

This document is found in the Suppliers and or Vendors sections of both the beaumontservices.com and the beaumonthospitals.com websites.

- Unless the vendor or the manufacturer takes **written** (email to the Purchasing agent is acceptable) **exception** to any of the terms included in this or any attached specifications sheets, the vendor/manufacturer shall comply with each provision.
 - Additional charges incurred in order to meet these specifications must be itemized.
 - **All requests for deviation from these specifications must be in writing and submitted to the Hospital's buyer prior to sale.**
 - Purchase specifications subject to change without notice.
- Additional purchase specifications have been attached. Please review and comply, or take written exception as needed.

IN-COMING INSPECTION

All in-coming equipment and accessories, art work, custom fabricated devices, systems, processes, etc., regardless of method of acquisition, will be inspected for proper performance and compliance with these general requirements and any attached specifications before equipment is used. The equipment cabinet may be opened for a visual inspection of internal parts. The hospital reserves the right to refuse payment and to return the unit at vendor's expense in the event of non-compliance with these specifications, regardless of time lapse from shipment until time of inspection. The warranty period shall begin after the equipment has passed inspection, been operating problem-free for **30** consecutive days, and is accepted by clinical inspection or use.

GENERAL EQUIPMENT REQUIREMENTS

The equipment shall be constructed to provide safeguards against thermal, electrical, chemical and mechanical injury to personnel or damage to facilities or equipment. It shall conform to the requirements of OSHA, MIOSHA (Michigan OSHA), CPSC (Consumer Product Safety Commission), the National Electric Code (NFPA-70), BOCA (Building Official and Code Administrators), AAMI/ANSI ES1, and NFPA 99 as applicable. It shall also conform to the Radiation Control for Health and Safety Act, federal and state radiation protection standards and the requirements of the Federal Communications Commission (FCC). Clinical laboratory equipment shall also conform to the appropriate standards of the National Committee for Clinical Laboratory Standards. Equipment must be UL, CSA, CITECH, or other Nationally Recognized Testing Laboratory (NRTL) and have evidence of safety certification for the applicable environment. All equipment must bear the appropriated NRTL listing mark. The CE mark is applied by the manufacturer and alone is NOT evidence of recognized safety certification. All equipment to be supplied with "Declaration of Conformity" to IEC 60601 (Electromagnetic Compatibility Standard), and be compliant with all HIPAA (Health Insurance Portability and Accountability Act) requirements as applicable.

A. DEFINITIONS

Patient Equipment - Equipment that is intended to treat, diagnose, monitor, or otherwise likely to be contacted by a patient. All patient scales must be capable of being defaulted to read in kG units of measure **ONLY**.

Isolated Patient Connection - A connection between the patient and the device that is deliberately isolated from ground and the utility power system to the extent described below in Part D, "Grounding Resistance and Leakage Current."

Non-Patient Equipment - Equipment and devices which are not likely to come in contact with patients (housekeeping appliances, shop tools, lab and office equipment, etc.).

Equipment - Institutional, industrial devices, commercial building equipment, appliances, machinery, related subcomponents, subassemblies of equipment assembled on site, processes, systems, furniture, artwork, etc.

B. MANUALS AND TECHNICAL INFORMATION

Two complete sets of the following documentation written in English **must be provided** unless specifically waived in writing by the Hospital. **Payment will be withheld** until this material is received. Said documentation to be given directly to the service group responsible for maintenance of same.

1. Operators manual describing the operation of the equipment and accessories that are purchased with or separately from, but intended to be used with said equipment (or system if two or more devices are interconnected).
2. Service/maintenance manual, including installation instructions, lists of suggested spare parts inventory, special tools and test equipment (and associated costs) if any. Expert systems software, and access to remote diagnostics software packages, if available to your own service personnel, shall be provided to Beaumont at no extra charge.
3. Energy control procedures for lockout of hazardous energy sources.
4. Safety instructions, weight limitations, considerations, warnings, stickers, placards and signage.
5. Wiring diagrams and schematics.
6. Theory of operation and circuit description.
7. Parts list and diagrams.
8. Performance specifications and calibration procedures.
9. Operational tests.
10. Periodic maintenance program.
11. Test procedures.
12. Hydraulic / pneumatic piping diagrams for all fluids and gases.
13. Drawings, schematics, prints showing any and all field/engineering changes.
14. Approved method of cleaning and sterilization.
15. Statement of known potential hazards.
16. Software documentation detailing release date and compatibility with prior releases.
17. Requirements and special installation instructions for all energy sources including electrical, heating, cooling, water, drain, gas, vacuum, etc. **THESE SHALL BE SUBMITTED TO THE HOSPITAL BUYER FOR APPROVAL PRIOR TO SALE.**

18. Provide a "Statement of Conformity" that identifies the standard number of the UL or other NRTL Standard that the product was approved in accordance with.
19. Equipment that is assembled into a system that does not have a system wide UL or other NRTL listing to substantiate its safety must provide an alternative engineering approval from a Beaumont approved Engineering Firm, and comply with all WBH Safety Standards and requirements. All field modifications must be reviewed and approved by a Beaumont/BSC Inspecting department. The final assembled product must not create or cause any hazard or injury in its static or operational functional state.
All Fabricators of equipment must comply with the sub component's Original Equipment Manufacturer's (OEM) safety design, application, usage and specifications from those OEMs.
Equipment/systems/components that are assembled to become a final product on-site as part of a project requires Beaumont inspection and approval after assembly, and meet the OEM specifications. **See also Beaumont Services Construction Standards and contract language that is referenced with your Purchase Order.**
20. All other service materials furnished to vendor's own service personnel including training, service and maintenance videos, audio/visual training programs, or other electronic training media (e.g. computer media CD, DVD etc.). Passwords for all service and diagnostic processes, patient data screens, patient information databases, and archived patient data are to be provided to and maintained at a secure designated location where the device is in use. Patient information must be stored in a configuration manner that is retrievable and usable as a backup process to any catastrophic failure to the main patient information databases.
21. Material Safety Data Sheets (MSDS) for all hazardous chemicals and materials used with this device that is part of the equipment and used with the equipment including applicable consumable components, or items, such as batteries, etc. If MSDS sheets are not applicable, that "Product Information" sheets are provided and are required.
22. A listing of all chemicals, gasses, and their quantities and anticipated usage volumes on a daily, weekly or monthly basis if applicable.

C. ELECTRICAL REQUIREMENTS

1. POWER

- a. **IF THE EQUIPMENT REQUIRES ELECTRICAL SERVICE OTHER THAN 120 VAC/20 AMP SERVICE, THE EXACT REQUIREMENTS SHALL BE SUBMITTED TO THE HOSPITAL BUYER FOR APPROVAL PRIOR TO SALE.**
- b. Equipment designed to operate on 120 volts should operate without loss of safety or performance over the range of 100 to 130 volts. If the normal voltage is other than 120 volts, the operating range should be +10%, -15% of nominal.
- c. Equipment shall be operational and not damaged under conditions of transfer from normal to emergency power, regardless of length of time delay in transfer. Effects of power interruption shall be submitted to the hospital buyer for approval **by hospital engineering personnel** prior to sale.
- d. External low voltage supplies, such as battery chargers and wall mounted transformers shall be electrically isolated from the electric power distribution system.

2. POWER CORD, PLUGS AND RECEPTACLES

- a. All plugs and receptacles shall conform to NEMA standard configurations. Wall transformers must be double insulated (or grounded) and clearly labeled for intended use.
- b. All power cords will be three conductor industrial or Hospital Grade (SJ, SJO, ST, STO, SPT, HS, HSO, HSJ, HPN) and at least ten feet long. The conductor size shall be adequate for the current rating of the device, but in no case shall be smaller than #18 AWG.
- c. All equipment shall be provided with a grounding conductor in its power cord unless the device is listed as double insulated.
- d. The power cord of medical/patient equipment shall be terminated with a Hospital Grade, three-wire grounding type plug, such as a Hubbell #8215-C or equivalent. Non medical equipment power cords shall be provided with a minimum of industrial/specification grade plugs. The hot and neutral wires should be cut 3/8" shorter than the ground wire and attached to the proper terminals. Wire ends shall **not** be tinned.
- e. Separable cord sets are permitted if it can be shown that accidental disconnection is unlikely or not hazardous. Clinical equipment that is electrically powered will require a physical captive strain relief to assure the cord does not become disconnected from the equipment it is intended to power. Additionally, the end of the power cord intended to be connected to the instrument shall be opaque, so that potential confusion is lessened.
- f. A strain relief shall be provided at each attachment end of the power cord so that mechanical stress, either pull, twist, or bend is not transmitted to the internal connections.
- g. Auxiliary line power outlets will be Hospital Grade for patient equipment and industrial/ specification grade or better for non-patient equipment. For patient equipment, these outlets must be provided only when required for specific accessories. They must be labeled according to their intended use and amperage rating.
- h. Plugs and receptacles intended for other than line power shall have a distinctive configuration which does not permit interchangeable connection with line powered plugs or receptacles.

3. PATIENT CABLES AND LEADWIRES

Safety cables and leadwires intended for patient connection are required. Leadwire design must prevent accidental connection to any cable not intended to receive them.

4. POWER SWITCHES AND OVERCURRENT INTERRUPTERS

- a. Power switches located in the line cord are not acceptable for patient equipment. If used in non-patient equipment, in-line switches must be heavy duty and provided with an adequate strain relief.
- b. It is recommended that overcurrent protective devices be installed in all hot conductors supplying primary power to the unit. The protective device rating and type shall be easily read and clearly marked on the equipment exterior.

5. SUSCEPTIBILITY TO RF/EMI INTERFERENCE

All equipment must be hardened against RF/EMI interference in accordance to IEC 60601.

D. GROUNDING RESISTANCE AND LEAKAGE CURRENT

1. The grounding resistance of the device measured from the grounding prong on the plug to conductive surfaces on the cabinet, shall not exceed 0.5 ohms.

2. LEAKAGE CURRENT

- a. Leakage current for patient equipment shall meet the provisions of the latest version of NFPA 99. "Health Care Facilities Handbook".
- b. Non-patient equipment shall meet the Leakage Current requirements of ANSI C101.0, U/L, or NPFA 99 as applicable.
- c. **The following table of worst case limits is presented as a guideline only. The references listed above should be consulted for exact up-to-date values and testing methods.**

Chassis Source Current

Patient Equipment	300 uA
Non-patient Equipment	500 uA
Permanently Connected Equipment.	5000 uA

Patient Risk Current

Isolated Patient Connection	50 uA
Non-isolated Patient Connection	100 uA

- d. EXCEPTION: Computers and peripherals that are not likely to come into contact with a patient may have up to 5000 uA leakage current (per UL 478, Information - Processing and Business Equipment).
- e. EXCEPTION: Non-patient equipment that is required to have primary circuit filtering to meet FCC requirements may exceed the above limits if it is NRTL approved. **IF IT IS NOT NRTL APPROVED, DOCUMENTATION OF THE NORMAL EXPECTED LEAKAGE CURRENT VALUES AND EXPLANATION OF THE SPECIFIC REASON FOR HIGH LEAKAGE MUST BE SUBMITTED TO THE HOSPITAL BUYER FOR APPROVAL PRIOR TO SALE.**
- f. Tests shall be made using an AAMI STD test load, with a frequency response as specified in AAMI/ANSI ES1. Tests shall be made with the ground wire open and intact, with the device "on" and "off," and with the polarity normal and reversed.
- g. **IF THESE TESTS WILL CAUSE DAMAGE TO THE EQUIPMENT, A PERMANENT LABEL STATING THIS SHALL BE ATTACHED TO THE EQUIPMENT IN A PROMINENT LOCATION OR ATTACHED TO THE LINE CORD. A COPY OF THIS STATEMENT SHALL BE INCLUDED IN THE SERVICE MANUAL AND OPERATORS MANUAL.**
- h. Any equipment that is likely to be taken into the patient's bed, (electric bed controllers, nurse call and communication systems, CPM exercisers, etc.), must be constructed to resist fluid entry. It also must not exceed the above leakage current values, or perform in an unsafe manner, following the pouring of 1 liter of normal saline over the equipment.
- i. Equipment should be designed to meet the above limits throughout its expected life.

E. MECHANICAL REQUIREMENTS

- 1. Provide overall product dimensions for weight, height, width, and depth of the assembled final products. If the product is sent to the job site/building in a shipping crate, provide the same information as it relates to the size and weight of the packaging. This information to be sent to the buyer prior to sale, buyer will forward it onto the Project Manager.
- 2. Equipment/machinery/processes must have energy isolating devices for the control of hazardous energy sources and be designed to accept lockout devices as required by MIOSHA/OSHA.
- 3. Internal components must be protected against humidity, spilled liquids, dust, vermin and mechanical abuse. Openings on exposed horizontal surfaces are not allowed. Other openings (e.g., ventilation) must not allow entrance of fluid from vertical to an arc 30 degrees above the horizontal.
- 4. Openings in the instrument housing must not permit passage of a 3/16" rod inside the enclosure.
- 5. Belts, pulleys and other external moving parts likely to cause damage or injury must be guarded in conformance with MIOSHA Standards.
- 6. Moving panel/skirt guards cannot create pinch or snag points.
- 7. Sharp edges and protrusions shall be removed, covered, or guarded.
- 8. Portable devices shall have a cord wrap designed to contain excess power cord lengths.
- 9. Equipment purchased for the MRI environment must be "MRI SAFE" and labeled as such.

F. LABELING

- 1. Clear legible markings on the equipment exterior shall indicate manufacturer's name, device name, model, serial numbers, operating voltage, frequency, indicators, output voltage, and current, if applicable. Appropriate FCC, U/L or NRTL, and/or regulatory compliance and Standards numbers are to be identified on the product.
- 2. All control knobs, switches, displays and output connectors shall be clearly labeled.
- 3. All energy isolating devices for the control of hazardous energy sources must be prominently labeled.
- 4. Patient related devices shall indicate whether they have isolated leads.
- 5. Equipment that is intended to be used in an Oxygen Enriched Environment or a flammable atmosphere shall be appropriately labeled.
- 6. Labels denoting operational and safety precautions must be conspicuously located.
- 7. All labeling must remain legible for the expected life of the equipment.
- 8. All Patient Care Assist furniture, equipment, and transport equipment must be prominently labeled for maximum weight limitations.
- 9. All shelves, chairs, patient equipment and other weight bearing equipment of any kind shall have it's weight limits and any other warnings clearly labeled on the product.

G. TRAINING

- 1. The manufacturer or vendor shall provide comprehensive user training, free of tuition, for all users on all shifts, and will repeat this training at the hospital's request.

2. The manufacturer or vendor agrees to train two (2) WBH or designated agents service persons to maintain the equipment. This training will be made available during the initial warranty period, or at some later date chosen by the hospital, at no charge to the hospital for tuition. Travel costs, accommodations, and per diem expenses to be paid for by the vendor. This training will be at the same level as the training given to the manufacturer's own service persons.
3. The manufacturer or vendor training will include a listing of safety equipment required, safety procedures, practices and requirements for the safe operation, repair and maintenance of the equipment, system, machinery or process etc. Training shall include proper lock-out procedures of the equipment, machinery, process, or system, etc.

H. INSTALLATION

1. The manufacturer/vendor/contractor/installer is expected to: a) assemble, install and calibrate all equipment that has been purchased or brought in for evaluation, b) install and post all weight limitations, safety signage, stickers, placards that are associated with the equipment/process/system. **IF ANY OF THESE FUNCTIONS ARE REQUIRED OF THE HOSPITAL, THIS INFORMATION SHOULD BE SUBMITTED TO THE BUYER FOR APPROVAL PRIOR TO SALE, INSTALLATION, OR FINAL ASSEMBLY.**
2. Upon completion of installation, all hardware and components will be installed, electrical safety tests performed and overall system performance documented. This documentation must be received by the hospital service group responsible for said equipment (either Biomedical Engineering, Facilities Management, Facilities Development [Design Build], Radiation Oncology, or Nuclear Medicine).
3. All installation instructions, drawings/templates/safety requirements/stickers, warnings must be given to the Beaumont Service section responsible for said equipment.
4. All wall mounted devices must be installed in compliance with the **WBH WALL MOUNTING STANDARD**. Contact BSC for further information. Construction projects and materials used in projects must be in compliance with the **WBH CONSTRUCTION STANDARD**.
5. Any field engineering/built/fabricated system, process, equipment, or artwork must meet OSHA/MIOSHA, CPSC, ANSI, and other applicable National Safety Standards.
6. Any equipment or installation that produces a noise level of 85 dBA must be approved prior to installation.
7. Any installation requiring wall, ceiling, or floor penetration for any purpose (e.g. cable/wire) must be approved by BSC Facilities Development. **Such installations require proper fire stopping** measures to be employed.
8. Installations involving removal or **displacement of ceiling tiles, penetration of walls, floors, or ceiling** in a clinical or patient care setting must be approved by BSC and the Department of Epidemiology as **all such work require** special dust containment measures.

I. SERVICE POLICY. ALL Service and Sales personnel must adhere to specific guidelines as identified by Beaumont Hospitals.

Whether or not WBH elects to enter into a service agreement with the vendor/manufacturer, the vendor/manufacturer shall provide at no charge to WBH all software updates, parts availability, and passwords normally provided as part of a service agreement.

1. Vendor/manufacturer agrees to send only qualified and capable Field Service Engineers (FSE's) authorized to perform both warranty and non-warranty maintenance services on hospital premises. Competency and credentials of FSE's must be available upon our request.
2. Performance Assurance checks must be accomplished and documented upon installation, and one month prior to warranty expiration.
3. All safety and performance tests must be accomplished after each repair or other service event, and a copy be given to the department.
4. Response time is expected to be within one (1) hour by phone from an FSE, and within eight (8) hours physically on site.
5. WBH must receive notice and agree on schedule well in advance of a vendor/manufacturer initiated service action, estimate of any costs, and probable effect related to system operation or potential safety ramifications.
6. Documentation: FSE's must provide the following documentation, written in plain English, unless specifically waived by the hospital. Payment will be withheld until following documents are received:
 - a. FSE's must log in and log out at the designated Security checkpoint.
 - b. The vendor/manufacturer will provide written test procedures upon request.
 - c. FSE's will provide a written summary of service performed via a vendor/manufacturer Service Report. The report shall include details of work performed to resolve the problem, parts used, time used, parts cost, travel time, mileage, total travel costs, specific reasons why the action required was necessary, and if there were any safety ramifications.
 - d. Cost summaries of parts, labor, and other maintenance costs on request.
 - e. FSE will secure a signature on the Service Report from the department representative that requested the service to acknowledge work has been performed to satisfaction.
7. The vendor/manufacturer must use manufacturer approved test equipment specific to the device being tested or repaired, and that said test equipment bears obvious evidence (tag) that it has been periodically tested and calibrated within one year of the date of service performed at WBH.
8. Field Service Engineers will perform and comply with all safety requirements and procedures including arc flash regulations/standards.

J. UPS EQUIPMENT REQUIREMENTS

1. Any UPS connected to emergency power shall be generator compatible (i.e., have the ability to compensate for input frequency deviations having a slew rate of 1.5 Hz/second, in addition to operating at 60 Hz \pm .5 Hz).
2. UPS output harmonic current shall be 5% or less THD (total harmonic distortion).
3. Output voltage regulation shall be \pm 1% steady state and \pm 8% at 50% load step.
4. UPS shall have fail-safe bypass, to utility power, to protect loads from UPS failure (Type 7 or 8).
5. Portable UPS backup units must have audible indicators for faulty or low battery conditions.

K. NETWORK CONNECTIBILITY

All systems intended to connect to and/or communicate via the WBH Information Systems network shall run a virus protection program that is up-to-date, and updated frequently. Other conditions for equipment intended to function via the WBH IT network are specified in the WBH IT Standards document.