- report-number: [redacted]
- manufacturer-link-flag-: Y
- adverse-event-flag: Y
- product-problem-flag: N
- date-report: [redacted]
- date-of-event: [redacted]
- reprocessed-and-reused-flag: N

- date-manufacturer-received: [redacted]
- single-use-flag: N
- previous-use-code: U
- date-added: [redacted]
- date-changed: [redacted]
- event-type: IN
- event-type-description: Injury
- report-source-code: M
- report-source-description: Manufacturer report
- report-to-fda: *
- report-to-fda-description: No answer provided
- event-location: I
- name: Medtronic
- original-name: [redacted]
- street-1: [redacted]
- street-2: [redacted]
- city: [redacted]
- state-code: [redacted]
- zip-code: [redacted]
- zip-code-ext: [redacted]
- country-code: [redacted]
- postal-code: [redacted]
- text: CURRENTLY IT IS UNKNOWN WHETHER OR NOT THE DEVICE MAY HAVE CAUSED OR CONTRIBUTED TO THE EVENT. THE DEVICE HAS BEEN RETURNED, BUT NOT YET EVALUATED. FURTHER INFORMATION WILL FOLLOW ONCE THE ANALYSIS HAS BEEN COMPLETED. NO CONCLUSION CAN BE DRAWN AT THIS TIME.
- text: IT WAS REPORTED VIA PHONE CALL THAT INSULIN PUMP EXPERIENCED DISPLAY ANOMALY. IT WAS REPORTED THAT THERE WAS MISSING SEGMENTS ON DISPLAY SCREEN. CUSTOMER'S BLOOD GLUCOSE WAS BETWEEN 400 MG/DL AND 500 MG/DL. CALLER WAS ADVISED THAT INSULIN PUMP WOULD NEED TO BE REPLACED.
- device-sequence-no: 1.0
- date-received: [redacted]
- brand-name: [redacted]
- generic-name: [redacted]
- model-number: [redacted]
- catalog-number: [redacted]
- device-availability: R
- date-returned-to-manufacturer: [redacted]
- device-evaluated-by-manufactur: N
- device-operator: 0LP
- device-operator-description: LAY USER/PATIENT
- device-report-product-code: OYC
- device-name: Pump, Infusion, Insulin, To Be Used With Invasive Glucose Sensor
- review-panel-code: CH
- review-panel-description: Clinical Chemistry
- device-class-code: 3
- device-class-description: Devices subject to General Controls, Special Controls, and Premarket Clearance
- third-party-review-eligible-code: N
- third-party-review-eligible-description: Not Eligible for Accredited Persons Program
- submission-type-code: 2
- submission-type-description: PMA
- patient-sequence-number: 1

- date-received: [redacted]
- sequence-number-outcome: 8.