

| Incubators (保育器) | | | | | | |
|------------------|-------------------------------------|--------------------------|--------------|------------------------|--------|--|
| Device CODE | Device Failure | 機器の不具合 | Patient CODE | Influence on Patient | 患者への影響 | |
| 1027 | Ambient temperature, changes | 周囲温度の変化 | 1711 | Anoxia | 無酸素症 | |
| 1071 | Burned | 燃焼 | 1727 | asystole | 心停止 | |
| 1086 | Charred | 焦げ | 1735 | Infection, bacterial | 細菌性感染 | |
| 1090 | Clean, failure to | 清浄(洗浄)の不具合 | 1757 | Burn(s) | 熱傷 | |
| 1091 | Cleaning, inadequate | 清浄(洗浄)が不十分 | 1765 | Cardiopulmonary arrest | 心肺停止 | |
| 1105 | Falling component(s) | 部品の落下 | 1781 | Comatose | 昏睡状態 | |
| 1120 | Contamination | 汚染 | 1802 | Death/expired | 死亡 | |
| 1126 | Control settings incorrect | 制御設定(control setting)の誤り | 1827 | Electrocution | 感電死 | |
| 1176 | Disinfection, inadequate/improper | 消毒が不適當 | 1833 | Encephalopathy | 脳症 | |
| 1184 | Display, incorrect | 表示の誤り | 1851 | Asphyxia | 仮死 | |
| 1194 | Electro-magnetic interference (EMI) | 電磁干渉 | 1852 | Brain injury, fetal | 胎児脳損傷 | |
| 1218 | Explode | 爆発 | 1858 | Fever | 発熱 | |
| 1237 | Filter leak(s) | フィルターの漏れ | 1870 | Fracture(s) | 骨折 | |
| 1238 | Filter break(s) | フィルターの破損 | 1871 | Urgency | 尿意切迫 | |

| | | | | | |
|------|-----------------------------------|--------------------------|------|-----------------------------|------|
| 1242 | Filter tear(s) | フィルターの破れ | 1918 | Hypoxia | 低酸素症 |
| 1244 | Filter, inadequate | 不適切なフィルター | 1930 | Infection | 感染 |
| 1265 | Gas delivery system failure | ガス送出システムの故障 | 2074 | Discoloration of skin | 皮膚変色 |
| 1266 | Gas output, improper | ガスの出力が不適当 | 2096 | Body temperature, elevated | 体温上昇 |
| 1286 | Failure to heat | 加熱されない | 2138 | Vision, impaired | 視力減退 |
| 1287 | Heating, inadequate | 加熱不十分 | 2139 | Vision, loss of | 視力喪失 |
| 1379 | Failure to maintain | 保守不十分 | 2140 | Visual disturbances | 視覚障害 |
| 1406 | Alarm, failure of monitor display | モニター・ディスプレイに関する 警告の故障 | 2348 | Injury | 損傷 |
| 1437 | Overheat | 過熱 | 2461 | Body temperature, decreased | 体温低下 |
| 1568 | Failure of shielding | 遮蔽(シールド)の不具合 | 2569 | Decreased blood pressure | 血圧低下 |
| 1628 | Device, tears, rips holes in | 医療用具に破損、亀裂、穴 | | | |
| 2296 | Loose temperature probe | 温度プローブの緩み | | | |
| 2409 | Malfunction | 故障(誤作動、作動不良) | | | |
| 2593 | Failure of locking mechanism | 固定(鎖錠、ロッキング)機構の 故障 | | | |

Cardiopulmonary By-Pass Equipment (人工心肺装置)

| Device CODE | Device Failure | 機器の不具合 | Patient CODE | Influence on Patient | 患者への影響 |
|-------------|-------------------------------------|--------------|--------------|------------------------|--------|
| 1009 | Alarm, failure of arterial pressure | 動脈圧に関する警報の故障 | 1697 | Air embolism | 空気塞栓症 |
| 1010 | Alarm, audible | 可聴警報 | 1706 | Anemia | 貧血 |
| 1011 | Alarm, delayed | 警報の遅延 | 1711 | Anoxia | 無酸素症 |
| 1012 | Alarm, failure to | 警報の故障 | 1716 | Aortic regurgitation | 大動脈逆流症 |
| 1013 | Alarm, false | 警報の誤り | 1721 | Arrhythmia | 不整脈 |
| 1014 | Alarm, defective | 警報の欠陥 | 1727 | Asystole | 心停止 |
| 1015 | Alarm, intermittent | 警報が断続的 | 1729 | Atrial fibrillation | 心房細動 |
| 1015 | Alarm, low audible | 下限可聴警報 | 1730 | Atrialflutter | 心房粗動 |
| 1019 | Alarm, not audible | 警報が可聴できない | 1731 | Atrial tachycardia | 心房頻脈 |
| 1022 | Alarm, not visible | 警報が目視確認できない | 1738 | Bleeding | 出血 |
| 1024 | Alarm, error of warning | 警告警報の誤り | 1747 | Blood pooling | 血液貯留 |
| 1025 | Alarm, failure of warning | 警告警報の故障 | 1751 | Bradycardia | 徐脈 |
| 1054 | Battery charge, defective | バッテリー充電器の欠陥 | 1762 | Cardiac arrest | 心停止 |
| 1055 | Battery failure | バッテリーの故障 | 1765 | Cardiopulmonary arrest | 心肺停止 |

| | | | | | |
|------|---------------------------------|------------|------|--------------------|------------|
| 1056 | Battery, premature discharge of | バッテリーの過早放電 | 1802 | Death/expired | 死亡 |
| 1070 | Bubble(s) | 気泡 | 1817 | EKG/ECG changes | 心電図の変化 |
| 1085 | Charge, failure to | 充電の不具合 | 1829 | Embolism | 塞栓症 |
| 1094 | Clogged | 詰まり(閉塞) | 1830 | Embolus | 塞栓 |
| 1095 | Clumping | 凝集 | 1841 | Exsanguination | 失血 |
| 1096 | Coagulation | 凝固 | 1842 | Extravasation | 溢血 |
| 1116 | Connection error | 接続の誤り | 1843 | Extreme exhaustion | 極度の消耗 |
| 1135 | Crack(s) | 亀裂 | 1851 | Asphyxia | 仮死 |
| 1138 | Crush | 圧潰 | 1912 | Hypoglycemia | 低血糖症 |
| 1144 | Declotting | 凝結塊の除去 | 1914 | Hypotension | 低血圧 |
| 1237 | Filter leak(s) | フィルターの漏れ | 1915 | Hypothermia | 低体温 |
| 1238 | Filter break(s) | フィルターの破損 | 1917 | Shock, hypovolume | 血液量減少性ショック |
| 1242 | Filter tear(s) | フィルターの破れ | 1918 | Hypoxia | 低酸素症 |
| 1244 | Filter, inadequate | 不適切なフィルター | 1930 | Infection | 感染 |
| 1294 | Hose line occlusion | ホース管路の閉塞 | 1938 | Intravasation | 血管内異物侵入 |
| 1294 | Hose line rupture | ホース管路の破裂 | 1942 | Ischemia | 虚血 |

| | | | | | |
|------|-------------------------------------|----------------------|------|-------------------|---------|
| 1296 | Hose mismatch | ホースの不適合 | 1971 | Necrosis | 壊死 |
| 1328 | Interference with monitoring device | モニター装置への干渉(妨害) | 2243 | Hypovolemia | 循環血液量減少 |
| 1399 | Misconnection | 接続の誤り | 2244 | Infection, direct | 直接感染 |
| 1406 | Monitor display alarm, failure of | モニター・ディスプレイに関する警報の故障 | 2259 | Regurgitation | 逆流 |
| 1407 | Monitor failure | モニターの故障 | | | |
| 1408 | Monitor, image quality poor | モニターの画質不良 | | | |
| 1423 | Occlusion | 閉塞 | | | |
| 1424 | Occlusion, incorrect | 不正確な閉塞 | | | |
| 1464 | Poor gas exchange | ガス交換が不十分 | | | |
| 1465 | Port leak(s) | 管接続口(出入り口)の漏れ | | | |
| 1489 | Pressure sensor failure | 圧力センサー(感知装置)の故障 | | | |
| 1490 | Pressure, decreased | 圧力低下 | | | |
| 1491 | Pressure, increased | 圧力上昇 | | | |
| 1500 | Pump speed, decreased | ポンプのスピード低下 | | | |
| 1501 | Pump speed, increased | ポンプのスピード増加 | | | |
| 1502 | Pump, failure to | ポンプの故障 | | | |

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|-------------|--------------------------|---------------|--|--|--|
| 1503 | Pumping, stopped | ポンピング(吸入排出)停止 | | | |
| 1518 | Recannulation | カニューレ再挿入 | | | |
| 1531 | Reservoir | リザーバー(貯血槽) | | | |
| 1559 | Sensing, none | 感知しない | | | |
| 1560 | Sensibility | 感度 | | | |
| 1561 | Sensor problem | センサーの問題 | | | |
| 1676 | Warning light, incorrect | 警告灯の誤り | | | |

Infusion Pumps (輸液ポンプ、シリンジポンプ)

| Device CODE | Device Failure | 機器の不具合 | Patient CODE | Influence on Patient | 患者への影響 |
|-------------|----------------------------|-------------------------|--------------|--------------------------------------|----------|
| 1001 | AC/DC, failure o run on | AC/DC(交流/直流)電力で 作動不能 | 1697 | Air embolism | 空気塞栓症 |
| 1002 | Abnormal | 異常 | 1802 | Death/expired | 死亡 |
| 1010 | Alarm,audible | 可聴警報 | 1807 | Dehydrated | 脱水 |
| 1012 | Alarm, delayed | 警報の遅延 | 1817 | EKG/ECG changes | 心電図の変化 |
| 1012 | Alarm, failure to | 警報の故障 | 1820 | Edema | 浮腫 |
| 1013 | Alarm,false | 警報の誤り | 1905 | Hyperglycemia | 高血糖 |
| 1014 | Alarm, defective | 警報の欠陥 | 1908 | Hypertension | 高血圧 |
| 1015 | Alarm, intermittent | 警報が断続的 | 1912 | Hypoglycemia | 低血糖症 |
| 1016 | Alarm, low audible | 下限可聴警報 | 1914 | Hypotension | 低血圧 |
| 1017 | Alarm, failure of low flow | 低流量に関する警報の故障 | 1988 | Overdose | 過量投与 |
| 1019 | Alarm, not audible | 警報が可聴できない | 1989 | Overmedicated | 薬物投与過剰 |
| 1022 | Alarm not visible | 警報が目視確認できない | 2196 | Electrolyte imbalance | 電解質失調 |
| 1024 | Alarm, error of warning | 警告警報の誤り | 2199 | No consequences or impact to patient | 患者に影響なし |
| 1025 | Alarm, failure of warning | 警告警報の故障 | 2242 | Hypernatremia | 高ナトリウム血症 |

| | | | | | |
|------|---|-----------------------|------|---------------------------------|-----------|
| 1045 | Automatic injection system, incompatible | 自動注入システムの不適合 | 2259 | Regurgitation | 逆流 |
| 1046 | Automatic injection system overinfusion | 自動注入システムの注入過剰 | 2264 | Shock, insulin | インスリンショック |
| 1047 | Back-up, failure to | バックアップの不具合 | 2271 | Therapeutic response, decreased | 薬効低下 |
| 1048 | Back-UP, failure to convert to | バックアップに変換不可能 | 2272 | Therapeutic response, increased | 薬効過多 |
| 1057 | Battery, premature discharge of | バッテリーの過早放電 | 2330 | Discomfort | 不快感 |
| 1089 | Circuit failure | 回路の故障 | 2331 | Complaint, ill-defined | 曖昧な愁訴 |
| 1102 | Compatibility | 適合性 | 2359 | Malaise | 倦怠感 |
| 1194 | Electro-magnetic interference(EMI) | 電磁干渉 | 2378 | Healing, impaired | 治癒不良 |
| 1249 | Flowrate, inaccurate | 流量が不正確 | | | |
| 1311 | Overinfusion | 注入過剰 | | | |
| 1312 | Injector system failure, no infusion | 注入装置の注入機能に関する不具合 | | | |
| 1313 | Injector system failure, overinfusion of | 注入装置の過剰注入に関する不具合 | | | |
| 1314 | Injector system failure, underinfusion of | 注入装置の注入不足に関する不具合 | | | |
| 1409 | Motor failure | モータの故障 | | | |
| 1410 | Motor drive unit (MDU) stalled or jammed | モーター駆動装置(MDU)が停止または故障 | | | |
| 1438 | Oversensing | 過度の感知 | | | |

| | | | | | |
|-------------|-------------------|--------|--|--|--|
| 1532 | Reset, failure to | リセット不能 | | | |
| 1545 | Runaway | 暴走 | | | |
| 1559 | Sensing, none | 感知しない | | | |

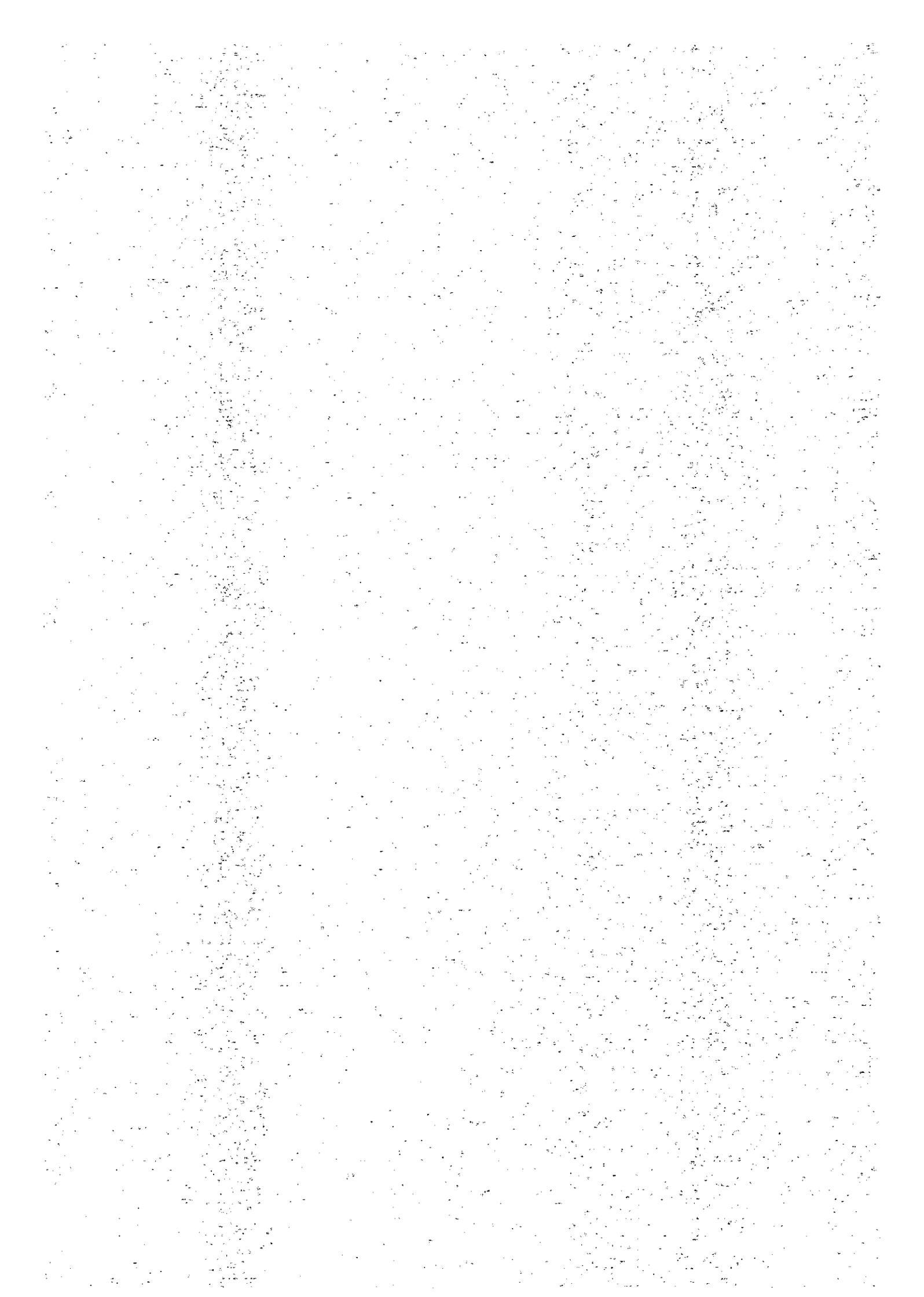
| Syringes & Injectors (シリンジ及び注入器) | | | | | |
|----------------------------------|-----------------------------|--------------------|--------------|--------------------------------------|---------|
| Device CODE | Device Failure | 機器の不具合 | Patient CODE | Influence on Patient | 患者への影響 |
| 1120 | Contamination | 汚染 | 1697 | Air embolism | 空気塞栓症 |
| 1135 | Crack(s) | 亀裂 | 2199 | No consequences or impact to patient | 患者に影響なし |
| 1250 | Fluid leak(s) | 液漏れ | | | |
| 1259 | Foreign material | 異物 | | | |
| 1381 | Marking unclear | マーキングが不鮮明 | | | |
| 1382 | Marking, none | マーキングなし | | | |
| 1398 | Missassembly | 組み立て不良 | | | |
| 1402 | Mislabeled | バル表示の誤り | | | |
| 1420 | Nonstandard | 規格外 | | | |
| 1611 | Syringe drive problem | 注射器(注入器)の駆動の問題 | | | |
| 1612 | Syringe, defective | 注射器(注入器)の欠陥 | | | |
| 1613 | Syringe, hole(s) in | 注射器(注入器)に穴 | | | |
| 1614 | Syringe markings inaccurate | 注射器(注入器)のマーキングが不正確 | | | |
| 1638 | Tip breakage | 先端の破損 | | | |

| | | | | | |
|------|--------------------------------------|---------------------|--|--|--|
| 2259 | Regurgitation | 逆流 | | | |
| 2303 | Contamination, bacterial | 細菌汚染 | | | |
| 2405 | Syringe markings, incorrectly placed | 注射器(注入器)のマーキング位置の誤り | | | |

Surgical Latex Glove (天然ゴム製手術用手袋)

| Device CODE | Device Failure | 機器の不具合 | Patient CODE | Influence on Patient | 患者への影響 |
|-------------|-----------------------------|-----------------|--------------|----------------------------------|--------------|
| 1054 | Charger, defective battery | バッテリー充電器の欠陥 | 1125 | Contraindicated patient | 患者の禁忌 |
| 1091 | Cleaning, inadequate | 清浄(洗浄)が不十分 | 1685 | Abdominal pain | 腹痛 |
| 1102 | Compatibility | 適合性 | 1701 | Allergic reaction | アレルギー反応 |
| 1120 | Contamination | 汚染 | 1703 | Anaphylactic shock | アナフィラキシーショック |
| 1153 | Degradation | 分解(劣化) | 1735 | Infection, bacterial | 細菌感染 |
| 1184 | Incorrect display | 表示の誤り | 1743 | Blister(s) | 水疱 |
| 1216 | Date of expiration exceeded | 有効期限(使用期限)切れ | 1745 | Blood/fluids, contamination from | 血液/体液からの汚染 |
| 1293 | Hole(s) | 穴(ホール) | 1840 | Erythema | 紅斑 |
| 1339 | Kink | ねじれ | 1858 | Fever | 発熱 |
| 1382 | Markings, none | マーキングなし | 1943 | Itching | そう痒 |
| 1444 | Packaging, unsealed | 包装が密封(封印)されていない | 2066 | Sensitization | 感作 |
| 1504 | Puncture | 破裂(刺し穴、穿刺) | 2038 | Eye(s), red | 眼の充血 |
| 1583 | Incorrect size | 大きさ(サイズ)の誤り | 2095 | Tachycardia | 頻脈 |
| 1584 | Slippage | 滑り | 2144 | Vomiting | 嘔吐 |

| | | | | | |
|------|---------------------------------|------------|------|---------------------------|------|
| 1591 | Accidental spillage | 偶発的流出 | 2466 | Nasal obstruction | 鼻閉塞 |
| 2385 | Holes, rips, tears in packaging | 包装に穴、亀裂、破損 | 2567 | Blood pressure, decreased | 血圧低下 |



Nomenclature – Sub-Categories for Medical Devices

Initial List of “Sub-Categories” of Medical Devices to be used for purposes of identification of general groupings, families, of medical devices, for purposes of data exchange within the European Union Member States, being part of the new Nomenclature System being developed for Medical Devices.

This list is not complete but indicates a number of identified “family” or other headings which might be appropriate.

The principle upon which these groups are obtained may be on the basis of any of the following, for example:

1. Common Technology applied
2. Similar Medical Procedure
3. Similar Manufacturing/Technical Requirements
4. Similar Materials used
5. Similar Risk-Associated Considerations
6. Other Family-Related Considerations

The attached list is intended to provoke discussion and further development.

M.F. Freeman

Sub-Categories

Absorbable Implants

Anaesthesia – Gas Supply Equipment – Work Stations

Analgesia Devices

Angioplasty Devices

Aspirators

Bandages – Compresses, Gauze, Swabs

Blood Gas Monitors

Blood Pressure Measuring Devices

Breast Pumps

C.T. Scanners

Cardiac Output Measuring Devices

Cardiopulmonary By-Pass Equipment

Catheters

- urological
- cardiovascular
- various

Cell & Tissue collection Devices

Contact Lens Care Products

Contraceptive Devices

Cryosurgical Apparatus

Dental Chairs

Dental Equipment – non powered

Dental Equipment – powered

Dental Materials

Devices Incorporating Ancillary Medicinal Products

Diathermy Equipment

Drains / Drainage Kits

Drug Delivery Systems – Implantable

EEG Equipment

Electrosurgical Units

Electro Therapy Equipment

Electrocardiographs and other Cardiography Devices
Electroconvulsive Therapy Units
Electrodes
Endoscopes & Accessories
Enteral Feeding Equipment
External Cardiac Stimulators
Filters – breathing system
Filters – various
Flow Measurement Devices
Fluid Drainage Devices
Foetal Heart Monitors
Gynaecological & Obstetrical Equipment
Haemodialysis / Haemofiltration Equipment + Accessories
Haemostatic Materials
Hearing Aids
Heart-Lung Bypass Units & Accessories
Humidification Devices
Hypothermia – Hyperthermia Apparatus for Body Temperature Control
Implantable Defibrillators
Implantable Drug Delivery Systems, Infusion Pumps
Implantable Pacemakers
Incubators
Infusion Controllers
Insufflators
Intraocular Implants
Intravenous Administration Sets
Iontophoresis Equipment
Irrigation & Lavage Equipment
Lasers – Medical
Lithotripters
Magnetic Resonance Imaging Equipment
Magnetic Therapy Units
Massage Equipment

Nebulisers for liquid or powder dispersal, inhalers
Needles
Nerve Stimulators
Neurological Diagnostic Equipment
Nuclear Medicine Equipment
Operating Theatre Lighting
Operating Theatre Tables & Accessories
Ophthalmological Diagnosis Equipment
Ophthalmological Instruments
Optical Products – Contact lens – Correcting Lens
Ostomy Appliances
Patient Monitoring Devices – By Intended Purpose (e.g. blood pressure, tidal volume, inflation pressure, CO₂, O₂ concentration, etc.)

- electronic
- other

Patient Support Devices:

- Wheel-chairs
- Hospital/other beds for medical purposes
- Walking and other Mechanical aids for disabled

Peritoneal Dialysis Devices
Phototherapy Devices
Powered Furniture for Diagnosis / Treatment
Pressure Measuring Devices
Pressure Redistribution Support Apparatus – Decubitis Devices
Prostheses – Breast
Prostheses – Vascular
Prostheses for Augmentation of Body Parts
Prosthetic Heart Valves
Protective Clothing – Gloves
Protective Clothing – Masks, Gowns, Drapes, Hats, etc.
Radiation Protection Shields
Radiological Equipment
Radiotherapy Equipment

Respiratory System Monitors
Skin & Tissue Stapling / Suturing Devices
Speech Therapy Aids
Sponges / Swabs
Stents
Stethoscopes
Stimulators – Muscle / Nerve
Suction and Drainage Devices, Aspirators
Surgical Drills
Surgical Instruments – Non-Powered
Surgical Instruments – Powered & Accessories
Sutures animal origin
Sutures – non-animal origin
Syringes & Injectors
Tracheostomy Tubes – Accessories – Airways
Transducers & Sensors
Tubes & Tubing
Ultrasonic Equipment – Diagnostic – Therapeutic
Urinary Drainage & Collection Devices
Urological Diagnostic Equipment
Ventilators / Respirators & Ancillary Equipment
Wound Dressings

- simple
- medicated

Nomenclature – Sub-Categories for Medical Devices

| Sub-Category (英語) | 日本語 | 具体例 |
|--|----------------------------------|---------------------|
| Absorbable Implants | 吸収性インプラント | 吸収性縫合糸 |
| Anaesthesia · Gas Supply Equipment · Work Stations | 麻酔 – ガス供給装置 – ワークステーション | |
| Analgesia Devices | 吸入無痛法機器 | |
| Angioplasty Devices | 血管形成術用機器 | PTCAカテーテル / ガイドワイヤー |
| Aspirators | 吸引器 | |
| Bandages · Compresses , Gauze, Swabs | 包帯 – 圧迫包帯、ガーゼ、綿棒 | |
| Blood Gas Monitors | 血液ガスモニタ | |
| Blood Pressure Measuring Devices | 血圧測定機器 | 血圧計 |
| Breast Pumps | 搾乳器 | |
| C.T. Scanners | CTスキャナ | |
| Cardiac Output Measuring Devices | 心拍出量測定装置 | 心拍出量計 |
| Cardiopulmonary By-Pass Equipment | 人工心肺用機器 | 心肺回路 |
| Catheters · urological · cardiovascular · various | 泌尿器用カテーテル 心臓用カテーテル 各種カテーテル | フューリーカテーテル |
| Cell & Tissue collection Devices | 細胞・組織採取器具 | |
| Contact Lens Care Products | コンタクトレンズ関連製品 | |
| Contraceptive Devices | 避妊用器具 | 避妊用ベッサリー |
| Cryosurgical Apparatus | 冷凍手術装置 | |
| Dental Chairs | 歯科用椅子 | |
| Dental Equipment – non powered | 歯科用装置 – 手動 | |
| Dental Equipment · powered | 歯科用装置 – 電動 | |
| Dental Materials | 歯科材料 | |
| Devices Incorporating Ancillary Medicinal Products | 補助的な医薬品を含有する機器 | ヘパリンコートカテーテル |