A MAUDE Reports for product code "MRN" between 10/01/2009 and 11/30/2011								
WP Heim on November 21, 2015								
ps://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/results.cfm								
rted by Event Date (column G)								Note: report number MW1042540 omitted because it is clearly an error (reports on GENZYME SEPRA MESH Hernia repair)
Web Address	**Report Number**	**Manufacturer**	**Brand Name**	**Date Report Received**	**Product Code**	**Event Date**	**Event Type**	**Event Text**
p://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?lrfoi__id=606433	606433	DATEX-OHMEDA	INOVENT	5/13/2005	MRN	3/16/2005	Malfunction	Event Description: INOVENT WAS DISPLAYING "WEAK NO CELL" IN DISPLAY WINDOW. A NEW CELL WAS INSTALLED; AS PER MANUFACTURER RECOMMENDATIONS. THE MACHINE ALARMED DELIVERY AND FAILURE SHUT DOWN. AN ATTEMPTED RESTART AND PURGE WERE NOT SUCCESSFUL. SAME DISPLAY OCCURRED. THE PATIENT WAS DECOMPENSATING; BAGGED AND THE ENTIRE MACHINE WAS CHANGED OUT. THE MACHINE WAS TAKEN OUT OF SERVICE AND RETURNED TO THE RENTAL COMPANY.
p://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?lrfoi__id=606433	606433	DATEX-OHMEDA	INOVENT	5/13/2005	MRN	3/16/2005	Malfunction	Event Description: INOVENT WAS DISPLAYING "WEAK NO CELL" IN DISPLAY WINDOW. A NEW CELL WAS INSTALLED; AS PER MANUFACTURER RECOMMENDATIONS. THE MACHINE ALARMED DELIVERY AND FAILURE SHUT DOWN. AN ATTEMPTED RESTART AND PURGE WERE NOT SUCCESSFUL. SAME DISPLAY OCCURRED. THE PATIENT WAS DECOMPENSATING; BAGGED AND THE ENTIRE MACHINE WAS CHANGED OUT. THE MACHINE WAS TAKEN OUT OF SERVICE AND RETURNED TO THE RENTAL COMPANY.
p://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?lrfoi__id=889138	2112667-2006-00056	GE HEALTHCARE	INOVENT	9/29/2006	MRN	4/1/2006	Malfunction	Event Description: ACCORDING TO THE SUSPECT ADVERSE EVENT REACTION REPORT RECEIVED FROM INOT; "A NURSE WAS CHANGING OVER AN EMPTY INOMAX CYLINDER FOR A NEW ONE WHILE ON A PATIENT. ANOTHER STAFF MEMBER WAS READING THE INSTRUCTIONS. ON TURNING THE NEW CYLINDER ON; IT SOUNDED LIKE A HISS WHICH WAS THOUGHT TO BE A LOW LEVEL LEAK. THE NURSE WAS ABOUT TO INVESTIGATE FURTHER WHEN A TORRENTIAL LEAK OCCURRED WITH A REPORTED PROMINENT SMELL OF NITRIC OXIDE GAS. THE CYLINDER WAS TURNED OFF AND THE NURSE LEFT THE ROOM. ABOUT ONE HOUR AFTER THE INCIDENT; THE NURSE WAS SEEN IN A&E DEPT. FOR COMPLAINTS OF TIGHTENING IN THE CHEST AND PAIN SIMILAR TO BRONCHITIS. HE RECEIVED TREATMENT WITH O2 AND WAS HOSPITALIZED OVERNIGHT. THE OTHER TWO STAFF MEMBERS PRESENT DURING THE EVENT ALSO DEVELOPED CHEST TIGHTNESS AND WERE ATTENDED TO IN THE A&E DEPT. BUT RETURNED STRAIGHT TO DUTY WITH NO FURTHER SIDE EFFECTS. FOLLOWING DISCHARGE IN 2006; THE NURSE HAS DEVELOPED FOUR EPISODES OF SUDDEN CHEST TIGHTENING AND DIFFICULTY BREATHING. DURING A FOLLOW-UP VISIT AT THE HOSPITAL; THE DOCTOR THOUGHT THE EVENTS MIGHT CONTINUE FOR THE NEXT 3 WEEKS DUE TO AN INHALATION INJURY. THE NURSE HAS REPORTED BREATHING DIFFICULTIES ONCE PER WEEK AT THE TIME OF THE REPORT WITH HOPE THAT THEY WILL RESOLVE COMPLETELY. THE SUSPECT ADVERSE EVENT REACTION REPORT STATES THE EVENT INVOLVED A NURSE AND TWO STAFF MEMBERS. THIS MEDWATCH REPORT WILL REPRESENT THE FIRST STAFF MEMBER. Manufacturer Narrative: INVESTIGATION/CONCLUSION: NO PARTS WERE RETURNED TO GE HEALTHCARE FOR INVESTIGATION. ACCORDING TO THE SUSPECT ADVERSE EVENT REACTION REPORT; "THE FAULT SEEMS TO BE THE RUBBER O-RING ON THE TIP OF THE HIGH PRESSURE ASSEMBLY; CAUSING A BAD PRESSURE SEAL PER THE HOSPITAL REPORTER. THE INOVENT; CYLINDER; AND O-RING CONCERNED WERE REMOVED FROM THE HOSPITAL FOR INVESTIGATION. ALL O-RINGS PREVIOUSLY SENT TO THE HOSPITAL WERE REPLACED IN CASE OF A BATCH PROBLEM. THE HOSPITAL STAFF RECEIVED FURTHER TRAINING ON EXPOSURE AND SAFE LEVELS OF NO/NO2 IN THE ATMOSPHERE AND CYLINDER MANAGEMENT." THE DISTRIBUTOR RETURNED THE O-RING TO THE VENDOR FOR INVESTIGATION. THE VENDOR CONFIRMED THE O-RING WAS DAMAGED. THE INOVENT OPERATION & MAINTENANCE MANUAL INDICATES THE CORRECT PROCEDURE TO CONNECT AN NO CYLINDER TO AN INOVENT; HOW TO CHECK FOR LEAKS; AND THE APPROPRIATE ACTION TO TAKE IF A LEAK IS DETECTED.
p://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?lrfoi__id=880307	2112667-2006-00057	GE HEALTHCARE	INOVENT	9/29/2006	MRN	4/1/2006	Malfunction	Event Description: ACCORDING TO THE SUSPECT ADVERSE EVENT REACTION REPORT RECEIVED FROM INOT "A NURSE WAS CHANGING OVER AN EMPTY INOMAX CYLINDER FOR A NEW ONE WHILE ON A PT. ANOTHER STAFF MEMBER WAS READING THE INSTRUCTIONS. ON TURNING THE NEW CYLINDER ON; IT SOUNDED LIKE A HISS WHICH WAS THOUGHT TO BE A LOW LEVEL LEAK. THE NURSE WAS ABOUT TO INVESTIGATE FURTHER WHEN A TORRENTIAL LEAK OCCURRED WITH A REPORTED PROMINENT SMELL OF NITRIC OXIDE GAS. THE CYLINDER WAS TURNED OFF AND THE NURSE LEFT THE ROOM. ABOUT ONE HOUR AFTER THE INCIDENT; THE NURSE WAS SEEN IN A&E DEPT. FOR COMPLAINTS OF TIGHTENING IN THE CHEST AND PAIN SIMILAR TO BRONCHITIS. HE RECEIVED TREATMENT WITH O2 AND WAS HOSPITALIZED OVERNIGHT. THE OTHER TWO STAFF MEMBERS PRESENT DURING THE EVENT ALSO DEVELOPED CHEST TIGHTNESS AND WERE ATTENDED TO IN THE A&E DEPT. BUT RETURNED STRAIGHT TO DUTY WITH NO FURTHER SIDE EFFECTS. FOLLOWING DISCHARGE ON THE DAY AFTER EVENT DAY; THE NURSE HAS DEVELOPED FOUR EPISODES OF SUDDEN CHEST TIGHTENING AND DIFFICULTY BREATHING. DURING A FOLLOW-UP VISIT AT THE HOSPITAL; THE DOCTOR THOUGHT THE EVENTS MIGHT CONTINUE FOR THE NEXT 3 WEEKS DUE TO AN INHALATION INJURY. THE NURSE HAS REPORTED BREATHING DIFFICULTIES ONCE PER WEEK AT THE TIME OF THE REPORT WITH HOPE THAT THEY WILL RESOLVE COMPLETELY." THE SUSPECT ADVERSE EVENT REACTION REPORT STATES THE EVENT INVOLVED A NURSE AND TWO STAFF MEMBERS. THIS MEDWATCH REPORT WILL REPRESENT THE SECOND STAFF MEMBER. Manufacturer Narrative: INVESTIGATION/CONCLUSION: NO PARTS WERE RETURNED TO GE HEALTHCARE FOR INVESTIGATION. ACCORDING TO THE SUSPECT ADVERSE EVENT REACTION REPORT; "THE FAULT SEEMS TO BE THE RUBBER O-RING ON THE TIP OF THE HIGH PRESSURE ASSEMBLY; CAUSING A BAD PRESSURE SEAL PER THE HOSPITAL REPORTER. THE INOVENT; CYLINDER; AND O-RING CONCERNED WERE REMOVED FROM THE HOSPITAL FOR INVESTIGATION. ALL O-RINGS PREVIOUSLY SENT TO THE HOSPITAL WERE REPLACED IN CASE OF A BATCH PROBLEM. THE HOSPITAL STAFF RECEIVED FURTHER TRAINING ON EXPOSURE AND SAFE LEVELS OF NO/NO2 IN THE ATMOSPHERE AND CYLINDER MANAGEMENT." THE VENDOR CONFIRMED THE O-RING WAS DAMAGED. THE INOVENT OPERATION & MAINTENANCE MANUAL INDICATES THE CORRECT PROCEDURE TO CONNECT AN NO CYLINDER TO AN INOVENT; HOW TO CHECK FOR LEAKS; AND THE APPROPRIATE ACTION TO TAKE IF A LEAK IS DETECTED.

Web Address	Report Number	Manufacturer	Brand Name	Date Report Received	Product Code	Event Date	Event Type	Event Text
p://www.accessdata.fda.gov/scripdrh/cfdocs/cfMAUDE/detail.cfm?lrfoi__id=766265	2112667-2006-00055	GE HEATHCARE	INOVENT	9/29/2006	MRN	4/1/2006	Injury	Event Description: ACCORDING THE SUSPECT ADVERSE EVENT REACTION REPORT RECEIVED FROM INOT; "A NURSE WAS CHANGING OVER AN EMPTY INOMAX CYLINDER FOR A NEW ONE WHILE ON A PATIENT. ANOTHER STAFF MEMBER WAS READING THE INSTRUCTIONS. ON TURNING THE NEW CYLINDER ON; IT SOUNDED LIKE A HISS WHICH WAS THOUGHT TO BE A LOW LEVEL LEAK. THE NURSE WAS ABOUT TO INVESTIGATE FURTHER WHEN A TORRENTIAL LEAK OCCURRED WITH A REPORTED PROMINENT SMELL OF NITRIC OXIDE GAS. THE CYLINDER WAS TURNED OFF AND THE NURSE LEFT THE ROOM. ABOUT ONE HOUR AFTER THE INCIDENT; THE NURSE WAS SEEN IN A&E DEPT. FOR COMPLAINTS OF TIGHTENING IN THE CHEST AND PAIN SIMILAR TO BRONCHITIS. HE RECEIVED TREATMENT WITH O2 AND WAS HOSPITALIZED OVERNIGHT. THE OTHER TWO STAFF MEMBERS PRESENT DURING THE EVENT ALSO DEVELOPED CHEST TIGHTNESS AND WERE ATTENDED TO IN THE A&E DEPT. BUT RETURNED STRAIGHT TO DUTY WITH NO FURTHER SIDE EFFECTS. FOLLOWING DISCHARGE IN 2006; THE NURSE HAS DEVELOPED FOUR EPISODES OF SUDDEN CHEST TIGHTENING AND DIFFICULTY BREATHING. DURING A FOLLOW-UP VISIT AT THE HOSPITAL; THE DOCTOR THOUGHT THE EVENTS MIGHT CONTINUE FOR THE NEXT 3 WEEKS DUE TO AN INHALATION INJURY. THE NURSE HAS REPORTED BREATHING DIFFICULTIES ONCE PER WEEK AT THE TIME OF THE REPORT WITH HOPE THAT THEY WILL RESOLVE COMPLETELY." THE SUSPECT ADVERSE EVENT REACTION REPORT STATES THE EVENT INVOLVED A NURSE AND TWO STAFF MEMBERS. THIS MEDWATCH REPORT WILL REPRESENT THE NURSE INVOLVED IN THE ALLEGED EVENT. Manufacturer Narrative: INVESTIGATION/CONCLUSION: NO PARTS WERE RETURNED TO GE HEALTHCARE FOR INVESTIGATION. ACCORDING TO THE SUSPECT ADVERSE EVENT REACTION REPORT; "THE FAULT SEEMS TO BE THE RUBBER O-RING ON THE TIP OF THE HIGH PRESSURE ASSEMBLY; CAUSING A BAD PRESSURE SEAL PER THE HOSPITAL REPORTER. THE INOVENT; CYLINDER; AND O-RING CONCERNED WERE REMOVED FROM THE HOSPITAL FOR INVESTIGATION. ALL O-RINGS PREVIOUSLY SENT TO THE HOSPITAL WERE REPLACED IN CASE OF A BATCH PROBLEM. THE HOSPITAL STAFF RECEIVED FURTHER TRAINING ON EXPOSURE AND SAFE LEVELS OF NO/NO2 IN THE ATMOSPHERE AND CYLINDER MANAGEMENT." THE DISTRIBUTOR RETURNED THE O-RING TO THE VENDOR FOR INVESTIGATION. THE VENDOR CONFIRMED THE O-RING WAS DAMAGED. THE INOVENT OPERATION & MAINTENANCE MANUAL INDICATES THE CORRECT PROCEDURE TO CONNECT AN NO CYLINDER TO AN INOVENT; HOW TO CHECK FOR LEAKS; AND THE APPROPRIATE ACTION TO TAKE IF A LEAK IS DETECTED.
p://www.accessdata.fda.gov/scripdrh/cfdocs/cfMAUDE/detail.cfm?lrfoi__id=744085	2112667-2006-00029	GE HEALTHCARE	INOVENT	8/3/2006	MRN	6/17/2006	Death	Event Description: PER MEDWATCH REPORT SUBMITTED BY DISTRIBUTOR; A PATIENT WAS BEING TREATED WITH INOMAX. THE CYLINDER WAS REPORTEDLY LEAKING AND HAD TO BE CHANGED. IN ATTEMPTING TO CHANGE THE INOMAX CYLINDER; IT WAS REPORTEDLY NOTED THAT THE KEL F TIP WAS MISSING FROM THE SECOND REGULATOR AND A NEW CYLINDER COULD NOT BE CONNECTED. A SECOND INOVENT UNIT WAS BROUGHT TO THE BEDSIDE. THERAPY WAS STOPPED WHILE THE INOVENT WAS REPLACED. DURING THIS TIME; THE PATIENT'S HEART RATE; OXYGEN SATURATION; AND BLOOD PRESSURE REPORTEDLY DECREASED. THE STAFF REPORTEDLY DID NOT USE THE MANUAL BACK UP SYSTEM TO MAINTAIN THE FLOW OF INOMAX TO THE PATIENT. ONCE THERAPY WAS RESTARTED; THE PATIENT'S VITAL SIGNS RECOVERED. WHEN THE REGULATOR WAS REMOVED FROM THE EMPTY CYLINDER; THE KEL F TIP REPORTEDLY REMAINED IN THE VALVE. THE PATIENT REPORTEDLY DIED 4 DAYS LATER. ACCORDING TO DISTRIBUTOR; THE DEATH WAS REPORTEDLY NOT RELATED TO THE INTERRUPTED THERAPY TO THE PATIENT. Manufacturer Narrative: INVESTIGATION/CONCLUSION: SAMPLES WERE RETURNED TO THE MANUFACTURER FOR INVESTIGATION. THE KEL-F TIP USED DURING THE ALLEGED EVENT WAS VISUALLY INSPECTED AND WAS NOTED TO BE IN GOOD CONDITION WITH A MINOR SCRATCH ON THE SEALING FACE. THE 'LEGS' OF THE SEAL WERE SLIGHTLY DAMAGED; AND THE DAMAGE APPEARS TO BE DUE TO THE INTERNAL THREADS CUTTING INTO THEM WHEN IT WAS REMOVED FROM THE FITTING. THE TIP WAS REASSEMBLED TO ONE OF THE REGULATOR ASSEMBLIES ON THE CART AND THEN LEAK TESTED. NO LEAKS WERE OBSERVED. A TORQUE TEST WAS SUBSEQUENTLY PERFORMED ON THE FITTING TO VERIFY IF IT WAS POSSIBLE FOR THE KEL-F TIP TO BECOME DISLODGED AND JAM IN THE CYLINDER CONNECTOR AS REPORTED. TESTING DID NOT DISLODGE THE KEL-F TIP. HOWEVER; USING A LARGE WRENCH ON THE FLATS OF THE HAND WHEEL AND APPLYING AN EXTREME TORQUE; IT WAS POSSIBLE TO JAM THE TIP IN THE CYLINDER CONNECTOR AND DISLODGE THE TIP FROM THE END OF THE FITTING AS REPORTED. THE INOVENT OPERATION AND MAINTENACE MANUAL WARNS THE USER TO VERIFY THAT THE HOSE TIP IS IN PLACE AND IS NOT DAMAGED BEFORE CONNECTING TO THE CYLINDER; AND NOT TO OVER-TIGHTEN THE FITTING. THE MANUAL ALSO INSTRUCTS THE USER TO FOLLOW THE PRE-USE PROCEDURE BEFORE THE START OF EACH PATIENT; AND TO PERFORM A HIGH-PRESSURE LEAK TEST AT LEAST ONCE A MONTH.
p://www.accessdata.fda.gov/scripdrh/cfdocs/cfMAUDE/detail.cfm?lrfoi__id=779466	2112667-2006-00075	DATEX-OHMEDA	INOVENT	11/2/2006	MRN	9/10/2006	Other	Event Description: ACCORDING TO THE DISTRIBUTOR; IT WAS NOTED AT THE FACILITY THAT A PATIENT WAS BEING ADMINISTERED NITRIC OXIDE VIA A FLOWMETER ON THE WALL; WHILE SPONTANEOUSLY BREATHING INTO A FACE MASK THAT ENTIRELY COVERED THE PATIENT'S HEAD. THE INOVENT WAS SET AT 40PPM. ACCORDING TO THE DISTRIBUTOR; THE CUSTOMER IS USING THE DEVICE IN AN UNAPPROVED MANNER. THE DISTRIBUTOR INFORMED THE CUSTOMER OF THE IMPROPER USAGE OF THE DEVICE; HOWEVER; THE CUSTOMER CHOSE TO CONTINUE USE IN THE UNAPPROVED MANNER. PROPER SETUP OF THE UNIT IS DESCRIBED IN THE INOVENT OPERATION AND MAINTENANCE MANUAL; AND A DIAGRAM DEPICTING PROPER SETUP IS AFFIXED TO THE SIDE OF THE INOVENT. Manufacturer Narrative: H6: CUSTOMER IS USING THE DEVICE IN AN UNAPPROVED MANNER.
p://www.accessdata.fda.gov/scripdrh/cfdocs/cfMAUDE/detail.cfm?lrfoi__id=809142	2112667-2007-00002	DATEX-OHMEDA	INOVENT	1/16/2007	MRN	12/13/2006	Malfunction	Event Description: CUSTOMER REPORTED THE UNIT HAD AN O-RING FAILURE. PATIENT REPORTEDLY DESATURATED. HOSP STAFF SWITCHED TO THE BACKUP SYSTEM AND STARTED MANUAL VENTILATION WITH NITRIC OXIDE. HOSP STAFF REPORTEDLY HEARD A LEAK; AND THE UNIT WAS EXCHANGED. SOME OF THE STAFF IN THE ROOM REPORTEDLY BECAME DIZZY FROM THE SMELL OF NITRIC OXIDE. THERE WAS NO REPORTED INJURY WITH PATIENT OR STAFF. INVESTIGATION/CONCLUSION: NO PARTS WERE RETURNED TO GE HEALTHCARE FOR INVESTIGATION AS THE CUSTOMER REPORTEDLY DISCARDED THE O-RING. WITHOUT THE SAMPLE FOR INVESTIGATION; THE MANUFACTURER AND/OR EXACT ROOT CAUSE OF THE REPORTED COMPLAINT CANNOT BE DETERMINED. THE REPORTER'S MAINTENANCE MANUAL INDICATES THE CORRECT PROCEDURE TO CONNECT AN NO CYLINDER; HOW TO CHECK FOR LEAKS; AND THE APPROPRIATE ACTION TO TAKE IF A LEAK IS DETECTED. Manufacturer Narrative: NO PARTS WERE RETURNED TO GE HEALTHCARE FOR INVESTIGATION AS THE CUSTOMER REPORTEDLY DISCARDED THE O-RING. WITHOUT THE SAMPLE FOR INVESTIGATION; THE MANUFACTURER AND/OR EXACT ROOT CAUSE OF THE REPORTED COMPLAINT CANNOT BE DETERMINED.
p://www.accessdata.fda.gov/scripdrh/cfdocs/cfMAUDE/detail.cfm?lrfoi__id=832241	832241	PULMONOX MEDICAL INC	AERONOX	3/7/2007	MRN	2/13/2007	Malfunction	Event Description: READINGS FLUCTUATING ON DISPLAY 0-70; DISPLAY THEN READS 666666 PER TRANSPORT NURSE.

Web Address	Report Number	Manufacturer	Brand Name	Date Report Received	Product Code	Event Date	Event Type	Event Text
p://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?lrfoi__id=981925	2112667-2008-00003	DATEX-OHMEDA	INOVENT	1/22/2008	MRN	12/21/2007	Death	Event Description: PER MEDWATCH REPORT FROM IKARIA: "A FEMALE INFANT WAS BORN IN 2007 WITH A WEIGHT OF 3.6 KILOGRAMS. SHE WAS DELIVERED VIA CESAREAN SECTION DUE TO FETAL DISTRESS. SHE REQUIRED TRANSFER TO ANOTHER FACILITY FOR AORTIC ARCH RECONSTRUCTION AND A NORWOOD PROCEDURE. ON SEVENTEEN DAYS LATER; THE INFANT WAS DISCONTINUED FROM EXTRA CORPOREAL MEMBRANE OXYGENATION (ECMO) AND PLACED ON INOMAX AT 20 PARTS PER MILLION FOR THE TREATMENT OF PULMONARY HYPERTENSION. ON THE NEXT DAY; THE GAS OUTLET LINE FROM THE JET VENTILATOR BECAME DISCONNECTED. THE INFANT DEVELOPED BRACHYCARDIA. INOVENT HAD A HIGH NITRIC OXIDE LEVEL ALARM (OVER 24 PARTS PER MILLION AND RISING) AND WAS PLACED ON MANUAL STANDBY. HER SPO2 WAS BELOW 60%; HEART RATE AND BLOOD PRESSURE DECREASED. SHE WAS HAND BAGGED WITH INOMAX AND 100% OXYGEN. THE STAFF FOUND THE TUBING LEADING TO THE INJECTOR MODULE SATURATED WITH WATER. THE STAFF DID A LOW RANGE PURGE OF THE LINE AND A CALIBRATION. THE INFANT EXPERIENCED HYPOTENSION RESULTING IN CARDIOPULMONARY ARREST. RESUSCITATION EFFORTS WERE UNSUCCESSFUL. THE INFANT EXPIRED ON THE SAME DAY." GE HEALTHCARE'S INVESTIGATION INTO THE REPORTED OCCURRENCE IS STILL ONGOING. A FOLLOW-UP REPORT WILL BE ISSUED WHEN THE INVESTIGATION HAS BEEN COMPLETED.
p://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?lrfoi__id=989023	2112667-2008-00006	DATEX-OHMEDA	INOVENT	1/31/2008	MRN	12/28/2007	Malfunction	Event Description: A FEMALE INFANT WAS HOSPITALIZED. SHE WAS RECEIVING INOTHERAPY FOR SEVEN DAYS AND WAS NOT EXPECTED TO SURVIVE. IN 2007 INOVENT EXPERIENCED AN ELECTRONIC FAILURE WHILE ON THE INFANT. FOLLOWING TH INOVENT MACHINE FAILURE; THE INFANT WAS MANUALLY BAGGED WHILE THE INOVENT WAS INITIALLY RE-STARTED AND THEN REPLACED WITH A BACK-UP INOVENT. IT WAS NOTED THAT THE INFANT EXPERIENCED AN EPISODE OF BRADYCARDIA DURING THIS PERIOD. THE INFANT SUBSEQUENTLY EXPIRED THE FOLLOWING DAY WHICH WAS EXPECTED; BUT MAY OR MAY NOT HAVE BEEN HASTENED BY THE EVENT. THE REPORTER DEEMED THE EVENT POSSIBLY RELATED AS THE PT'S CONDITION CHANGED DUE TO THE BRADYCARDIA." GE HEALTHCARE'S INVESTIGATION INTO THE REPORTED OCCURRENCE IS STILL ONGOING. A F/U REPORT WILL BE ISSUED WHEN THE INVESTIGATION HAS BEEN COMPLETED.
p://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?lrfoi__id=981940	2112667-2008-00004	DATEX-OHMEDA	INOVENT	1/22/2008	MRN	12/31/2007	Death	Event Description: ACCORDING TO THE DISTRIBUTOR; PT WAS HOSPITALIZED AWAITING A LUNG TRANSPLANT. PT WAS REPORTEDLY PLACED ON INOMAX AT 20 PPM FOR THE TREATMENT OF PULMONARY HYPERTENSION. THE UNIT REPORTEDLY HAD A FAILURE MESSAGE. THE NURSE REPORTEDLY HAND BAGGED THE PT DUE TO A SIGNIFICANT DECREASE IN OXYGEN SATURATION. HER PULMONARY ARTERY PRESSURE WAS 90/39. THE PT REPORTEDLY DIED. GE HEALTHCARE'S INVESTIGATION INTO THE REPORTED OCCURRENCE IS STILL ONGOING. A FOLLOW-UP REPORT WILL BE ISSUED WHEN THE INVESTIGATION HAS BEEN COMPLETED.
p://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?lrfoi__id=1178783	2112667-2008-00011	DATEX-OHMEDA	INOVENT	3/11/2008	MRN	2/1/2008	Malfunction	Event Description: ACCORDING TO DISTRIBUTOR FILED MEDWATCH REPORT; "A (B) (6) FEMALE; STATUS POST LUNG TRANSPLANT; RECEIVED INOMAX AT 20 PPM ON (B) (6); 2008 FOR THE OFF-LABELED INDICATION OF SEVERE HYPOXEMIA. AT THE START OF INOMAX TREATMENT THE PATIENT'S OXYGEN SATURATION WAS 87%. THE INOVENT ((B) (6)) ALARMED AND THE ERROR "ELECTRONIC DELIVERY SHUTDOWN" DISPLAYED AND THE PATIENT'S OXYGEN SATURATION DECREASED INTO THE 70'S. THE PATENT ARRESTED AND WAS RESUSCITATED USING INOVENT FLOW METER/MANUAL VENTILATION AND THE PATIENT'S PULSE RETURNED AFTER CHEST COMPRESSIONS WERE INITIATED. THE PATIENT WAS PUT ON A NEW INOVENT AND THE PATIENT'S OXYGEN SATURATION RETURNED TO BASELINE (89%). INOMAX THERAPY WAS DISCONTINUED LATER THAT SAME DAY." GE HEALTHCARE'S INVESTIGATION INTO THE REPORTED OCCURRENCE IS STILL ONGOING. A FOLLOW-UP REPORT WILL BE ISSUED WHEN THE INVESTIGATION HAS BEEN COMPLETED.
p://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?lrfoi__id=1327623	1327623	IKARIA	INOVENT	12/23/2008	MRN	2/4/2008	Injury	Event Description: PT ON VENTILATOR IN ICU AT THIS HOSPITAL HAD ORDER TO INITIATE INOTHERAPY IN 2008. EQUIPMENT BROUGHT TO HOSPITAL FROM MANUFACTURER; SETUP AND INSERVICING OF STAFF DONE; DELIVERY OF NITRIC OXIDE WAS TO BE 60 PPM. THE NEXT DAY; ALARM SOUNDED FOR LOW TO NO DELIVERY OF NITRIC OXIDE AS PPM'S FELL BELOW SET PARAMETER. PT MANUALLY BAGGED WHICH DELIVERS 20 PPM. THREE BRIEF EPISODES OF THIS OCCURRED; WITH PATIENT'S O2 SATURATION DROPPING INTO 60'S EACH TIME. MANUFACTURER CONTACTED AND NEW EQUIPMENT DELIVERED. PT EXPIRED THE FOLLOWING DAY OF HER UNDERLYING DISEASE UNRELATED TO THIS EVENT.
p://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?lrfoi__id=1066287	2112667-2008-00023	DATEX-OHMEDA	INOVENT	6/26/2008	MRN	4/29/2008	Injury	Event Description: PER ADVERSE EVENT REPORT SUBMITTED BY DISTRIBUTOR; "A FEMALE WITH A HISTORY OF HIGH PEAK PRESSURE ON MECHANICAL VENTILATION AND DIFFICULTY WITH GAS EXCHANGE WAS HOSPITALIZED. IN 2008; SHE BEGAN 10 PARTS PER MILLION (PPM) OF INO THERAPY FOR PULMONARY HYPERTENSION. ON A WEEK LATER 01:50 HOURS; THE GRAPHIC USER PANEL OF INOVENT FLASHED "ELECTRONIC DELIVERY FAILURE" ON THE SCREEN THEN CHANGED TO A SCREEN WITH TWO ICONS. THE MACHINE THEN ALARMED AND CEASED DELIVERY OF NITRIC OXIDE TO THE PT. WHEN THE DEVICE BECAME INOPERATIVE; THE PT EXPERIENCED IMPAIRED OXYGENATION AND INCREASED BAROTRAUMA. THE OUTCOMES OF THE EVENTS ARE NOT KNOWN. THE REPORT DEEMED THE EVENTS RELATED TO THE USE OF INOTHERAPY. LAB TESTS UNK." GE HEALTHCARE'S INVESTIGATION INTO THE REPORTED OCCURRENCE IS STILL ONGOING. A FOLLOW-UP REPORT WILL BE ISSUED WHEN THE INVESTIGATION HAS BEEN COMPLETED.

Web Address	Report Number	Manufacturer	Brand Name	Date Report Received	Product Code	Event Date	Event Type	Event Text
p://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?rfoi__id=1080074	3004531588-2008-00002	INO THERAPEUTICS LLC/IKARIA	INOMAX DS (DELIVERY SYSTEM)	7/15/2008	MRN	5/30/2008	Other	Event Description: ON (B) (6) 2008; AN ADVERSE EVENT WAS REPORTED VIA A HEALTH CARE PROFESSIONAL. THE ADVERSE EVENT OCCURRED WHEN A HEALTH CARE PROFESSIONAL ENGAGED THE INOMAX DS BACK UP SWITCH WHILE 20 PARTS PER MILLION (PPM) OF INHALED NITRIC OXIDE (INO) WAS STILL BEING DELIVERED TO THE PT VIA INOMAX DS (B) (4). THE INO EXCEEDED 100 PPM AND AS DESIGNED; ALARMED AND CEASED DRUG DELIVERY. THE BACKUP SWITCH WAS TURNED ON IN A MISTAKEN ATTEMPT TO TURN ON FLOW FOR MANUAL BAGGING AND THE ALARMS THAT IMMEDIATELY OCCURRED WERE IGNORED OR MISUNDERSTOOD. AT THE TIME; THERE WAS A LARGE SIGN ATTACHED TO THE FRONT OF THE INOMAX DS DEVICE EXPLAINING HOW TO TURN ON THE GAS FLOW FOR MANUAL VENTILATION. BUT IT WAS NOT OPTIMALLY POSITIONED AND WAS OVERLOOKED. THE REPORTER INDICATED THAT EARLIER THE SAME DAY; THE HEALTH CARE PROFESSIONAL INVOLVED IN THE INCIDENT WAS ASKED BY THE RESPIRATORY THERAPIST IF THEY KNEW HOW TO TURN ON THE FLOW FOR MANUAL VENTILATION. THE HEALTH CARE PROFESSIONAL INDICATED AN UNDERSTANDING OF THE PROCEDURE. DURING THE EVENT; A THERAPIST WAS PAGED AND THE SITUATION WAS CORRECTED. IT WAS REPORTED THE EVENT OCCURRED DUE TO HUMAN ERROR; INCOMPLETE EDUCATION; AND INADEQUATE POSITIONING OF THE SIGNAGE BY THE FACILITY. FOLLOWING THIS EVENT; ADDITIONAL EDUCATIONAL SESSIONS WERE CONDUCTED; THE SIGNAGE POSITIONING WAS MODIFIED BY THE FACILITY; AND THE BACKUP SWITCH WAS INACTIVATED BY USING A THIN RIBBON OF REINFORCED STRAPPING TAPE. THE REPORTER DID NOT THINK THE EVENT WAS SERIOUS. FOLLOW UP INFO WAS RECEIVED ON JUNE 27; 2008; VIA A MEDWATCH REPORT RECEIVED FROM THE FDA THAT WAS SUBMITTED BY THE HOSPITAL. THE PT IS A (B) (6); (B) (6) FEMALE WITH A WEIGHT OF (B) (6). SHE WAS BORN PREMATURE AND HAS A HISTORY OF CHRONIC LUNG DISEASE AND PULMONARY HYPERTENSION. ON (B) (6) 2008; THE PT HAD A SUDDEN DESATURATION (VALVES NOT REPORTED) DUE TO THE ENDOTRACHEAL TUBE BEING UNPLUGGED. WHEN THE NURSE ATTEMPTED TO USE THE BAG VALVE MASK (BVM) FROM THE SYSTEM; IT WOULD NOT INFLATE. THE RESPIRATORY THERAPIST WAS CALLED IMMEDIATELY. THE NURSE TURNED ON THE INOMAX DS BACKUP SWITCH IN AN ATTEMPT TO TROUBLESHOOT THE PROBLEM; APPLIED 100% OXYGEN BAG VALVE MASK (BVM); AND THEN CORRECTED THE SYSTEM. THE NITRIC OXIDE DELIVERY SYSTEM'S SWITCH DISPLAYED A SIGN SAYING; "DO NOT TURN ON". ADDITIONAL INFO ATTACHED TO THE SYSTEM DESCRIBED HOW TO TURN ON THE GAS FLOW MANUALLY; AS DID EDUCATION POSTERS DISPLACED IN THE INTENSIVE CARE UNIT (ICU). THE RESPIRATORY THERAPIST SAID THEY WERE GOING TO CHECK WITH THE NURSE INVOLVED TO SEE IF SHE KNEW HOW TO VENTILATE THE PT MANUALLY. THE NURSE REPLIED YES; BUT SHE OBVIOUSLY DID NOT FULLY UNDERSTAND THE PROCEDURE IN THIS PARTICULAR CASE. THIS WAS AN EXAMPLE OF AN OPERATOR ISSUE ERROR AND NOT A MACHINE ISSUE. Manufacturer Narrative: USE ERROR REPORTED BY USER FOLLOWING THEIR INVESTIGATION AND (B) (6) FOLLOW UP. THEREFORE THE INOMAX DS WAS NOT RETURNED FOR EVAL.
p://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?rfoi__id=1067184	1067184	IKARIA	INOMAX DS	6/19/2008	MRN	5/30/2008	NA	Event Description: THE INOMAX DS HAS A BACKUP SWITCH THAT IS EASILY ACTIVATED OR INACTIVATED. THE PATIENT HAD A SUDDEN DESATURATION DUE TO THE ENDOTRACHEAL TUBE BEING PLUGGED. WHEN THE NURSE ATTEMPTED TO USE THE BVM FROM THE SYSTEM; IT WOULD NOT INFLATE; SO RESPIRATORY THERAPY WAS CALLED IMMEDIATELY. THE NURSE TURNED ON THE BACKUP SWITCH IN AN ATTEMPT TO TROUBLESHOOT THE PROBLEM; HOWEVER; THE PATIENT CONTINUED TO DECOMPENSATE. AT THIS TIME; THE RESPIRATORY THERAPIST ENTERED THE ROOM AND APPLIED 100% O2 BVM; AND THEN CORRECTED THE SYSTEM. THE NITRIC OXIDE DELIVERY SYSTEM'S SWITCH DISPLAYED A SIGN SAYING: DO NOT TURN ON. ADDITIONAL INFORMATION ATTACHED TO SYSTEM DESCRIBED HOW TO TURN ON THE GAS FLOW MANUALLY; AS DID EDUCATION POSTERS DISPLAYED IN ICU. THE RESPIRATORY THERAPIST SAID THEY WERE GOING TO CHECK WITH THE NURSE INVOLVED TO SEE IF SHE KNEW HOW TO VENTILATE THE PATIENT MANUALLY. THE NURSE REPLIED YES; BUT SHE OBVIOUSLY DID NOT FULLY UNDERSTAND THE PROCEDURE IN THIS PARTICULAR CASE. THIS WAS AN EXAMPLE OF AN OPERATOR ISSUE ERROR AND NOT A MACHINE ISSUE.
p://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?rfoi__id=1220574	2112667-2008-00046	DATEX-OHMEDA	INOVENT	11/3/2008	MRN	10/22/2008	Death	Event Description: PER REPORT FROM DISTRIBUTOR: "PATIENT CARE BEING DONE ON BABY - BABY WAS TURNED - JET VENTILATOR PUT INTO STAND-BY MODE. HIGH NO ALARMED. INOVENT WORKED AS INTENDED WHEN 100 PPM REACHED. BABY MANUALLY RESUSCITATED. INOVENT REPLACED. RECALIBRATED NEW INOVENT IN 15 MINUTES. PATIENT BACK ON INOVENT; BUT NEVER FULLY RECOVERED. SHUT DOWN OCCURRED 4 TO 5 HOURS PRIOR TO PATIENT DEATH. AFTER INOVENT SHUT DOWN; BABY DECOMPENSATED AND HR INCREASED; AND WAS MANUALLY RESUSCITATED. PATIENT'S STATUS DETERIORATED AND NEVER RETURNED TO PREVIOUS STATUS. APPROXIMATELY 2 HOURS LATER; BOWEL PERFORATION FIRST NOTICED. PATIENT HAD SURGERY FOR BOWEL PERFORATION; BUT PATIENT'S STATUS NEVER CAME BACK TO BASELINE. PATIENT WENT INTO DIC AND DID NOT RECOVER." GE HEALTHCARE'S INVESTIGATION INTO THE REPORTED OCCURRENCE IS STILL ONGOING. A FOLLOW-UP REPORT WILL BE ISSUED WHEN THE INVESTIGATION HAS BEEN COMPLETED. Manufacturer Narrative: .
p://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?rfoi__id=1456028	2112667-2009-00025	DATEX-OHMEDA	INOVENT	4/28/2009	MRN	1/14/2009	Death	Event Description: PER DISTRIBUTOR MEDWATCH REPORT: "AN ADULT MALE RECEIVED 20 PPM OF INHALED NITRIC OXIDE FOR THE TREATMENT OF PULMONARY HYPERTENSION. IN EARLY 2009; AT 02:30; INOVENT UNIT CCAD00655 ALARMED AND HAD AN ELECTRONIC SHUT DOWN WHILE ON THE PATIENT IN THE OPERATING ROOM. THE PATIENT DECOMPENSATED; HIS OXYGEN SATURATION DECREASED IN THE 60S; AND HIS HEART RATE DECREASED TO 40 BPM. THE ANESTHESIA DID NOT MANUALLY BAG THE PATIENT AND THE EVENTS RESOLVED AFTER THE INOVENT UNIT WAS SWITCHED OUT; AND THE PATIENT CONTINUED TREATMENT. THE REPORTER DEEMED THE EVENTS RELATED TO THE INOVENT FAILURE. APPROX. TWO WEEKS LATER; THE PATIENT EXPIRED FROM AN UNKNOWN CAUSE OF DEATH; AND IT IS UNKNOWN IF AN AUTOPSY WAS PERFORMED." GE HEALTHCARE'S INVESTIGATION INTO THE REPORTED OCCURRENCE IS STILL ONGOING. A FOLLOW-UP REPORT WILL BE ISSUED WHEN THE INVESTIGATION HAS BEEN COMPLETED. Manufacturer Narrative: .

Web Address	Report Number	Manufacturer	Brand Name	Date Report Received	Product Code	Event Date	Event Type	Event Text
p://www.accessdata.fda.gov/scripts/drh/cfdocs/cfMAUDE/detail.cfm?lrfoi__id=1369217	1369217	IKARIA INOTHERAPEUTICS INC	DATEX-OHMEDA INOVENT SYSTEM	4/9/2009	MRN	1/14/2009	Death	Event Description: PT HAD A DIAGNOSIS OF IPF AND ACUTE RESPIRATORY FAILURE. WAS MAINTAINED IN THE ICU INTUBATED; SEDATED AND FULLY SUPPORTED ON A VENTILATOR RECEIVING INHALED NITRIC OXIDE THRU AN INO VENT DELIVERY DEVICE. PT WAS TRANSPORTED FROM ICU TO OR FOR RT. LUNG TRANSPLANT WITHOUT INCIDENT. WHILE PT WAS WAS IN OR RECEIVING NITRIC OXIDE THRU THE INOVENT AND PRIOR TO SURGERY; THERE WAS A FAILURE OF THE INOVENT MACHINE. THE PT SUFFERED AN ARREST; CPR WAS INITIATED; PT GIVEN EPINEPHRINE; AND REGAINED HIS BLOOD PRESSURE. THE INOVENT MACHINE WAS CHANGED OUT FOR ANOTHER MACHINE. THE PT WAS EMERGENTLY PLACED ON BYPASS AND THE SURGERY PROCEEDED. POST-OP THE PT WAS SENT BACK TO ICU;UNDERWENT 2 ADDITIONAL SURGERIES; A MEDIASTINAL EXPLORATION AND WASHOUT THE NEXT DAY AND DECANNULATION FROM EXTRACORPOREAL LIFE SUPPORT/REMOVAL OF EXTRACORPOREAL VENTRICULAR ASSIST DEVICE THREE DAYS AFTER EVENT OCCURRED. PT HAD DETERIORATING NEUROLOGICAL STATUS AND WEEKS LATER HAD BRAIN CT. SHOWED MULTIPLE FOCI OF HEMORRHAGE IN THE RT PARIETAL AND RT FRONTAL LOBES AS WELL AS SUBARACHNOID HEMORRHAGE IN LEFT FRONTAL AND LEFT PARIETAL LOBES. ALSO A SMALL INTRAVENTRICULAR HEMORRHAGE WAS NOTED. PT'S SURGEON AND PT FAMILY OPTED TO WITHDRAW CARE AND PT EXPIRED.========== MANUFACTURER RESPONSE FOR NITRIC OXIDE GAS & DELIVERY SYSTEM; DATEX-OHMEDA==========WILL EVALUATE DEVICE.
p://www.accessdata.fda.gov/scripts/drh/cfdocs/cfMAUDE/detail.cfm?lrfoi__id=1394996	1394996	GE MEDICAL SYSTEMS; LLC	INOVENT DELIVERY SYSTEM	5/15/2009	MRN	3/13/2009	Malfunction	Event Description: LOUD BANG AND SPARKS COMING FROM INOVENT WHICH WAS BEING USED IN THE OR VIA VENTILATOR CIRCUIT.
p://www.accessdata.fda.gov/scripts/drh/cfdocs/cfMAUDE/detail.cfm?lrfoi__id=1543768	2112667-2009-00060	DATEX-OHMEDA	REUSEABLE CO2 ABSORBENT CANISTER	11/20/2009	MRN	9/23/2009	Injury	Event Description: A CUSTOMER ALLEGES THAT A HOSPITAL TECHNICIAN INJURED HER WRIST WHILE FILLING A MEDISORB; REUSEABLE CO2 ABSORBENT CANISTER. THE PROCESS OF FILLING THE CANISTER INVOLVES TWISTING OFF THE LID TO REFILL AND THEN CLOSING THE LID AND LOCKING IT. THE EXTENT OF THE INJURY COULD NOT BE DETERMINED; HOWEVER; THE EMPLOYEE'S WRIST HAS BEEN SPLINTED. THE TECHNICIAN IS REPORTEDLY OF SMALL BUILD AND HAS DIFFICULTY COMPLETING THE TASK OF FILLING THE CANISTER DUE TO THE SMALL SIZE OF HER HANDS. THE ALLEGATION OF INJURY IS NOT DUE TO A MALFUNCTION OF A SPECIFIC CANISTER OR LOT# BUT RATHER TO THE DESIGN OF THE PRODUCT IN GENERAL. GE HEALTHCARE'S INVESTIGATION INTO THE REPORTED OCCURRENCE IS STILL ONGOING. A FOLLOW-UP REPORT WILL BE ISSUED WHEN THE INVESTIGATION HAS BEEN COMPLETED.
p://www.accessdata.fda.gov/scripts/drh/cfdocs/cfMAUDE/detail.cfm?lrfoi__id=1523317	2112667-2009-00056	DATEX-OHMEDA	INOVENT (DELIVERY SYSTEM)	11/4/2009	MRN	10/1/2009	Injury	Event Description: A MALE BORN IN 2003; HAS A HISTORY OF HEMORRHAGIC ACUTE RESPIRATORY DISTRESS SYNDROME (ARDS) AND BONE MARROW TRANSPLANT. HE RECEIVED 40 PARTS PER MILLION (PPM) OF CONTINUOUS INHALED NITRIC OXIDE FOR THE TREATMENT OF ARDS. THE PT WAS ON A 3100A SENSORMEDICS VENTILATOR IN A HIGH FREQUENCY OSCILLATORY VENTILATION (HFOV) UNFILTERED PT CIRCUIT WITH THE FOLLOWING SETTINGS: RESPIRATORY RATE 7 HERTZ; HFOV MODE; AND TOTAL FLOW RATE 25-30 LITERS/MINUTE. IN 2009; A RESPIRATORY THERAPIST ATTEMPTED TO PERFORM A LOW CALIBRATION ON INOVENT MACHINE; WHILE ON THE PT. THE INOVENT MACHINE WAS RUNNING IN NORMAL OPERATION MODE AT 40 PPM AND NO SUCTIONING OR NURSING CARE WAS BEING PERFORMED AT THIS TIME. THE LOW CALIBRATION FAILED AND THE RESPIRATORY THERAPIST PROCEEDED TO PERFORM A HIGH CALIBRATION. FOLLOWING HIGH CALIBRATION WHICH LASTED APPROXIMATELY 1 MINUTE; MONITORED NITRIC OXIDE (NO) BEGAN TO RISE. WHEN NO MEASURED REACHED 100 PPM; THE HIGH NO ALARMED AND THE INOVENT WENT INTO ELECTRONIC SHUTDOWN. AFTER INOVENT SHUTDOWN; THE PT'S OXYGEN SATURATION DECREASED FROM 88% TO APPROX 77%. HE WAS MANUALLY BAGGED BY THE RESPIRATORY THERAPIST WITH 80 PPM NO AND THE PT'S OXYGEN SATURATION RESOLVED TO PREVIOUS LEVEL OF OXYGEN SATURATION IN APPROXIMATELY 10 MINUTES. THE INOVENT MACHINE WAS REPLACED AND NO DELIVERY CONTINUED. THE PT WAS MANUALLY BAGGED FOR ABOUT 1 HOUR. THE RESPIRATORY THERAPIST DEEMED THE OXYGEN SATURATION DECREASE TO BE RELATED TO THE INOVENT SHUTDOWN. Manufacturer Narrative: THE DEVICE INVESTIGATION RESULTS ARE AS FOLLOWS: THE ERROR LOGS INDICATED MULTIPLE INSTANCES OF LOW RANGE CALIBRATION FAILURE DUE TO THE NO SENSOR WHILE IN USE. THE ERROR LOGS CONFIRMED A SYSTEM SHUTDOWN OCCURRED DUE TO THE DEVICE MONITORING 100 PPM NO. INOVENT WAS RETURNED MISSING THE INJECTOR MODULE THAT WAS IN USE AT THE TIME OF THE REPORTED INCIDENT. THE INOVENT ELECTRONIC DELIVERY SYSTEM WILL NOT FUNCTION WITHOUT AN INJECTOR MODULE. A NEW INJECTOR MODULE WAS USED IN ORDER TO TEST THE DEVICE. THE DEVICE MONITORED 9PPM NO ON ROOM AIR AFTER INITIAL BOOT-UP. NO DOSE WAS SET TO 40PPM AND THE MONITORED NO WAS 42PPM; WHICH IS WITHIN +/- 8PPM SPECIFICATION. LOW RANGE CALIBRATION WAS SUCCESSFULLY PERFORMED. AFTER WHICH; NO MEASURED 0.3PPM ON ROOM AIR. HIGH RANGE NO CALIBRATION WAS SUCCESSFULLY PERFORMED. FOLLOWING CALIBRATION; NO DOSE WAS SET TO 40PPM AND THE MONITORED NO WAS 39PPM; WHICH IS WITHIN +/- 8PPM SPECIFICATION. THE REPORTED CONDITION OF NO RISING TO 100PPM FOLLOWED BY SYSTEM SHUTDOWN COULD NOT BE REPRODUCED AND THE REPORTED FAILURE COULD NOT BE CONFIRMED. THE NO SENSOR WAS REPLACED AS A PRECAUTIONARY MEASURE DUE TO THE ERROR LOGS INDICATING MULTIPLE INSTANCES OF LOW RANGE CALIBRATION FAILURES DUE TO THE NO SENSOR WHILE IN USE AT THE CUSTOMER SITE. INO THERAPEUTIC/IKARIA HAS ASSUMED SPECIFICATION DEVELOPER AND GLOBAL REGULATORY RESPONSIBILITIES FOR INOVENT AND NOW HOLDS THE 510(K) AND THE DEVICE LISTING FOR THE DEVICE. INOVENT WAS MANUFACTURED BY DATEX-OHMEDA/GE HEALTHCARE AND IS NO LONGER IN PRODUCTION. FUTURE COMMUNICATIONS OR QUESTIONS REGARDING INOVENT MDRS SHOULD BE DIRECTED TO INO THERAPEUTICS AS INDICATED. WE ARE; PER DIRECTION FROM FACILITY; SPECIFYING DATEX-OHMEDA/GE HEALTHCARE AS THE MFR. MEDICALLY SIGNIFICANT.

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.