

Safety & Functional Testing of Medical Equipment What to test, and how often?

There are two sorts of testing:

- Electrical safety – typically 2-6 parameters
- Functional testing – less well defined, device dependent

Manufacturers' specifications can seem excessive – for well known reasons

- To protect their image for equipment reliability
- For reasons of legal liability
- To sell services

Manufacturers' specifications are hard to criticise

- They claim experience of all units, we have a small number in our hospital(s)
- Manufacturers' specs are first point of reference in legal proceedings

No service organisation is funded to the extent required by manufacturers' specs

Standards

- 3551 – annually or risk-based assessment
- 4360 – Risk management requires buy-in of all from CEO down - rarely occurs
- IEC standards on Risk Management – only address equipment design & manufacture

Current practice

- BmE departments undertake Risk Management all the time
- There is little consistency – some are working towards standardised tests
- There is no official endorsement – of the methods of setting priorities, or the resulting details

Conclusion

- There is a need for a consistent approach to the setting of testing priorities for the ongoing management of clinical medical equipment.
- This approach needs to be accepted – accreditors, health departments, general public..?

Next Step

A draft document on the setting of priorities for the management of a clinical inventory is currently being developed and will be circulated for comment.

REQUIREMENTS FOR ROUTINE MAINTENANCE ON MEDICAL EQUIPMENT

(Draft for circulation & discussion – not for implementation)

BACKGROUND

Medical equipment is designed to monitor, diagnose, or treat patients in hospitals, health centres or sometimes in the home.

To monitor and diagnose patients medical equipment has to measure physiological parameters and apply algorithms to yield meaningful results. To treat patients it has to supply energy in the form of electrical, mechanical, chemical or sound energy or sometimes in the form of ionising radiation.

Any medical device must be safe and functional - it must “do no harm” to the patient on whom it is being used. To achieve this, it must be electrically safe and it must measure the physiological parameters or deliver the set energy to the accuracy required.

Routine maintenance can assist in mitigating the risk associated with the use of medical equipment on patients.

ROUTINE MAINTENANCE

Routine maintenance can be defined as any service carried out on a regular basis that is not a repair. It can include:

- inspections,
- electrical safety tests,
- functional tests on critical performance parameters,
- calibration,
- software upgrades, or
- full preventative maintenance where parts are replaced.

It is a mistake to assume that all medical equipment needs “preventative maintenance”. Many people think that because a car needs a regular “service” where the spark plugs, oil filter, oil and various other parts are replaced, that medical equipment is the same. Some medical equipment needs to have “its oil changed” on a regular basis but the majority does not.

Most medical equipment needs to have some sort of inspection and/or test on a regular basis to ensure its safety and function. As a result of the inspection and/or test it may need to have further maintenance to bring the safety and/or performance parameters into line with design specifications.

All medical equipment should be identified with a tag or label which specifies the level and frequency of routine maintenance required. An example of such a tag appears below.

ANYTOWN BME DEPARTMENT	
EQUIPMENT MAINTENANCE REQUIREMENTS	
No maintenance required	<input type="checkbox"/>
Electrical Safety Test	<input type="checkbox"/> 6 12 24 36
Function Test	<input type="checkbox"/> 6 12 24 36
Calibration	<input type="checkbox"/> 6 12 24 36
Preventative Maintenance	<input type="checkbox"/> 6 12 24 36

CATEGORIES OF ROUTINE MAINTENANCE

No maintenance required

Some types of equipment may not need any maintenance at all or possibly just an inspection to check the integrity of the case. Equipment that is battery powered often falls in this category.

Electrical Safety Test

Equipment which is powered by 240volt, 50Hz mains electricity can be constructed with a protective earth (3-wire mains cable) or be of double insulated construction (2-wire mains cable). These are known respectively as Class I and Class II devices.

Mains powered equipment which is double insulated (Class II) and doesn't have a patient circuit (applied part) as a rule doesn't need an electrical safety test and should be checked for function only.

Mains powered equipment which has a protective earth (Class I) but doesn't have a patient circuit (applied part) needs a basic electrical safety test and also should be checked for function.

Mains powered equipment of either Class I or II construction which has a patient circuit (applied part) needs an electrical safety test and a function test. The Class II equipment will only need the patient connection parameters tested.

AS/NZS-3551:2004 specifies what parameters should be tested. These include:

Basic Parameters

Insulation Resistance
Earth Wire Resistance
Earth Leakage Current

Patient Connection Parameters

Patient Lead (Applied Part) Leakage
Mains On Applied Parts (Mains Contact Current)

Note: 240volt electrical leads on medical equipment do not need to be separately tested and tagged.

Function Test

It is important to know if a medical device is measuring the physiological parameters or delivering the set energy to the accuracy required. These parameters are largely device dependent or class-of-device dependent and so are harder to define than the electrical safety parameters.

AS/NZS-3551:2004 gives some guidance on what parameters should be tested. These include the accuracy of such parameters as pressure, rate, volume, voltage, current, power, energy and illumination levels. They also include the operation of alarms, interaction with other equipment including networks and the fidelity of printed output.

Calibration

Some medical equipment requires calibration either periodically or when it is found to be operating outside of design specifications during routine testing. Biomedical Engineering Departments will sometimes send equipment to specialised facilities for calibration if they do not have sufficient numbers of equipment to justify purchase and re-calibration of the specialist test equipment required to perform calibration. These facilities may be the service departments of the equipment vendors or specialist test houses.

Preventative maintenance

Some medical equipment requires regular maintenance to keep it operating at optimum performance. This may take the form of replacing parts with a “service kit” or may involve lubricating moving parts. Advice on what routine maintenance is required is best obtained from the manufacturers’ service manuals. Training from the manufacturer or vendor is usually required to enable BME Departments to conduct routine preventative maintenance.

Some examples of equipment that requires preventative maintenance include ventilators, anaesthetic machines, gas regulators, oil-filled suction pumps, heart-lung machines, dialysis machines and some infusion pumps.

Software upgrades

Many types of medical equipment now contain microprocessors, microcomputers or are in fact computers. As such these devices rely on embedded software for their operation. Software needs to be updated or upgraded from time to time to add features to the devices’ operation or to fix problems such as bugs or viruses.

Visual Inspection

Discerning visual inspection often reveals equipment problems instantly, and should not be overlooked in the management of medical equipment. Evidence of fluid spills, case or covers fractures, screen damage or inappropriate in-ward use can all be pointers to the need for more detailed testing. This can be part of a “walk-through” visit to clinical

units to identify issues not regarded by users as sufficiently major to warrant equipment withdrawal from service and sending to the service organisation.

FREQUENCY OF ROUTINE MAINTENANCE

For all medical devices in a BME Department's asset register, a plan for the maintenance of each device is required. The plan will involve performing one or more of the types of routine maintenance described or possibly no maintenance. The department should document the reasons for the type of maintenance regime chosen with appropriate justifications and risks identified.

AS/NZS-3551:2004 prescribesrisk management or if all else fails 12 months frequency.

Most BME Departments currently carry out routine testing every 12 months with a few departments using risk management principles to alter testing frequencies.

Methods of working out risk are abundant, with AS-4360 leading the way in methodology for risk calculation. Most risk scenarios are based in multiplying the likelihood of an incident happening with the severity or consequences of that incident. With medical equipment it also has to be modified by the acuity of the patients in the location in which the equipment is operating.

One system of rating equipment according to risk has been developed by the American Society of Healthcare Engineering (ASHE) – other systems exist.

If a BME Department has good records of its function and electrical safety testing over a number of years the data can be used to determine whether testing every 12 months is identifying any problems and whether the testing interval could be extended to, say, 24 months.

So when should a piece of equipment have a safety and function test?

- At the interval decided by the BME Department using risk management principles or every 12 months using the AS-3551 "if all else fails" frequency,
- Whenever the equipment is opened up for repair or modification, or
- If the equipment is dropped.

RESULTS OF ELECTRICAL SAFETY TESTING OVER MANY YEARS

Extent of testing

The first reference for safety and function testing of medical equipment is inevitably the manufacturer's specifications for the particular equipment. However few clinical engineering services are currently resourced to undertake testing to the extent specified by most equipment service manuals. Even the manufacturer's service agent rarely follows the manufacturer's specifications slavishly.

While a simplistic explanation would suggest that it is too time consuming and expensive to implement the complete procedures in most cases, we believe there is more to it. In many cases, it is easy to identify tests in the manufacturer's specifications which have little relevance to the safe and reliable function of a medical device. It is also often possible to identify tests which are made redundant by other tests in the test routine. Often a few specific parameters are critical to safe operation, and should be tested more regularly than other minor parameters, though often all are specified with the same high regularity in the manufacturer's documentation. It should be noted that not all parameters on a critical piece of equipment are necessarily critical parameters for testing.

In some cases, the pre-use calibration or testing by the clinical user further reduces the need for testing by the service organisation. Examples of heavy or light use of equipment can also justify deviation in test frequency from the manufacturer's specifications - leading to more frequent or less frequent testing than the manufacturer's advised test intervals.

Many clinical engineering services justifiably make priority decisions in order to optimise the use of resources without significantly reducing the effectiveness of their equipment procedures. While such practices can be essential if equipment is to be returned to clinical use in a timely manner, the health service which benefits from such savings is generally unaware of these steps, or their necessity. While the equipment service agents are often exercising responsible risk management in their equipment services, few area health services or CEOs are aware or involved in this process. Since risk management is a strategy which must be understood and endorsed by the whole organisation from the CEO down, this document aims to formalise the risk management approach taken, and to draw it to public attention.

Setting the priorities for testing (not frequency at this stage)

The parameters identified for regular testing in the management of medical equipment are required by AS3551 to be identified and documented at Acceptance Testing, and then tested throughout the clinical life of the equipment. There are three major inputs to the identification of parameters for testing:

- The equipment manufacturer's service manual provides the first reference.
- The track record of similar equipment in an area health service with extensive records over many years
- A detailed analysis of the equipment, its function, and the implications of its potential malfunction, as well as the mode and location of its intended use.

In most cases, more than one of the above three sources can contribute to the identification of testing to be undertaken throughout the life of medical equipment.

While the Standard suggests that the identified parameters should be documented and tested throughout the life of the equipment, there can be a need for periodic review of the testing undertaken. An increase in user problems, a change in the areas where equipment is used, or a problem with battery life or software upgrades may all result in additional parameters being added to the testing schedule during the life of the equipment. Alternately, the downgrading of equipment from high dependency areas to outpatient areas, or significant improvements in equipment reliability (supported by database records of service faults) may justify a reduction in the parameters being tested. It is important that any change in the extent of safety and function testing of medical equipment is based on sound information, is well documented, and is periodically reviewed for appropriateness.

There are no hard and fast rules for setting the regularity of equipment testing, but the general approach has long been summed up as follows:

*If you find heaps of faults, you are not testing often enough.
If you find no faults, you probably can test less often
Aim to achieve an acceptable level between these extremes*

Risk Management

While much of this discussion has used the terminology of Risk Management, some managers of medical equipment have moved against the terminology and concept of Risk Management. They claim to undertake all testing according to manufacturers' specifications because Risk Management is not accepted by their directors, or in some cases, the ACHS accreditors.

Others have claimed that the process of Risk Management is really a justification for not doing the repetitive and meticulous testing specified by manufacturers.

We would suggest that every aspect of the management of medical equipment involves aspects of Risk Management – whether the terminology is used or not. The decisions to purchase medical equipment, to implement user training, to service it in house or to take out a comprehensive contract, and the means by which this is all achieved all involve the principles of Risk Management.

Say what you do...

It is essential that any coherent plan for the management of medical equipment be documented in order to provide criteria against which a service can be assessed – whether by the accreditor, the coroner or the general public! The more a plan deviates from manufacturer's specifications, the more it is essential that it be well documented and based on sound risk management principles.

and do what you say...

It is essential to set the testing priorities in a manner which recognises the different priorities of equipment, and then to expect these to be met whether for high or low risk equipment. An example of this may be to allocate the testing of defibrillator batteries for six monthly testing, and the testing of stand-alone NIBP machines for every 24 months. However if these are the prescribed test intervals, then a coherent plan should aim for say 95% compliance with both within a 10% interval overrun. This approach recognises the difference between the appropriate testing needs of different equipment, and provides a much better management tool for knowing the status of the equipment and its testing.

Not doing what you say...

An alternative to the above is to allow an overrun on the testing schedule according to the nature of the equipment and its application. An example of such a proposal might look like this:

Life Support Devices - Inspection and PM completed 100% within 10% interval overrun on scheduled date.

High Risk Devices - Inspection and PM completed 90% within 20% interval overrun on scheduled date and 100% within 120% interval overrun on scheduled date.

Medium Risk Devices - Inspection and PM completed 70% within 20% interval overrun on scheduled date and 100% within 120% interval overrun on scheduled date.

Low Risk Devices - Inspection and PM completed 50% within 20% interval overrun on scheduled date and 100% within 220% interval overrun on scheduled date.

This approach argues that it is essential to adhere to the advertised testing program for life support devices, but that some over-run on testing is allowed for critical non life-support devices. While the testing outcome of this approach is similar to that above, we believe it is better to specify what will be done quarterly, annually, two-yearly etc and then expect this to be achieved with a similar level of compliance for all categories of equipment.

This is certainly open to discussion.

Where next?

Ideally the clinical engineering community would be united on what testing is to be undertaken on medical equipment, and would develop a unified practice which is documented, published and updated periodically as process or thinking changes.

A useful contribution to the standardisation of testing would involve the publication of standard test sheets for medical devices, and their periodic updating. While the resources to undertake this are not insignificant, a greater problem is the willingness of practitioners to commit to this process. An inevitable conservatism amongst medical establishments makes it unattractive to publish anything which might be seen to undermine the specifications of medical equipment manufacturers.

It remains unclear where this discussion should go next..

- Should there be an additional chapter to AS-3551 which specifies good practice in the management of medical equipment? Would Standards Australia publish it if seen to undermine some of the recommendations of equipment manufacturers who have been influential with Standards?
- Should an Engineers Australia working group to refine these ideas and publish a guidance document?
- What resources are available to maintain and update this guidance as devices, practices and legal precedents change?
- What does the community want? The clinical engineering community, the health care administrators, the accreditors, the manufacturers of medical equipment...??? Is a practice document likely to be accepted, or rejected by major players within the health care arena?

Your comments are sought:

Feedback to either:

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