

Part One:

Failures of Medical Equipment

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Introduction

Equipment may fail even if it is correctly installed in the appropriate environmental conditions, and appropriately used and maintained.

Failure of equipment refers to its inability to perform its required function. Equipment failure occurs because certain components (or parts) that make up the equipment deteriorate or break down. The failure phenomena and failure mechanisms of the components are clarified by developers and researchers in the field of equipment components. In addition, the failure rate of each component based on extensive data and experiences is presumed or determined.

Failure of Medical Equipment ^{Note 1.1)} including Hospital Laboratory Equipment ^{Note 1.2)} sometimes becomes a major issue. Experience shows that many failures of medical equipment occur two or three years after installation. Moreover, a further increase in failures can be expected again after another two to three years. The pattern of these failures (failure occurrence distribution) practically conforms to statistics and theoretical failure prediction (e.g. failure rate curves and reliability predictions). On the other hand, causes of medical equipment failures vary and in some cases overlap. This is confirmed by analysing individual failures. The causes of equipment failures are considerably influenced by medical equipment installation environments, equipment usage, maintenance and inspections, etc.

According to statistics for medical equipment failures, about 80% of all failure cases are caused by preventable factors (Figure 1.1). For instance, failures due to inadequate maintenance account for about 60% of all the failure cases. In this case, most failures arise from deterioration of accessories and consumable components. The deterioration time of the accessories and consumable components can, however, be predicted by carrying out maintenance and inspection. Therefore, 60% of all these failures can be prevented by replacing such 'consumable parts' on a regular basis, or replacing them immediately when the equipment becomes defective. These are not real breakdowns of the equipment. In addition to this, failures due to inappropriate handling, environmental stress and wear-out account for about 20% of all the failure cases. Most of these can also be prevented by carrying out appropriate measures based on MMS. It can be said that 80% of medical equipment failures are, therefore, preventable.

This Part will first describe the time distribution

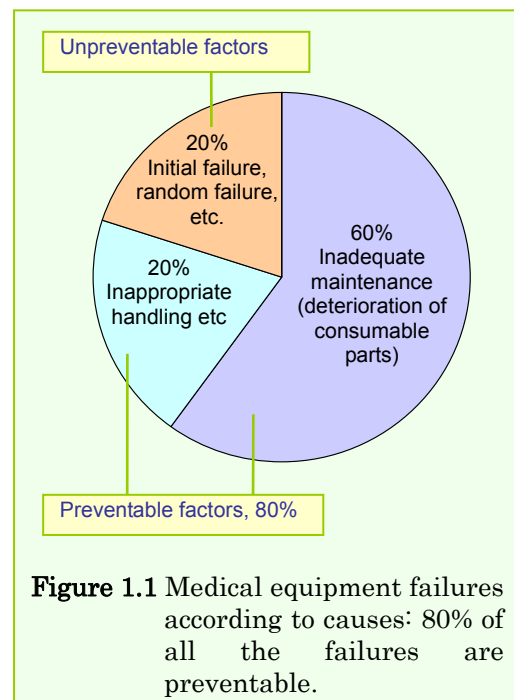


Figure 1.1 Medical equipment failures according to causes: 80% of all the failures are preventable.

of equipment failures without maintenance, and will then describe the case study, analysis, classification and statistics of the equipment failures. As a result, the conformity between the actual failure occurrence and the theoretical and statistical failure occurrence can be recognized. In addition, it describes maintenance and management issues for equipment based on the problems with the operating environment and technical service, and the importance of in-house services carried out by the hospital itself. Based on these, we can consider the root cause of problems in medical equipment failure.

1.1 Failure Rate Curve

Imagine someone has 1,000 identical colour televisions (CTVs) produced as one lot in the same environment and then turns the power on, and puts them into a state of continuous use. Breakdowns begin to occur with the passing of time. Some CTVs break down immediately after the switch is turned on, other CTVs break down after a certain time passes, and other CTVs do not break down even after exceeding the pre-set lifespan.

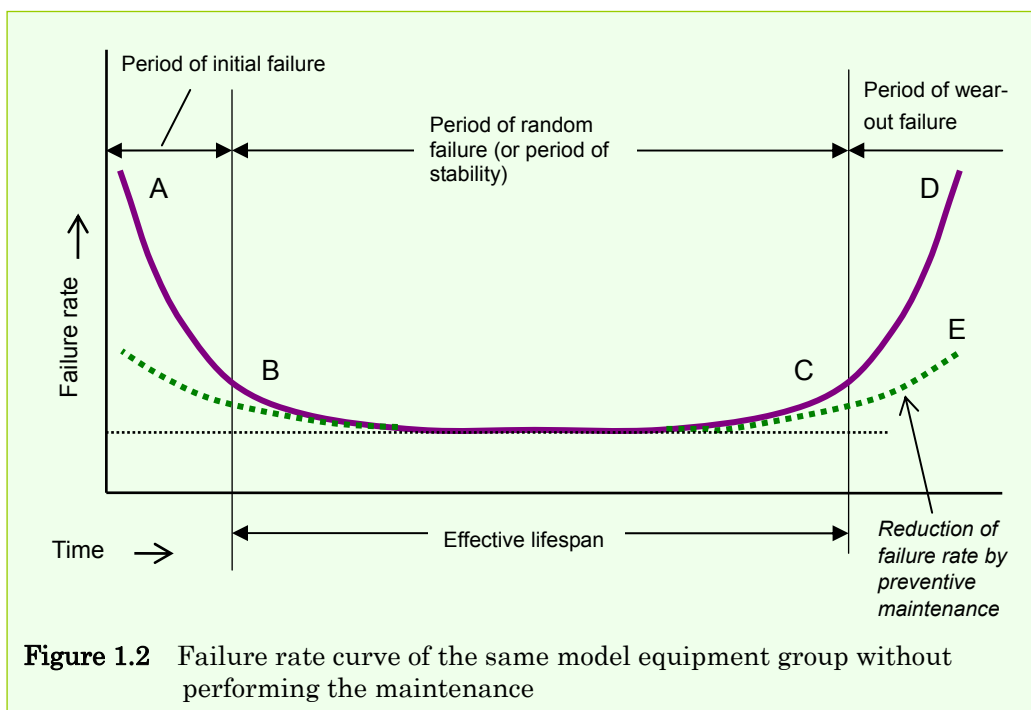
Taking statistics of such failure phenomena, a curve as expressed in Figure 1.2 is obtained. This is called a 'U' shaped curve, and is basin- or bathtub-shaped. This curve is applicable to general electronic equipment such as computers, copy machines, DVDs, CTVs, video cameras, etc. and also to general medical equipment, as well as to the mortality rate of human beings.

Equipment failures can be categorized into three stages according to the occurrence rate with the passage of time. That is, since the causes and phenomena of the failures in each stage are different, these are called Initial Failure, Random Failure and Wear-out Failure respectively.

The failure rate is high during the initial stage. This may occur as soon as the operation of equipment is begun (curve AB), resulting from inappropriate circuit design, improper choice of components, faults in the production process, etc. Such defects generally may not be detected by the user, because such shortcomings are often observed and rectified during examinations/inspections after manufacturing in the factory or at the installation process. In addition, progress in reliability engineering in recent years has remarkably decreased the initial failure rate. However, because unexpected initial failures occasionally occur, reputable manufacturers set the one-year guarantee after the equipment installation.

In the second stage (curve BC), the state of the equipment changes, and the equipment failure rate decreases^{Note 1.3)}. During this period, failures occur at random, however the failure rate is low. This can be said to be a period of stability, corresponding to the period of youth to middle age if compared to the lifetime of human beings.

In the third stage, the curve CD shows that the equipment's condition has deteriorated. Here, the failure rate starts rising again resulting from the deterioration, wear-out or breakdown of components of

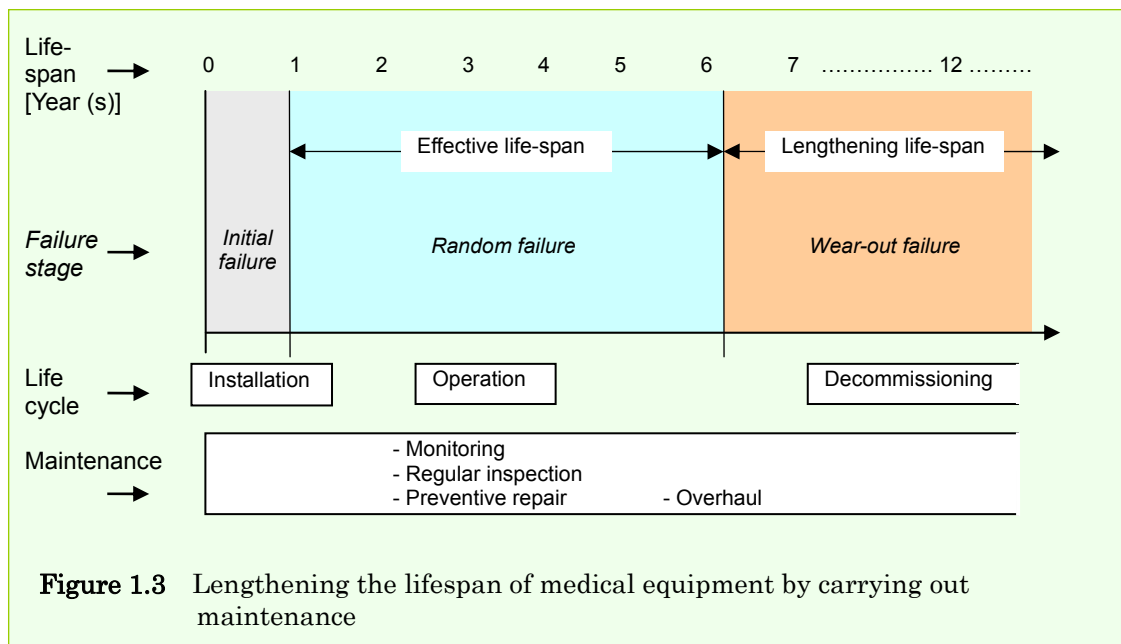


the equipment with the passage of time. However, during this period, the failure rate can be reduced through replacement of worn-out or faulty components, and by their proper adjustment. Note that this will extend the lifespan of the equipment as shown by curve CE.

When failures appear repeatedly, the budget expenditure on repairs increases and the equipment's reliability and safety cannot be guaranteed anymore. This should indicate the end of the equipment's life.

Equipment failures can be from many other causes besides the above-mentioned failures. In the case of medical equipment, there is usually a zero tolerance of breakdowns. The maintenance that prevents a breakdown of medical equipment, therefore, must be carried out even in the period of stability.

For example, in Japan where the depreciation and cost management system have progressed, the lifespan of medical equipment is generally set at four to seven years depending on the type of equipment (from '*Illustrated Medical Equipment Dictionary*' Sangyo Chosakai, Japan). Effective lifespan is about six years also in Figure 1.2. On the other hand, electronic circuits used in equipment have a long lifespan of ten years or more. For this reason, if maintenance to replace deteriorated components by new ones is carried out, actual lifespan of the equipment becomes ten years or more as shown in Figure 1.3.



1.2 Failure Analysis

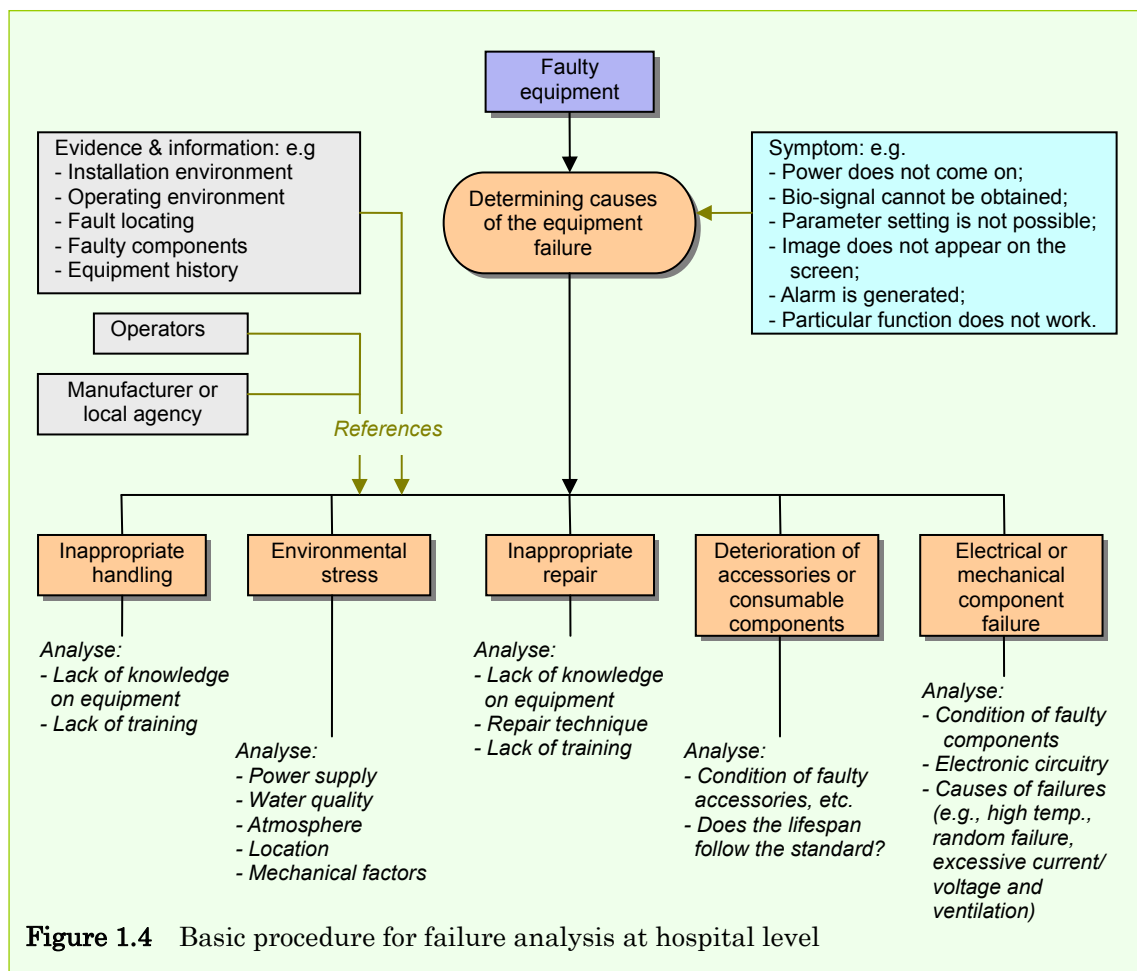
At clinical sites, medical equipment faces various stresses, and these stresses can cause an equipment failure. In addition, medical equipment might already have been exposed to some stresses before arriving at the site. These stresses can result in both preventable and unpreventable breakdowns. **The evaluation and analysis of these abnormalities is very important.**

At the hospital level, the failure analysis helps to maintain reliability and safety of medical equipment through:

- **Technical feedback to the equipment manufacturer;**
- Measures against environmental conditions;
- Improvement of maintenance and inspection methods.

Failure analysis at the hospital level looks at the cause of equipment failure from aspects of the installation and operating environments, symptom, fault locating, faulty components, equipment history, etc. Through analysis, the cause of the failure is determined and classified (see Figure 1.4). Based on this, maintaining the reliability and safety of equipment positively contributes to the effective provision of healthcare services in the hospital.

At the equipment manufacturer, the mechanisms of failure are studied in more detail. Faulty components are scientifically analysed using analytical instruments such as electron microscopes, X-ray microscopes, specially designed fault analysers, etc. This is an effort to develop a high quality product.



The number of failure cases remarkably decreases after implementing MMS. However, the failure analysis should not be stopped. Continuing the failure analysis can help to maximize hospital service and to prevent medical accidents even if equipment failure happens.

Equipment failures occur due to various causes. One method of classification uses nine chronological categories. These are as follows:

- 1) Improper storage and transportation,
- 2) Initial failure,
- 3) Inappropriate handling,
- 4) Inadequate maintenance,
- 5) Environmental stress,
- 6) Production deficiency,
- 7) Random failure,
- 8) Inappropriate repair technique,
- 9) Wear-out failure.

In certain cases, some of the above-mentioned failures overlap. One of the reasons is that although most of the failures could be prevented by implementing MMS, use of equipment continues without maintenance. If this is not rectified, equipment will be exposed to various stresses from inappropriate environment, inappropriate handling, wear and deterioration, etc. These overlapping stresses cause the equipment failure.

Most causes of medical equipment failures can be theoretically and technically analysed. Typical examples of the above-mentioned equipment failures from 1) to 9) that were directly experienced in some countries are shown below:

1.2.1 Improper Storage and Transportation

Medical equipment is exposed to various stresses from the time of leaving the manufacturer and agency to arriving at the end-user. The equipment is possibly exposed to vibration, high temperature and high humidity due to inadequate infrastructure such as roads, storage facilities, etc., and such exposure can cause equipment breakdown. On the other hand, medical equipment can possibly break down due to improper storage and transportation even after arriving at the hospital.

Examples:

■ Surgical Operating Microscope

An optical axis came off due to vibration while transporting it on the vehicle. Insurance was applicable in this case, and the local agency completed the repair of this equipment at no cost.

[Sanjay Gandhi Post-graduate Institute of Medical Sciences, India]

■ Autoclave

By applying heat and pressure to equipment that is used to sterilise medical instruments, linen, etc. for surgical operation, ward and laboratory procedures (Photo 1.1), every microbe (pathogenic and non-pathogenic) is killed.

Several parts of the equipment such as the frame, handle, power transformer, etc. were corroded because the equipment had been kept in the warehouse at both high temperature and humidity for a long time before arriving at the hospital. Insurance was not applied, because the hospital engineering unit was able to restore the equipment. The equipment was completely restored by cleaning the corroded parts, and carrying out performance and safety tests.

[National Maternal and Child Health Centre, Cambodia]



Photo 1.1 Example of an Autoclave

■ **Doppler Fetus Detector**

This is equipment that is used to detect fetal heart beats at 11 weeks of pregnancy (Photo 1.2).

The fault symptom was that the equipment randomly detected and counted heart beats in the absence of actual signal. The equipment had been stored in the warehouse at high temperature and humidity for a long time before arriving at the hospital. It was concluded that such improper storage caused characteristic changes of a high sensitivity electronic circuit inside the Doppler probe. As a result, the Doppler probe interpreted fictitious signal as a Doppler signal.

12 out of 20 Doppler machines that were imported had been defective with the same symptom. After consulting with the Engineering Department of the equipment manufacturer, technical advice was given on how to calibrate the electronic circuit inside the Doppler probe. As a result, problems with the defective items were rectified by the hospital engineering unit without requiring insurance.

[National Maternal and Child Health Centre, Cambodia]



Photo 1.2 Example of a Doppler Fetus Detector

■ **Mobile X-ray Equipment**

Mobile X-ray equipment is generally not fixed in the X-ray room, and is moved to where the patient is (Photo 1.3).

The mA/kV meter did not function. The equipment, packed in original boxes, had been kept in the hospital warehouse at high temperature and humidity for two years. As a result, part of the equipment was corroded, and the mA/kV control switch connection had become loose.

The corroded parts were cleaned; performance and safety examinations were carried out, completing the repair works. The equipment came to be fully utilised.

[Kompong Cham Referral Hospital, Cambodia]



Photo 1.3 Example of Mobile X-ray Equipment

■ **Mobile X-ray Equipment**

This equipment was being moved from place to place by a porter who had no technical know-how, so he was paying no attention to proper handling. As a result, due to vibrations, a Printed Circuit Board (PCB) was damaged, and the equipment became inoperative.

After completing the repair of the PCB, instructions were given to the responsible person on how to move the equipment properly. This case overlaps with inappropriate handling of equipment.

[Islamabad Children's Hospital, Pakistan]

1.2.2 Initial Failures

This equipment breakdown occurs less than one year after installation as described in section 1.1. Inadequacy in the design, improper choice of components, faulty manufacturing process, etc. bring this failure. Symptoms of this type of breakdown do not have specific characteristics; it is often similar to random failures and/or wear-out failures. In general, equipment that fails for any reason in the first year after installation is classified as having an initial failure even if the cause of the failure is random failure. In the case of production deficiency, the reputable equipment manufacturer makes it public.

Generally, a breakdown that occurs less than one year after installation is considered under the one year guarantee system, and receives free repair services from the equipment manufacturer or its agency. However, in developing countries it is difficult to receive the guarantee directly from the equipment manufacturer. Moreover, it is very difficult to receive the guarantee from the local agency.

This is because some local agencies do not have enough ability and capacity to recognise initial failure, nor in repair techniques, customer management or replacement of faulty equipment.

Examples:

■ **Ultrasonic Diagnostic Equipment**

This refers to diagnostic equipment that obtains images of internal organs in the abdomen such as the kidney, liver, spleen, pancreas, bladder, major blood vessels, etc. by using ultrasound (Photo 1.4).

Six months after installation, part of the ultrasonic image could not be displayed on the screen. It was diagnosed that the ultrasonic probe was defective. As a result of negotiation with the supplier, a new probe was exchanged for the faulty one at no cost. The faulty probe was collected in order to study the cause of failure at the equipment manufacturer.

[National Maternal and Child Health Centre, Cambodia]



Photo 1.4 Example of Ultrasonic Diagnostic Equipment

■ **Colour Monitor for Patient Education**

The internal power supply did not come on. This example was a typical random failure, but it was classified into initial failure because the equipment broke down within one year of installation.

Appropriate actions (e.g. repair by local agency or sending it back to the manufacturer for repair) could not be done because the guarantee arrangement with the manufacturer and local agency was not functioning in this country. In this situation, the hospital engineering unit carried out successful repair works, but it took a long time.

[National Maternal and Child Health Centre, Cambodia]

■ **Blood Gas Analyser**

This refers to equipment that is used to measure pH and gas levels in blood.

Six months after installation, calibration with a standard sample became impossible. The cause was that the gas detector whose lifespan is about two years in normal use became defective at an early stage.

Negotiations with the equipment manufacturer resulted in the faulty gas detector being replaced by a new one at no cost.

[University Teaching Hospital, Zambia]

1.2.3 Inappropriate Handling

Sophisticated equipment whose users have inadequate knowledge and skills to operate are often introduced. In addition to this, some local agencies are not able to install new equipment properly. In the case of imported equipment, the operators are not able to read the operating manuals either because of the foreign language or because they may not have any interest to read it. As a result, handling and operation of equipment is improper, and this causes equipment to break down.

It must be remembered that equipment failure caused by inappropriate handling often results in significant impact upon the hospital budget. On the other hand, improper operation of medical equipment increases risk of accidents to operators, patients and surroundings. Therefore, operators' skills in handling medical equipment should continuously be improved by conducting user training on operation and maintenance. Appropriate operation and application of medical equipment ensure reliability and safety, thus helping to achieve correct diagnosis and therapy.

Examples:

■ **Fetal Actocardiograph**

This refers to equipment that is used to monitor fetal heart beats and mother's uterine contraction (Photo 1.5). The other name is Cardiotocograph (CTG Monitor).

The failure symptom of the equipment was not being able to make measurements because of improper handling of the transducer. After the transducer was replaced by a new one, the equipment was able to make measurements and operate normally again.

Transducers are very expensive (approx. US\$ 660.00 each) for the hospital to afford. To avoid such unnecessary expenditure and to keep the equipment safe and reliable, an in-service training on the use and maintenance of this equipment was conducted in collaboration with the Nursing Division in the hospital (Photo 1.6).

[National Maternal and Child Health Centre, Cambodia]



Photo 1.5 Example of a Fetal Actocardiograph



Photo 1.6 In-service training on operation and maintenance of Fetal Actocardiograph for midwives: those who actually operate it (National Maternal and Child Health Centre, Cambodia): A former anaesthetic nurse as a C/P on medical equipment management gives a presentation.

■ Patient Monitor

This refers to equipment that is used to monitor the vital signs of the patient under surgical operation and intensive nursing care (Photo1.7); i.e. it measures blood pressure, breathing rate, ECG, as well as saturated oxygen (PO_2) and carbon dioxide gas (PCO_2) in blood.

The electronic parts and copper tracks on the PCB became corroded after the content of a medicine bottle that was put on the equipment spilt inside the equipment. As a result, the equipment became inoperative. This example could have been easily avoided by paying more attention to equipment usage.

If even one drop of water is spilled on the PCB of an electrical item while in operation, it causes corrosion of electronic parts or of the PCB due to electrolysis (Photo1.8). If the equipment is continuously operated in this status, the damage will develop into becoming serious, which can finally make it difficult to repair. When liquid is spilled into the equipment, turn off the power switch as long as the patient is not affected. Request ME section or local service agency to carry out inspection.

One week was spent on rectifying fault by changing the corroded parts, and calibrating electronic circuits repeatedly. Such effort is often necessary to save the budget of purchasing new equipment.

[Islamabad Children's Hospital, Pakistan]



Photo 1.7 Example of a Patient Monitor

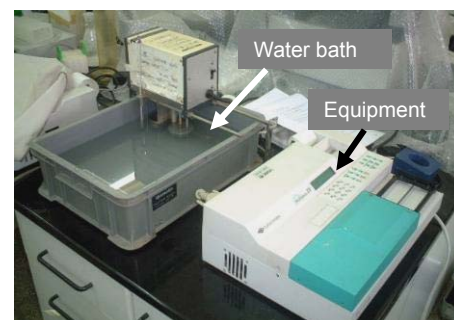


Photo 1.8 Inappropriate placement of equipment which could result in equipment failure

■ Haematocrit Centrifuge

A centrifuge is a rotating machine which uses centrifugal force to separate elements of different density. The haematocrit centrifuge is a centrifugal machine used for separating blood at high speed (12,000 rpm).

The screw on the sample holding lid was not tightly screwed (Photo 1.9). As a result, during rotation, the lid was blown off, destroying the chamber lid. In this case, either operator or surrounding staff could have been injured. In the worst case, it could have caused a fatal accident. Centrifuges can be hazardous if improperly used.

[National Maternal and Child Health Centre, Cambodia]

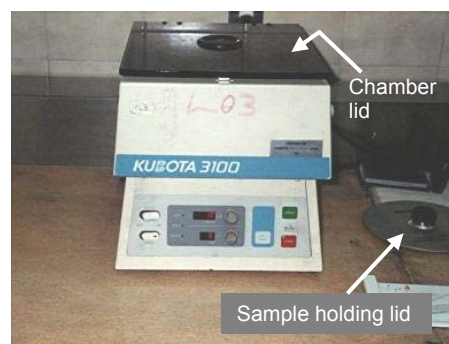


Photo 1.9 Example of a Haematocrit Centrifuge

1.2.4 Inadequate Maintenance

Generally speaking, medical equipment cannot be used without accessories and consumables. The lifespan of such 'consumable components (excluding daily consumables such as recording papers, disposable electrodes, gels and reagent)' is shorter than that of the actual equipment. For instance, bulbs for surgical operating lights last about six months^{Note 1.4)}, and electrodes of pH meters last about two years. In addition, some isolated components used for equipment assembly also deteriorate in a short time. These lifespans, of course, depend on the equipment usage.

The lifespan of consumable components is mostly predictable. Procuring these in advance can prevent equipment failures. As a result, the hospital will get better service from its equipment. To achieve this, carrying out regular maintenance and inspection of equipment is essential. On the other hand, such a concept is sometimes not understood. People only notice that consumable components are out of stock when the necessary components are required to service or to repair faulty equipment. Even if a local agency exists, procurement is very difficult and expensive. Equipment considered as 'broken down' is, therefore, left or abandoned in the corner of a storeroom.

In fact, the purpose of maintenance is to monitor and maintain the performance, reliability and safety of equipment. Replacement of deteriorated components is not always necessary for carrying out maintenance. For instance, carrying out user calibration (e.g. zero point, reference point and line voltage adjustment), which is important for accurate clinical diagnosis, is essential.

For clinical laboratory equipment (analytical), the cleaning of specific parts and daily calibration are essential. If this is not carried out, such equipment cannot be reliable. Once the equipment develops a malfunction as a result of such inadequate maintenance, a high restoration cost may be required.

Examples:

■ ECG Equipment

This means equipment that is used to record the heart activities in wave forms integrating spatially and time-wise, and to diagnose cardiac conditions (Photo 1.10).

In this example, the measurement conditions could not be achieved due to a fault in the battery circuit. By circuitry design, this equipment will not go into measurement when the back-up battery voltage has discharged below a certain minimum voltage. After replacing the rechargeable battery with a new one, the equipment became operational again.

Rechargeable batteries are also used in other medical equipment such as defibrillators, Doppler fetus detectors, infusion pumps, patient monitors, etc. The lifespan of the

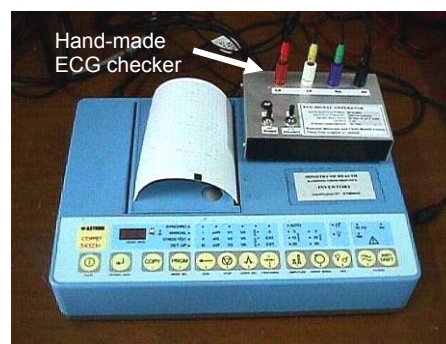


Photo 1.10 Example of ECG Equipment (under testing by using a hand-made ECG checker)

rechargeable battery is about two-three years, though it depends on the discharge frequency and usage temperature. The back-up battery should be procured in advance before the lifespan expires.
[Kompong Thom Referral Hospital, Cambodia]

■ Oxygen Concentrator

This is equipment that takes in air, separates oxygen from nitrogen and other gases, and generates concentrated oxygen for treatment. The other name is an oxygen generator.

Oxygen gas was not generated because the 'air separating filter (sieve bed assembly)' was past its life expectancy (see Figure 1.5). The lifespan of the sieve bed assembly is about two years, though it depends on use time, model number, etc. When oxygen is not generated due to an expired sieve bed assembly, the equipment generates an alarm. However, use of the equipment was still continued after turning off the alarm switch. The operator was convinced that there was no problem in the equipment function because the compressor that takes in and compresses air was working normally.

In this example, inadequate maintenance and inappropriate handling overlapped. Moreover, this was a critical mishandling of equipment that threatened a patient's life. The equipment supplier had to provide sufficient explanation about how to use the equipment correctly and how to replace such a critical consumable component.

[Malalai Maternal Hospital, Afghanistan]

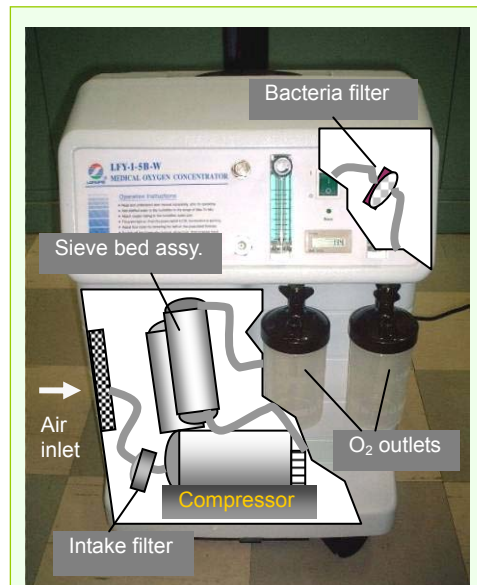


Figure 1.5 Main consumable components inside the oxygen concentrator: This equipment is a life-supporting equipment, therefore, regular inspection must be carried out to maintain safety for patients.

■ Centrifuge

The motor did not rotate due to a damaged commutator. The initial problem was worn-out carbon (or motor) brushes which were not replaced, but the equipment continued to be used resulting in the commutator getting damaged. Because the commutator cannot be repaired, US\$800 was spent on purchasing a new motor as compared to spending US\$20 to replace carbon brushes. Remember that repair is more costly than maintenance.

By checking motor brushes at least once a year, the condition of worn-out motor brushes should be monitored. This information is available in the operation manual for the operator to read and make use of (see Figure 1.6).

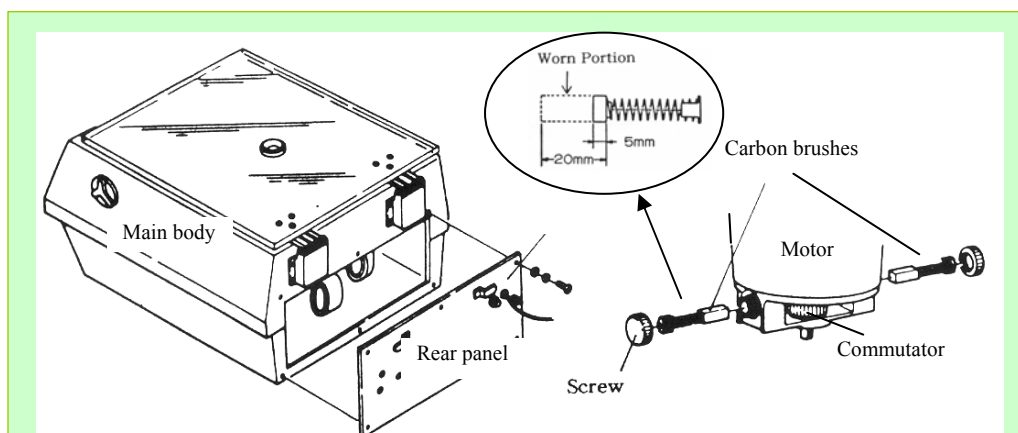


Figure 1.6 Guide for inspecting motor brushes as shown in instruction manual: Note that some of the latest models of centrifuge do not use motor brushes (brushless motor).

Because of this, an attempt was made to correct this situation by establishing a laboratory equipment maintenance system with clinical laboratory technologists.

[National Maternal and Child Health Centre, Cambodia]

■ **High-pressure Steam Steriliser**

Equipment that automatically sterilises medical instruments, linen, etc. for surgical operation, ward and laboratory procedures. To process a large amount of items at a time, this equipment is built on a larger scale than an autoclave (Photo 1.11).

Due to an open circuit on one of the three heaters, the temperature in the boiler could not rise to the required temperature. Acquisition of heaters which were ordered from India took one and half months. As a result, sterilisation facility in the hospital was badly affected, and the surgical operating function was nearly halted during this period.

In this example, the deterioration of the heater would have been noticed by carrying out periodic inspection at least once every three months. As a result, the heater would have been ordered in time, and such an incident would have been prevented (see Photo 1.12).

[Tribhuvan University Teaching Hospital, Nepal]



Photo 1.11 Example of a fixed installation type High-pressure Steam Steriliser



Photo 1.12 Preventive maintenance for a High-pressure Steam Steriliser (National Maternal and Child Health Centre, Cambodia): Two technicians carry out regular inspection and preventive repair to avoid equipment breakdown which would result in interrupting hospital function.

■ **Medical Freezer**

This equipment stores samples for research by keeping the temperature at -30°C .

The temperature alarm that indicates malfunctioning of temperature control was generated. This was caused by ice piled up inside the freezer compartment (Photo 1.13). If the equipment is continuously operated in this status, such a small fault will become severe due to overload of the compressor, which can finally make it difficult to repair. Medical freezers are also expensive. In addition, temperature rise will result in sample loss.

In this example, the fault could have been prevented by only a little attention such as removing frost and cleaning a filter and the inside/outside of the equipment. Temperature management is a basis of the quality assurance for research, and it starts with cleaning the freezer.

[University Teaching Hospital, Zambia]



Photo 1.13 Ice piled up inside the freezer compartment

■ **Ultrasonic Diagnostic Equipment**

The image could not be displayed on the screen. This breakdown was caused by dirt and dust piled up on PCBs, the chassis and connectors inside the equipment. This was because maintenance of this equipment had never been done in five years since installation. Dirt and dust are great enemies of equipment and if allowed to pile up, will result in equipment failure, as is the case in this example.

The equipment was stripped apart, dirt and dust were removed, and connectors were cleaned using alcohol. The result was that the equipment became operational again.

[Sihanouk General Hospital, Cambodia]

■ **Water Distiller**

Scale contained in the water supply piled up thickly on the glass cover of the heater due to inadequate regular maintenance. As a result, the glass cover cracked due to excessive heating.

The water supply in this country is hard water, and it is necessary to remove the scale frequently. To improve the installation environment of equipment, it was necessary to introduce a water treatment system. In this example, inadequate maintenance and improper environment overlap each other. In the absence of maintenance such a breakdown can happen anywhere.

[Islamabad Children's Hospital Pakistan]

■ **Blood Gas Analyser**

The accuracy on measured values had deteriorated. This was because routine cleaning and daily calibration had been neglected. This resulted in the sensitivity and stability level of measuring detectors becoming irreparable. The detectors were replaced by new ones at high cost (US \$1,200).

[University Teaching Hospital, Zambia]

1.2.5 **Environmental Stresses**

Medical equipment is composed of highly sensitive electronic circuits and structures. The installation environment of the medical equipment, therefore, demands clean air, good quality water, stable AC power supply, isolation from vibration and noise, appropriate temperature and humidity, etc. Improper environmental conditions can cause the occurrence of breakdown. In addition, there are many conditions where frequent power failure exists. In developing countries, however, it is not easy to put in place strict management of installation environments.

Besides the above, attention should be paid to loose connections between the power plug (or mains plug) and the power outlet (or socket). The loose connections give stress to the equipment, and in turn may cause the breakdown. Above all, it must be remembered that the loose connections cause remarkable decrease in the reliability and safety of medical equipment.

Examples:

■ **Ultrasonic Diagnostic Equipment**

The equipment had been previously used in an air-conditioned room, which was designated as an ultrasonic echo room. Afterwards, the equipment was moved to the emergency room, which was not air-conditioned, and which also had a sink nearby. Several weeks later, the operation keyboard became inoperative.

Since it had been assumed that both high temperature and humidity caused bad conductivity to the keyboard, the equipment was moved to another air-conditioned room, and operated normally again.

Thus, equipment failure that does not require repair work often occurs. This example gives us the basic concept on repair work, as follows: before opening the equipment, an 'appropriate failure diagnosis' based on the theory and knowledge of medical equipment is required.

[National Maternal and Child Health Centre, Cambodia]

■ **Oxygen Concentrator**

Part of the internal power supply broke down due to unstable power supply voltage. According to a report, there is sometimes rapid voltage change in the range of 170-240V in the concerned district; 220V is the nominal voltage in this country. The voltage regulator is not designed for use in an area

of such great power-supply voltage fluctuation. The internal power supply was repaired, and continued to monitor the environmental condition in the concerned area.

[Koh Kong Provincial Hospital, Cambodia]

■ **Ventilator**

Equipment that artificially breathes for a critically ill patient (Photo 1.14).

The excessive voltage supplied by the emergency generator during power failure damaged the internal power supply. Part of the power supply in the equipment was burnt due to excessive current.

The voltage regulator connected to the ventilator was also damaged at the same time. Such an accident must not happen in life-support equipment such as ventilators.

[Sanjay Gandhi Post-graduate Institute of Medical Sciences, India]

■ **Laboratory Incubator**

This relates to equipment that maintains a constant temperature of 37°C in the chamber, and is used for bacterial culture.

Loose connection between the power plug and the power outlet generated sparks and noise, which resulted into malfunctioning of the CPU temperature control circuit. As a result, the temperature setting could not be achieved. Sparks and noise in the power supply create a vital stress on the latest models of medical equipment that employ a CPU controlled circuit.

A high quality power plug is originally used for laboratory and medical equipment. On the other hand, it may be that the power outlet (socket) into which the power plug of the medical equipment is connected is of poor quality. The original power plug of the equipment may be replaced by a poor quality one to match to such a poor quality power outlet (see Figure 1.7). This remarkably decreases the reliability and safety of the medical equipment.

[Medical Research Institute, Sri Lanka]



Photo 1.14 Example of a Ventilator in connection with an anaesthesia apparatus

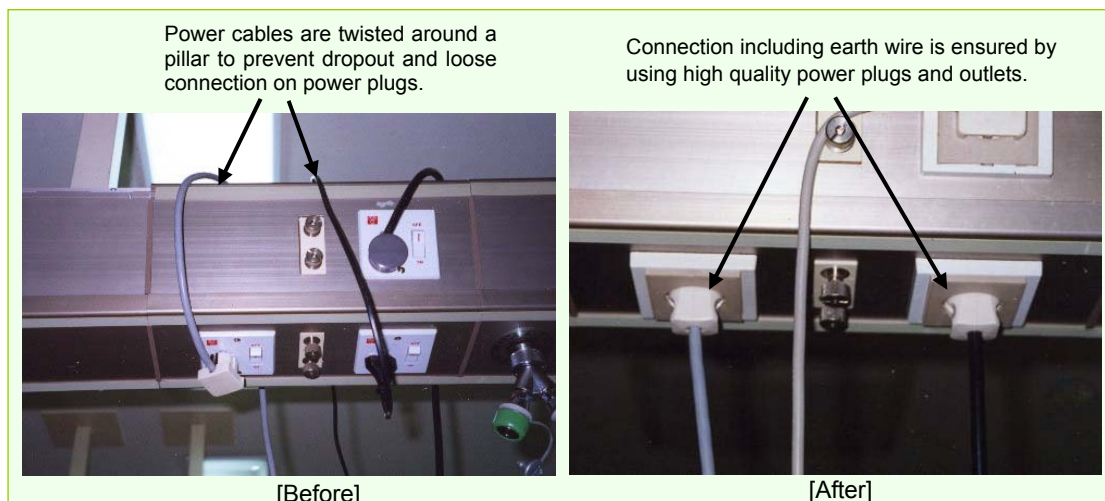


Figure 1.7 An example of improving the connection of power plugs and power outlets (Islamabad Children's Hospital): Because loose power supply connections remarkably decrease the reliability and safety of medical equipment, both plugs and outlets were replaced by high quality ones that ensure correct connections.

1.2.6 Production Deficiencies

Reputable medical equipment manufacturers launch their high quality products in accordance with national or international standards as well as internal quality control. However, malfunctions and failures of equipment of uncertain cause occasionally occur several years after equipment is put to use. This is as a result of inadequacy in the design, improper choice of components, improper manufacturing process, etc., and this is called production deficiency.

When defective medical equipment caused by a production deficiency is found, the reputable equipment manufacturer makes it public according to PL Law (Product Liability Law), and responds by offering a free repair or recalling the product. However, such announcements do not reach developing countries easily. The defect of the equipment is recognised, but the equipment is continuously used despite malfunctioning, or it might be assumed to have broken down and be irreparable.

Even if there is an ME engineer, he/she may not be able to judge whether it is a production deficiency until he is familiar with the malfunction in other identical items of equipment. Considerable technology and effort are necessary to communicate and negotiate with the equipment manufacturer or agency for the confirmation and measures to be taken when the defect due to production deficiency occurs.

Examples:

■ Electro-surgical Unit

Equipment used for incision and coagulation in surgical operations (Photo 1.15).

Two years after installation, one of the units of the same model developed a fault in the HF power output. The Singapore branch of the equipment manufacturer agreed that the output limitation circuit was defective as a result of improper design of Capacitor-Resistor (CR) time constant circuit. New CR components with instructions for correct parameter measurements were also received at no cost.

By following the manufacturer's instructions, this problem was successfully rectified on both units.

[Islamabad Children's Hospital, Pakistan]



Photo 1.15 Example of an Electro-surgical Unit

■ Patient Monitor

Five identical models were introduced at the same time. About two years after installation, sphygmomanometry values from all five pieces of equipment became abnormal.

When an inquiry was made to the manufacturer, it was found that the air tubing used in the sphygmomanometry module deteriorated prematurely causing air leakage, resulting in abnormal measurements. All modules were sent back to the equipment manufacturer, and the replacement of the air tubing and its sphygmomanometry calibration were done at no cost.

[National Maternal and Child Health Centre, Cambodia]

1.2.7 Random Failures

Random failures can occur, without warning, within any period of the equipment's lifespan, though they are most common between one and six years after installation. Equipment may suddenly fail even if it is operated appropriately. However, in this period, the rate of random failure is only about 5% of all breakdown cases; therefore, this period is also called the period of stability.

Although the failure rate is very low in the period of random failure, it is said that failures of equipment provided by donors are very high. This is, however, not true. The failure rate is a result of deterioration of accessories and consumable components, not breakdowns of the main body of the equipment.

The random failure is a 'real breakdown', and the cause is mostly **due to breakdown of electronic components such as capacitors, diodes, ICs, resistors and transistors.** To solve these types of failures, advanced knowledge and technology concerning electronic circuits is required. An interest of ME engineers and technicians concentrates on the repair of electronic circuits. One of the reasons is that such activity is easily evaluated from an external view. However, it comes off from the essence of the MMS. Details of this will be described in Part 2.

The random failure of course has a reason. Verification of the failure phenomenon and the fault mechanism of components such as resistors, ICs, transistors and other electronic parts are entrusted to developers and researchers of these parts.

Examples:

■ **Phototherapy Unit**

Equipment that treats a newborn baby's jaundice. It applies the principle of bilirubin absorption disintegration by light source of a specific wave length (526nm) emitted from a fluorescent tube (Photo 1.16).

An electronically controlled circuit that lights the fluorescent lamps suddenly broke down. The repair was achieved by replacing 8 defective electronic parts such as transistors, diodes and resistors.

In general, phototherapy units apply grow-starter and induction coil for starting a fluorescent lamp; on the other hand, the above-mentioned equipment was a new model, which applies an electrically controlled starter. In the case of such a new model, repair of its failure is rather difficult.

[National Maternal and Child Health Centre,
Cambodia]

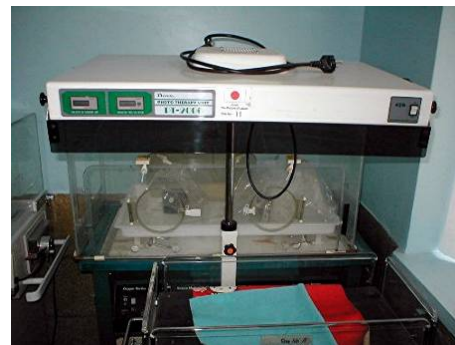


Photo 1.16 Example of a Photo-therapy Unit

■ **Fetal Actocardiograph**

The failure symptom of this equipment was that the internal power supply did not come on. Troubleshooting concluded that a resistor caused an open circuit in the DC power circuit. A high repair skill occasionally contributes to the hospital financial savings ^{Note 1.5)}. Equipment worth about US\$ 10,000 was repaired by replacing a resistor worth only two cents.

[National Maternal and Child Health Centre, Cambodia]

1.2.8 Inappropriate Repair Techniques

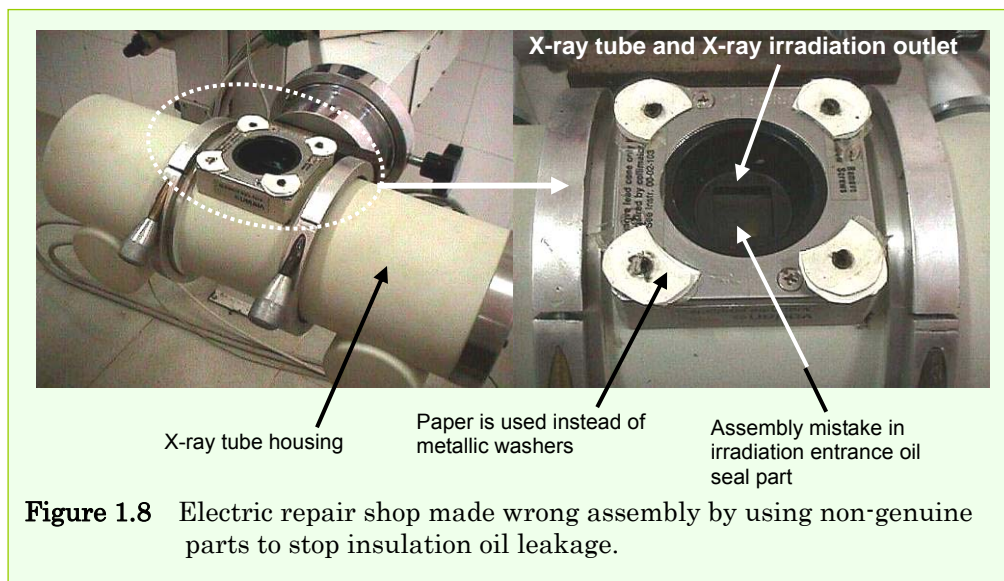
Logical troubleshooting **using wide-ranging knowledge of operating principles, structure of the equipment, comprehension of electronic circuits, functions of electronic parts, etc. is required to repair medical equipment.** However, failure often happens because of **human error,** including imitation and application of **non-genuine parts.** In addition, often no record of the repair process is kept, making it difficult or impossible to restore the item even after engaging an excellent engineer.

On the other hand, even well experienced repair engineers sometimes make simple mistakes such as a mis-connection of the anode and cathode for example. Avoiding such 'Human Error' is one of the important issues when servicing medical equipment.

Examples:

■ **Medical X-ray Equipment**

Insulation oil was leaking from the X-ray tube (actually, from X-ray tube housing). The hospital had earlier requested an electric repair shop to carry out repairs on the leaking tube-housing. The repair shop completed the repair works, but soon after, the same symptom reoccurred, and it was worse than before. As a second opinion, the hospital requested the MoH to carry out the repair work.



This was because the repair technician had made a mistake in the reassembly of the X-ray tube unit coupled with using non-genuine parts to repair it (see Figure 1.8). This repair was done by a person who did not understand the operating principles or have knowledge concerning X-rays. Repair of this manner could have resulted in a fatal accident or radiation hazard.

A bad example in similar circumstances took place in another hospital, where an electric repair shop topped up X-ray tube oil using car engine oil instead of genuine oil. As a result, a costly X-ray tube unit (approx. US\$ 10,000) never returned to its original condition.

The repair of the X-ray tube unit was completed by using the genuine parts and performing a correct assembly and leakage test.

[Kompong Thom Referral Hospital, Cambodia]

■ **Mobile X-ray Equipment**

The equipment was modified to use the commercial power supply directly instead of the built-in power supply battery. A few months after the modification, the modified internal power supply of the equipment broke down.

Restoration of the equipment became impossible because there was no work record to show the modifications done. Having no records of modification and repair work is the same as poor repair technique. However, it must be remembered that the user is strictly prohibited from modifying any type of medical equipment by National Notice in many countries.

[Kampot Referral Hospital, Cambodia]

■ **Ultrasonic Diagnostic Equipment**

When a random failure occurred, a faulty IC and faulty points were identified and the request for repair with necessary spare parts was made.

However, when the defective IC on a minute PCB around the CPU was replaced, short-circuits on the copper track with soldering happened; as a result, the equipment developed a new defect. This means the member who attempted to repair was acquainted neither with the CPU theory nor the handling of a minute circuit of the PCB.

[University Teaching Hospital, Zambia]

■ **High-pressure Steam Steriliser**

Over-tightening of the water-filter housing by the repairer caused water leakage. The water filter housing is made of plastic, and requires gentle force when loosening and tightening.

Other than the problem of repair technique, the repairer was not acquainted with materials and their specifications. Therefore, during training handling of delicate parts should be emphasised, not just repair techniques.

[National Maternal and Child Health Centre, Cambodia]

1.2.9 Wear-out Failures

In general, this type of failure occurs about five-six years after installation of equipment. Wear-out and deterioration of components that are composed of mechanical and chemical materials mainly cause this type of failure. The components that belong to this group include motors, switches, recorder heads, X-ray tubes, displays and charge-discharge capacitors, though all of these depend on usage time. In addition, the wear-out failures also occur in electronic components such as capacitors, resistors, transistors and ICs used in an improper circuit design.

In the case of wear-out failures, many parts are usually defective. For this reason, the wear-out failures need overall inspections. However, if the regular maintenance system has already been established, parts that are going to wear out or to deteriorate with the passing of time are almost predictable. This will keep the wear-out failures to the minimum in the case of equipment, which is ten years from installation.

Examples:

■ Defibrillator

This refers to equipment that revives a patient who is in a state of fibrillation or of cardiac standstill by giving an electrical shock to the chest.

This equipment had been used for five years. The fault symptom was the absence of power-energy on the external paddles due to the deterioration of an electrical charge-discharge capacitor. The faulty capacitor was replaced by a new one. As a result, the equipment became functional again. However, it took three months to procure this capacitor, and in the meantime the hospital was unable to defibrillate patients.

Deterioration time of electrical charge-discharge capacitors is predictable by monitoring the power-energy and discharge current curve (see Photo 1.17 and Figure 1.9). Therefore, this breakdown could have been prevented by acquiring a new capacitor in advance.

[Islamabad Children's Hospital, Pakistan]

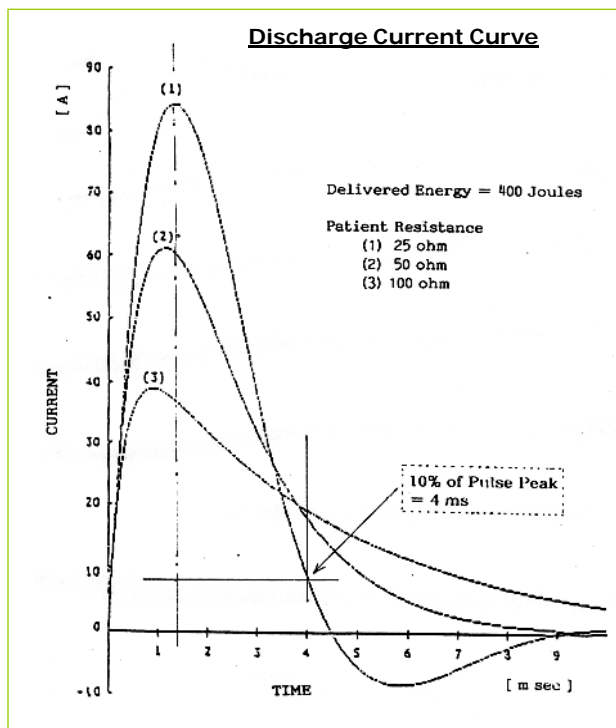


Photo 1.17 Example of a Defibrillator Analyser that is used to measure the power energy of defibrillators in periodic inspection

Figure 1.9 Discharge current curves in three different patients' loads: The equipment must not be used when the output current does not fall within the range of these curves.

■ Infant Incubator

This is equipment that maintains the body temperature of a prematurely born baby. Under such a condition, the child's treatment is done (Photo 1.18).

This equipment had been used for six years and the following faults were noted: a fan motor that helps in air circulation in the canopy where the child is accommodated did not rotate due to worn-out bearings; besides this, the gasket, hygrometer, mattress and window cover were damaged. Moreover, electrical insulation resistance exceeded normal level; as a result, high leakage currents were recorded.

A complete overhaul was done to restore the equipment. This was a typical wear-out failure, and inadequate maintenance overlapped with this. Failure such as this could have been prevented if preventive maintenance had been carried out by replacing the deteriorated parts.

[University Teaching Hospital, Zambia]



Photo 1.18 Example of an Infant Incubator

■ **Ultrasonic Diagnostic Equipment**

This equipment had been used for four years. The equipment developed a fault resulting in part of the image not displaying on the screen. This was due to a mechanical type ultrasonic scanning probe having been worn-out.

The repair was partly finished by replacing the probe with a new one. The mechanical type probe is hardly used now because it has been replaced by an electronic one (Photo 1.19). if appropriately used, it is estimated that the lifespan of the electronic ultrasonic probe is about 5 years or more.

Besides the probe, the surface of the screen and several parts inside the equipment had also deteriorated. This was a result of equipment being overused because of high patient demand. In such a case, the equipment becomes old before reaching the period of wear-out failure.

In developing countries, the concept of depreciation is not sufficiently widespread, particularly in the case of donated equipment. Management of both appropriate use of equipment and lifespan of equipment is, therefore, an important issue.

[University Teaching Hospital, Zambia]



Photo 1.19 Example of a Convex type Ultrasonic Probe (electronic scanning), 3.5 MHz

■ **ELISA Reader**

This means equipment that is used to determine and analyse many HIV negative and positive samples automatically at the same time (Photo 1.20).

The equipment had been used for six years. The sample holder did not move to sample measure position. As a result of troubleshooting, it was found that the printer mechanism did not move smoothly. Due to this fault, excessive current flowed to the printer unit, and CPU detected this abnormality and ordered that the equipment no longer be used.

The lifespan of this type of equipment is long if optical filters, sample holder and equipment enclosure are regularly cleaned and the light source bulb is also regularly replaced. The printer unit of this equipment should be considered as a consumable component of long lifespan.

[University Teaching Hospital, Zambia]

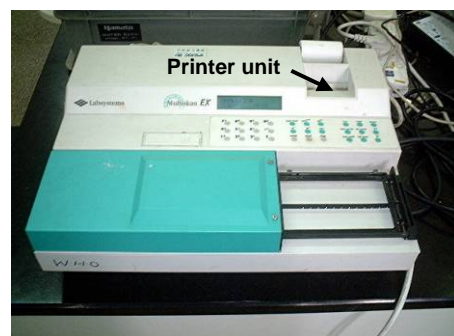
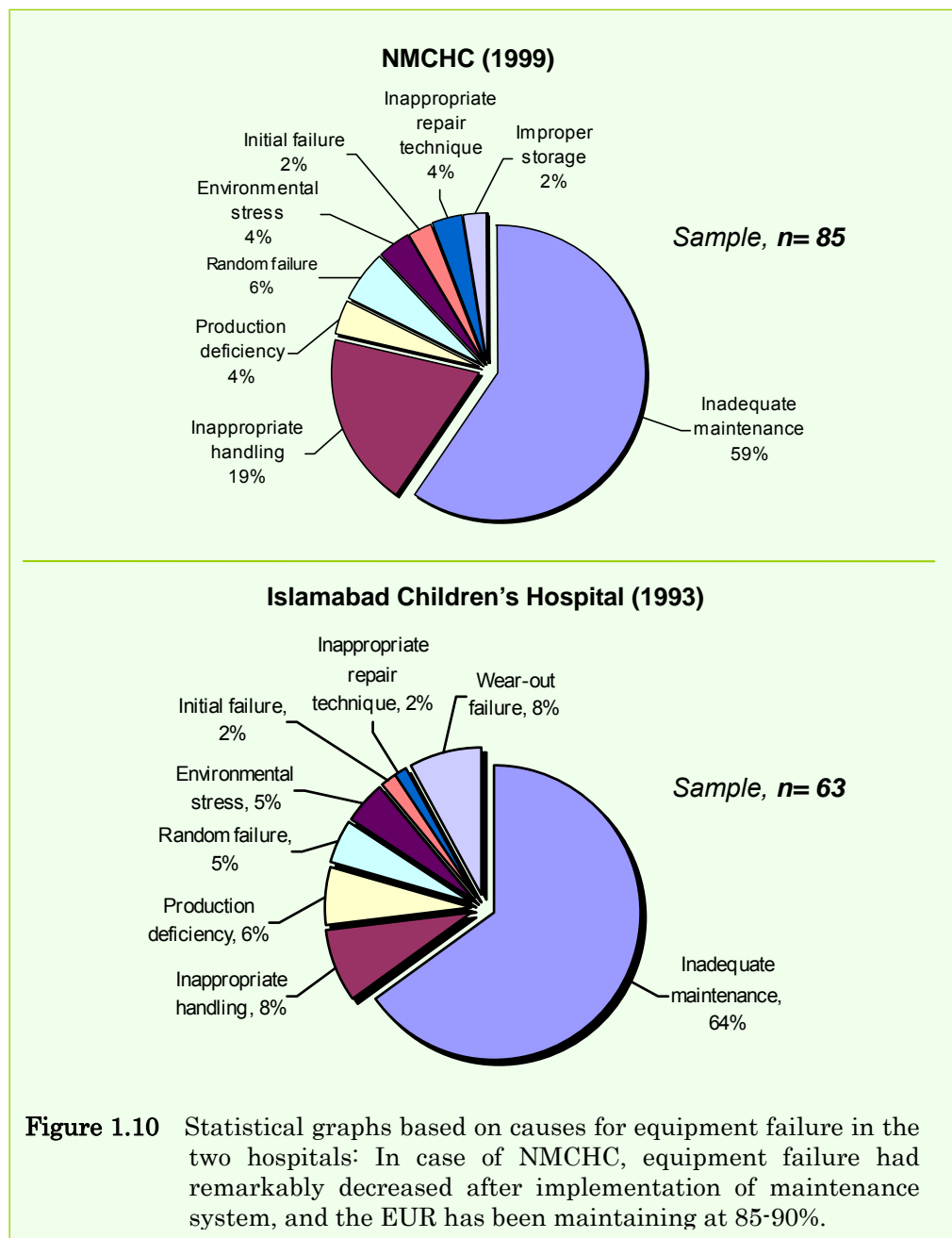


Photo 1.20 Example of an ELISA Reader

1.3 Statistics on Causes of Medical Equipment Failures

There are various forms of failure in medical equipment as mentioned in section 1.2. Almost all failures can be repaired by theoretical application and appropriate troubleshooting. The causes of failures can also be theoretically and technically analysed. By analysing individual cases based on repairs carried out as a result of daily failures, a statistical graph can be created as illustrated in Figure 1.10.

Figure 1.10 has two graphs showing causes of medical equipment failures based on the analysis of repair works in two hospitals. The upper graph refers to National Maternal and Child Health Centre (NMCHC), Cambodia, and the lower graph to Islamabad Children's Hospital, Pakistan.



These two statistics were based on the result of simply analysing each repair case before implementing the maintenance system or the MMS. The number of samples in NMCHC that was compiled in one and a half years is 85, and that for one year at Islamabad Children's Hospital is 63. In both cases, neither the type of equipment, provision and model nor date of installation was taken as a condition for these statistics. In addition, the conditions under which equipment in each hospital was introduced were different.

In NMCHC, the first batch of medical equipment was introduced in 1993 through primary grant aid by the Government of Japan. The second batch was the secondary grant aid introduced in 1997. In addition to these, other equipment has been introduced by JICA through the NMCHC-JICA technical cooperation programme, which commenced in 1995. Wear-out failures had not yet appeared when the statistics were carried out because only five years had passed since installation of the oldest equipment. This type of failure began after carrying out the statistics. However, all failures were solved by carrying out complete overhaul, which meant replacing all the deteriorated parts by new ones and calibrating the electronic circuits.

As for Islamabad Children's Hospital, the medical equipment had been provided by both grant aid of the Government of Japan and JICA technical cooperation programme since 1985. At the time the statistics were gathered, wear-out failures of some equipment had occurred because seven years had already passed since installation.

Classification of all failures explained in section 1.2 can be applied to both graphs, and each classified percentage in both graphs is somehow similar. This should not be a surprise, as will be seen in the following analysis.

Failures due to inappropriate operation in NMCHC account for 19% of all the failure cases, which is high compared to 8% of those at Islamabad Children's Hospital. This shows that the Islamabad Children's Hospital is more skilled in handling of equipment.

Attention should be paid to failures that are caused by inadequate maintenance accounting for many breakdowns. The failures due to inadequate maintenance in NMCHC account for 59% of all the failure cases. The same failures in Islamabad Children's Hospital account for 64%. At the time of these statistics, there was no ME section or staff in NMCHC. On the other hand, both ME section and its technical staff already existed in Islamabad Children's Hospital, which only implemented a repair system by waiting for equipment's breakdown.

In the absence of MMS, the failure ratio resulting from inadequate maintenance becomes almost the same even though an engineering section is set up and engineers and technicians exist. The difference between conditions in one country to another and conditions of introducing equipment does not relate to this. This means that the management of the medical equipment does not apply only in system of repair that waits until consumable parts have deteriorated^{Note 1.6)} or equipment has failed (refer to paragraph 1.2.4).

Failures caused by inadequate maintenance can be prevented by implementing the maintenance system. What about failures caused by other reasons? Failures due to improper storage and transportation before arrival at the hospital, initial failure and production deficiencies cannot be prevented because these are external factors. However, the number of failures caused by inappropriate handling can be reduced by conducting an in-service training. The number of failures caused by environmental stress can be reduced by improving the environment. Moreover, failures due to wear-out can be prevented by carrying out regular maintenance and inspection. In-service training, environmental improvement and wear-out failure prevention are all recognised as activities in MMS.

In both hospitals, failure caused by inadequate maintenance, inappropriate handling, environmental stress and wear-out failure totals 80% and above. This means that 80% of failures can be prevented by the above-mentioned activities, as well by preventive maintenance.

In graph 1.10, random failure in both hospitals accounts for 5% and 6% respectively amongst other failure cases, called 'breakdown'. According to other statistics in NMCHC, random failures which were recorded as actual failures needing repairs were 18 out of 336 service cases covering a period of five years between 1998 and 2002^{Note 1.7)}. It accounts only for 5%, which is almost the same

as 6% as shown in graph 1.10. This confirms that actual breakdowns that need repair account for only 5% to 6% of all failure cases ^{Note 1.8)}.

In addition to the cases of random failure, failures due to improper storage, inappropriate handling and improper environment may also result in cases that need repair. However, the number of these repairs accounts for only a small percentage of all maintenance services. In other words, equipment that frequently breaks down is more likely to have a maintenance issue than an inherent defect. In NMCHC, equipment failure was remarkably reduced after implementation of the MMS, and this resulted in EUR being maintained at 85-90%. In Islamabad Children's Hospital, implementation of MMS began after collecting these statistics.

In conclusion, almost 80% of failure cases can be prevented by implementing an appropriate MMS. The above situation is applicable in Cambodia, Pakistan and other countries. It has been proven that EUR can be as high as 85-90% if a good MMS is implemented as demonstrated at NMCHC. Therefore, the relevance of the management of equipment demands the implementation of a system to monitor utilisation of equipment and to replace deteriorated accessories and components regularly. In addition to this, it is necessary to prioritize the human resource development in the field of MMS.

1.4 Importance of Maintenance

In NMCHC for example, there were 188 pieces of equipment in the wards and laboratory. Most equipment is used independently but some types of equipment are used in the operating theatre in conjunction with other equipment. This equipment contributes to the health service for the public. This contribution could be enhanced if 80% of the equipment failures were prevented through implementing MMS. With lifespan maintenance and failure prevention, the most important purpose of maintenance is to ensure reliability and safety of equipment in order to offer safe and accurate healthcare service to the patient ^{Note 1.9}.

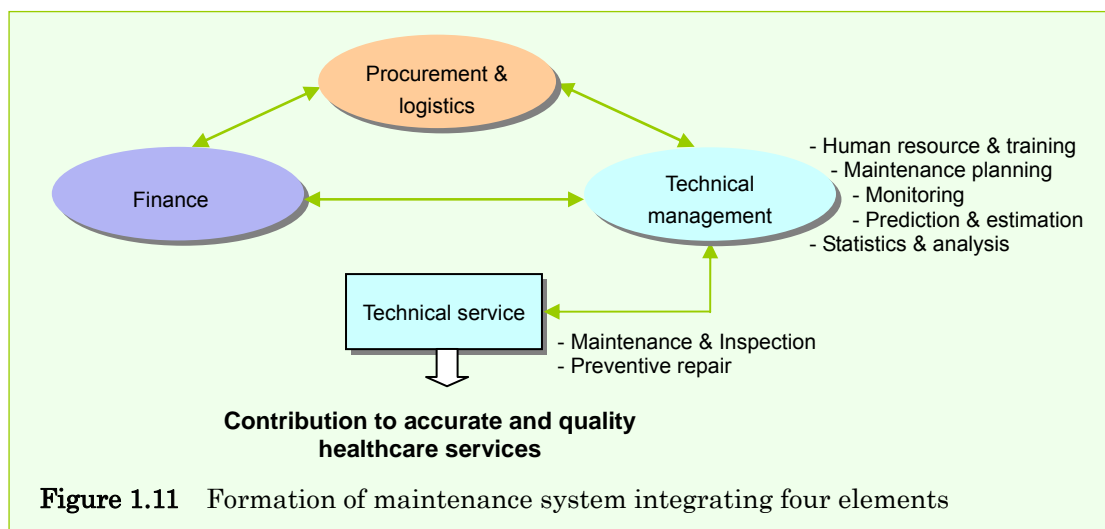
Reliability means that the equipment shall accomplish its diagnostic and therapeutic purposes and function perfectly. Safety means that equipment shall be operated without any risk to life for both patient and operator. Reliability and safety are closely related to each other. This relationship is important when considering procedures for developing, designing, certifying, manufacturing, shipment, and sale on one hand, and clinical application and maintenance management on the other.

Reliability and safety of medical equipment gradually decrease with the passing of time. In addition, the failure rate rises according to the failure rate curve of Figure 1.2. The user has the obligation to maintain reliability and safety by monitoring the process from installation to decommissioning of medical equipment.

The maintenance system for medical equipment adopts an integrated approach that considers aspects of the technical service, technical management, procurement/logistics, and finance. These are as follows (see also Figure 1.11):

- **Technical service** that carries out maintenance and inspection of medical equipment as well as basic repairs;
- **Technical Management** that carries out evaluation and analysis of the above-mentioned activities;
- **Procurement and logistics** that supply the necessary consumables and spare parts;
- **Finance** that provides the necessary budget.

The above-mentioned collective approach is applicable at both central and hospital levels.



1.5 Importance of In-house Services

1.5.1 Problems with Technical Service Environment

Usually, reputable medical equipment manufacturers offer efficient and effective after-sales service. In fact, these are carried out by local agencies that represent the manufacturers. These services are classified as follows:

- a) **Repair service** which is provided on call when the equipment breaks down or fails to function satisfactorily,
- b) Contract service under which contract terms are agreed upon between the supplier and the user for preventive as well as for corrective maintenance service.

However, large establishments and health facilities cannot depend solely on the services offered by manufacturers. More often, such services tend to be expensive and may not be available when needed especially during emergency breakdown of the equipment or the system. Additionally, because many different types of equipment from different manufacturers are used, integrated management is necessary.

On the other hand, problems with the medical equipment technical service in developing countries are as follows:

- Some manufacturers allow only technical services to be carried out by authorised local agencies. They do not provide the technical information and spare parts to the hospital engineering unit;
- Morality of some service providers is not so high. For instance, they replace undefective parts, and demand from the user the cost for replacing them. The undefective spare parts are then used as spare parts for other services;
- Some service providers replace normal parts randomly without logical troubleshooting, and in the end the cost is borne by the user;
- Most agencies do not have the stock of accessories and consumable components that need regular replacement every few months or years. Therefore, such accessories and consumables cannot be acquired in time when needed;
- Some agencies sell only the equipment, and do not consider after-sales service;
- The agency that appropriately performs the customer service and delivery of equipment management with customer files is extremely rare and prohibitively expensive.

The above constraints make it necessary and important to establish an in-house service so that the hospital can carry out maintenance and repair itself.

1.5.2 Necessity of In-house Services

The medical equipment technical service section that carries out the in-house service is called the ME section; we will use the word 'ME section' from now on unless otherwise noted.

Based on the problems with the local service environment, the maintenance system of the in-house service is a system in which not only deteriorated parts are replaced, but which is also involved in the following activities:

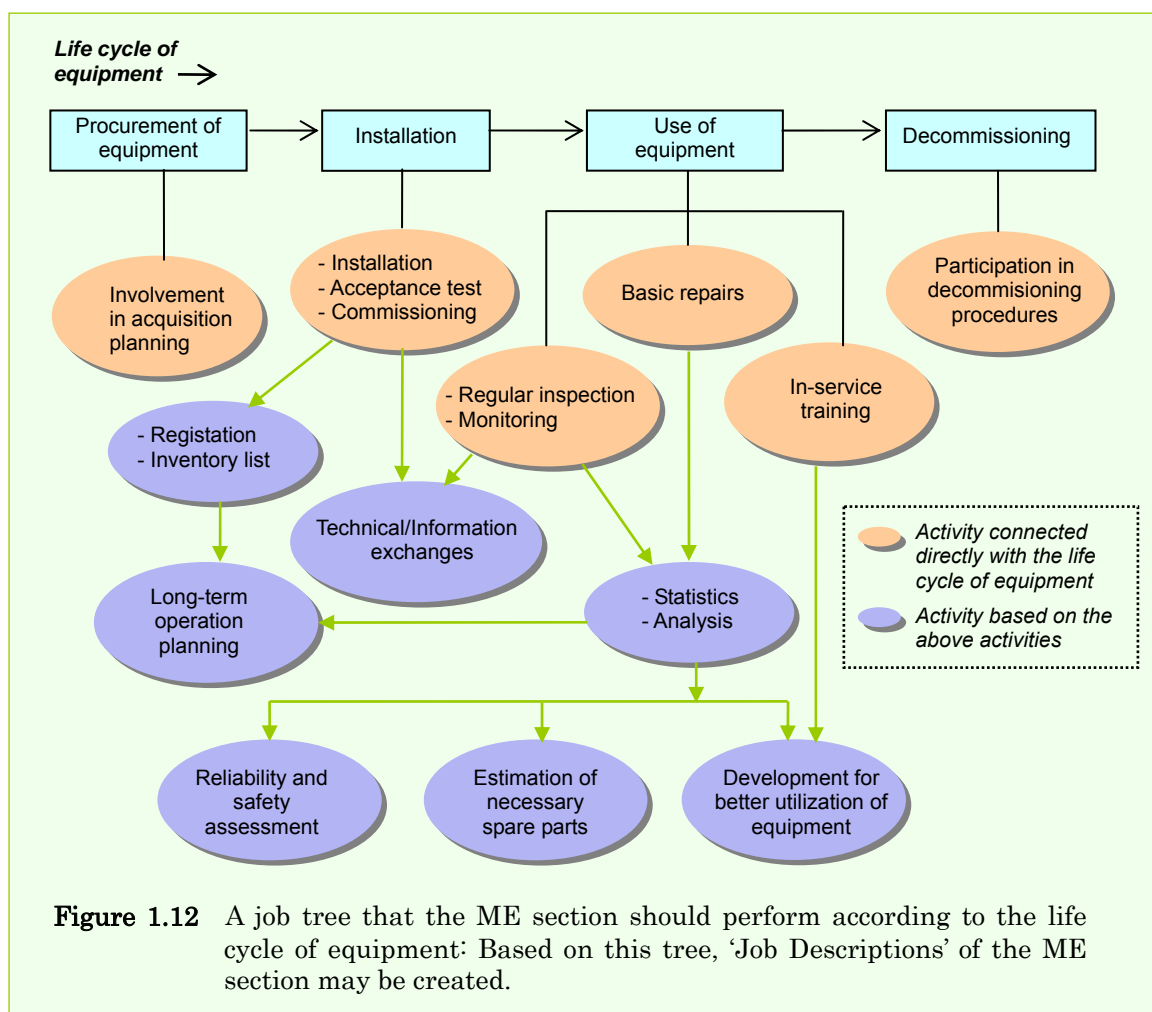
- Acquisition planning for equipment;
- Installation and acceptance test of incoming medical equipment in co-operation with manufacturer and local agency;
- Identification and registration of individual medical equipment (inventory management);
- Commissioning of a newly acquired equipment in co-operation with hospital management;
- Contribution to reliability and safety through safe operation and monitoring of equipment at the

clinical site;

- Replacement of deteriorated parts and preventive repair through regular inspection;
- In-service training in operation/maintenance/safety for the operator and technical staff;
- Basic repairs;
- Contribution to the prediction, estimation, procurement and management of necessary consumables and spare parts;
- Effective operation, reliability and safety assessment through statistics and analysis of equipment usage;
- Development and research for better utilisation of medical equipment
- Development of simple medical equipment and instruments ^{Note 1.10)};
- Technical/information exchanges with manufacturers and local agencies;
- Involvement in decommissioning, evaluation, processing and new equipment selection;
- Long-term operation planning (e.g. maintenance costs, life cycle costs and new updates);
- Management and record keeping related to the above-mentioned activities.

These activities are illustrated in Figure 1.12 as a job tree according to life cycle of equipment. As mentioned above, the ME section is not merely a site work group but should be recognised as a part of the hospital management.

Systematic flows of the ME section's activities will be described in further detail in Part 2.



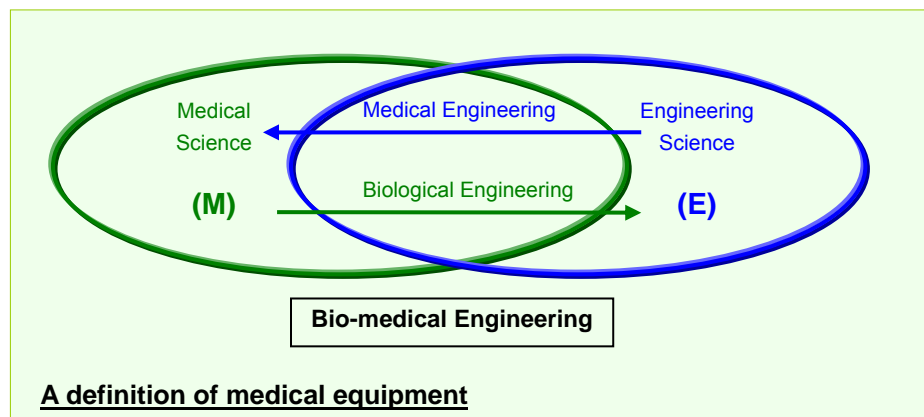
Notes

Note 1.1 **Equipment used for diagnosis and treatment at a clinical site** is called medical equipment. In fact, the term 'Biomedical Equipment' is now being used widely in the world.

Biomedical Engineering is a fusion of M (Medical Science) and E (Engineering Science) as shown in the figure below. Research in the field of medical science develops into Biological Engineering, and research in the field of engineering science develops into Medical Engineering. As a result of uniting the two, the study became a system called Bio-medical Engineering.

Therefore, equipment used at a clinical site is called biomedical equipment. The biomedical equipment is developed based on biomedical engineering technology. When a Biomedical Engineer works on the maintenance of biomedical equipment, etc. in the hospital, he/she is called a Clinical Engineer (CE), and this in-house service is called the Biomedical Engineering Department or the Biomedical Equipment Service Department.

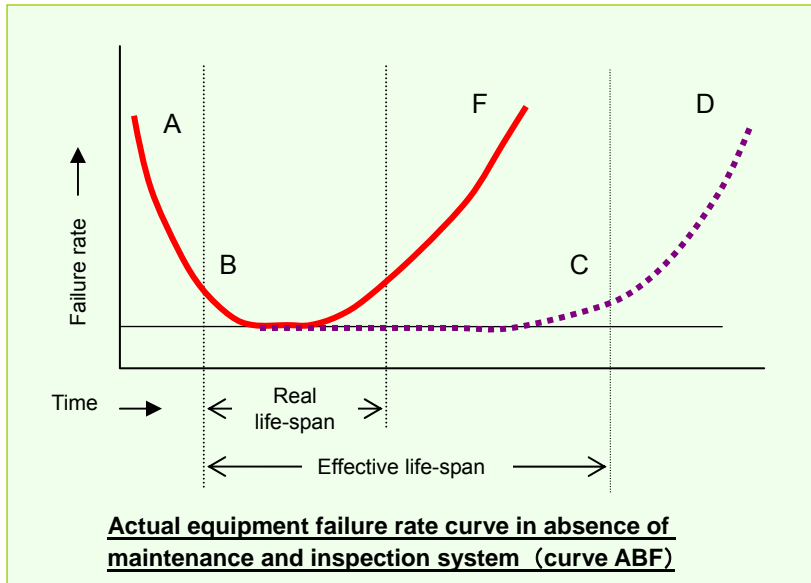
In this book, we use the word 'medical equipment' instead of biomedical equipment to avoid confusion.



Note 1.2 **Hospital laboratory equipment is used in biochemical analysis** by clinical laboratory technologists. Diagnostic data obtained from this equipment is used by diagnostic and therapeutic services in the hospital. Strictly speaking, it is necessary to distinguish hospital laboratory equipment from medical equipment as an equipment category. However, because the management methodology is basically similar to that of medical equipment, the hospital laboratory equipment is equated with the medical equipment in this book unless otherwise noted.

Note 1.3 **If equipment is not maintained**, the equipment failure curve becomes curve ABF (see the figure below). This means the effective lifespan is about three years. This cause is clear.

Most medical equipment is composed of the actual equipment (main body), consumables (e.g. filters, recording papers and reagents), consumable components (e.g. lamps, motor brushes and sensors) and accessories (e.g. probes, patient cables and electrodes). However, except for the consumables, the lifespan of many consumable components and accessories is about two-three years. With deterioration of these, the functioning of the equipment is impaired, and often there follows a break down. As a result, the failure rate increases sharply at two-three years after installation. But these are not real breakdowns.

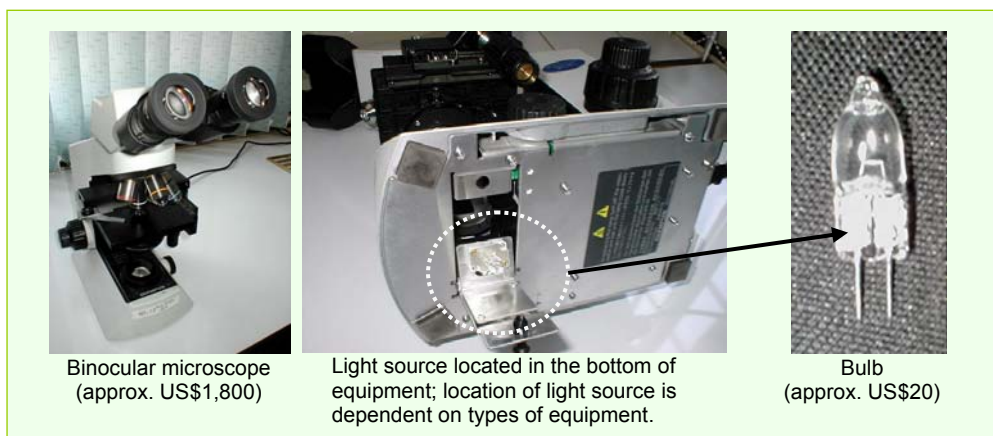


Still, the equipment may break down as a result of keeping it in use without noticing the malfunction though the equipment may seem to be normal. For instance, the wear-out of the motor brushes of a centrifuge is a typical example. The lifespan of the motor brush is about two-three years in normal use. However, if the equipment is continuously used with worn out motor brushes, the contact surface of the motor (commutator) that comes in contact with the brushes will be destroyed, and an irreparable breakdown follows.

To avoid the above-mentioned problem, it is essential to perform regular inspection and supply/replacement of accessories and consumable components from the time of installation.

Note 1.4 Many cases of equipment failures due to burnt out **bulbs** can be seen in developing countries. In the case of unavailability of the bulb, costly equipment is often abandoned, and new equipment will be purchased in its place. Various kinds of bulbs are used in particular examples of medical and laboratory equipment, e.g. colorimeters, ELISA readers, endoscopes, laryngoscopes, microscopes, operating lights and spectrophotometers. The lifespan of the bulb is short. When introducing new equipment that uses a bulb as a consumable component, purchasing spare bulbs in advance must be considered.

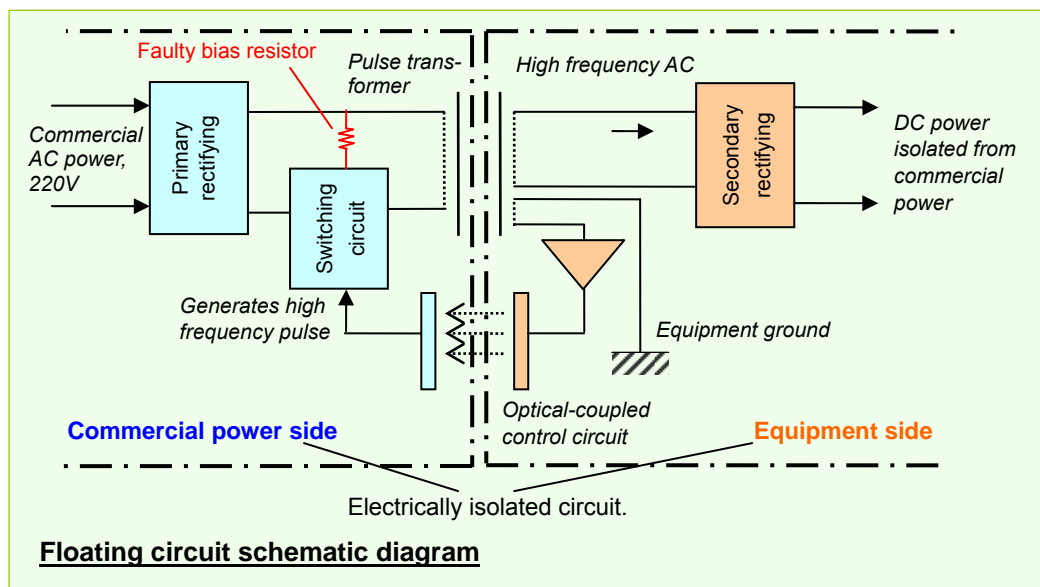
Bulb for microscope for example (see the figure below), the lifespan of this bulb is one-two years, though it depends on operating time. This means that even a newly purchased



microscope becomes defective one or two years after installation. However, this can be rectified by replacing the bulb. Conversely, hesitation to replace such consumable components (approx. US\$ 20) often results in purchase of new microscopes. (approx. US\$ 1,800). Such illogicality and financial mismanagement must be corrected.

Note 1.5 **Because a highly specialised repair technique was needed** in this situation, a JICA expert carried out the repair works. The fault was located (fault location) in the internal power circuit (called the floating circuit or the switching regulation circuit) that isolates the equipment side from the commercial power supply side to prevent electrical shock to the patient (see Figure below). The understanding of the flow of the circuit theory and the electronic device used is necessary for this type of troubleshooting. ‘Feeling’ and ‘watching’ can never solve the fault. Even the equipment manufacturer does not repair this type of fault in general because it requires skill and time, and usually the unit is replaced.

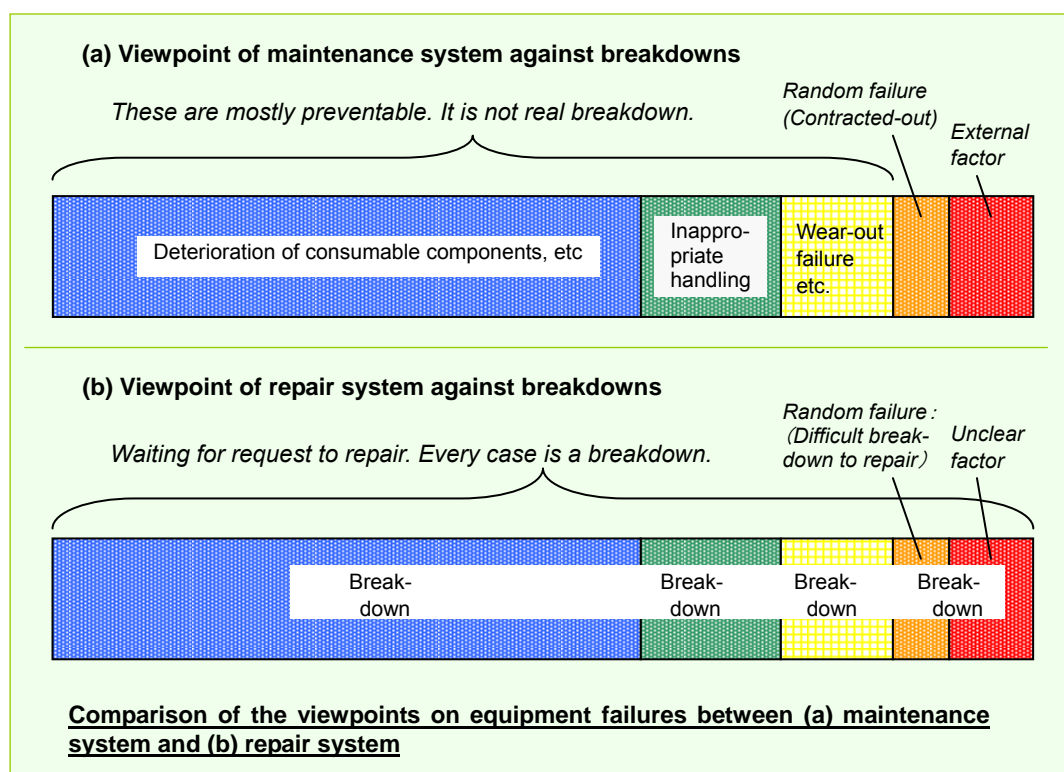
To train C/Ps in such repair techniques, basic electronic engineering must be taught and understood thoroughly. In most developing countries, engineers and technicians are most interested in performing such repairs of complicated electronic circuits. However, it must be remembered that Three Cycle Management be given priority in maintenance and management of medical equipment. This will be described further in Part 2.



Note 1.6 **Maintenance and management system, and the concept of failures**—In many developing countries, the ME section and MoH Central Workshop always emphasise the shortage of manpower and lack of technical skills. This is a reality, but you must have already noticed that at the root of this problem lies the difference between the ‘maintenance system’ and the ‘repair system’ (see Figure below).

In the case of the maintenance system, utilisation of individual equipment is monitored (see Figure (a)). Procuring and replacing accessories and consumable components in advance prevents the breakdowns, which may be expected as a result of adequate maintenance. Conducting in-service training will reduce the other breakdowns caused by inappropriate handling. Wear-out failure and such is prevented by regular inspection, improvement of installation environment, and so on.

The random failure case is a ‘real breakdown’ that needs repair, and it accounts for only about 5% of all failure cases. Try to repair this appropriately. When the repair completion is judged to be difficult by the ME section, it is entrusted to a contracted-out service. The contracted-out service is expensive, but the cost is relatively small



compared with the entire maintenance cost, because failure prevention is carried out by the maintenance system. Therefore, the repair case does not rise, and keeps a low value. This leads to improvement in labour efficiency.

For instance, the presence of one qualified person (not a repair person) taking charge of the technical management of medical equipment and one technical assistant are adequate for health facilities and equipment such as those in NMCHC, with a 154-bed capacity. Rough calculations for manpower are shown in the table below:

Table Manpower calculation for inspection

Group No.	Equipment Description	Qty.	Required hrs for inspection	Frequency/ year	Total hrs
1	Medical/mobile X-ray equipment, HP steam steriliser, Infusion pump	9	4 hrs	4	144 hrs
2	Anaesthesia apparatus, Oxygen concentrator, Infant incubator, Suction unit, V extractor, ECG, CTG monitor	30	2 hrs	4	240 hrs
3	Spectrophotometer, Water distiller, X-ray film processor, Ice maker	5	2hrs	2	20 hrs
4	Coagulator, Doppler fetus detector, Infant warmer, Pulse oximeter, Hematocrit centrifuge,	12	1 hr	2	24 hrs
5	Infant warmer, Microscope, Colposcope, Centriguge, Delivery simulator, OP light, Delivery table, Hnady Doppler,	29	1 hr	1	29 hrs
6	Medical refrigerator, Boiling steriliser, Electronic balancer, Examination light stand, Shaker, Water bath, etc.	18	--	Dependent on user's maintenance	--
7	Haematology Analyser	1	--	Contracted-out service	--
Grand total:					457 hrs

NOTE: - Unused equipment is not included.

- User's maintenance by equipment operators should be carried out.

- *Actual working hours a year: as 125 holidays in a year,*

$$240 \text{ days} \times 7 \text{ hrs} \doteq 1,680 \text{ hrs}$$
- *Remaining hrs from total hrs of inspection: $1,680 - 457 = 1,223 \text{ hrs}$*

Therefore, there is adequate time to carry out inspections by two staff. Necessary works that are mentioned in paragraph 1.5.2 can be done by using remaining time.

The maintenance system enhances the relationship with other managers, and enables cooperation to be built between them. This aspect develops management respect and becomes a comprehensive system for sustainability and further development in the future.

On the other hand, the repair system that waits for the call from the ward will respond to the individual request (see Figure (b)). All failures are considered as breakdowns, and each case is responded to by repair. Therefore, the number of repair cases correspondingly increases as the equipment becomes older. Furthermore, required spare parts must be ordered for each individual case, and repair will be tried again after arrival of the parts. In short, twice the time and effort is spent on this kind of repair. In such a situation, the random failure will be considered as a breakdown that is difficult to repair. Therefore, training and improvement of repair technique are emphasised.

The above-mentioned situation requires two-three times more staff than does the maintenance system. The ME section staff cannot physically cope with the increasing number of repair cases, and therefore try to repair only simple devices. A difficult case is abandoned, therefore, and irreparable equipment accumulates. As a result, even if the ME section repairs a large number of failure cases, the external evaluation does not recognise it as belonging to the hospital management section. It is considered just like an ordinary 'Electric repair workshop', which is located in town. This repair system, which exists under MoH or hospital management without a profit-pursuing system, will likely fail.

Note 1.7 **Services of simple failure solutions** such as plug replacement, battery replacement, mis-setting of a parameter, disconnection of electrodes, etc. are recorded in the notebook, but a service report is not issued. Therefore, the number of such simple cases is not included in this figure. This number is surprisingly large, and if this number is included, the total number of service cases would rise to 600.

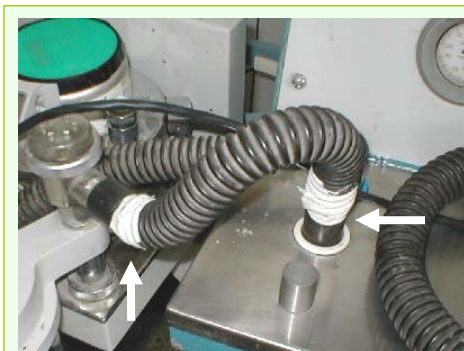
Note 1.8 **This failure of 5% requires a highly specialised repair technique** because it was caused by electronic parts and devices. JICA experts or equipment manufacturers, therefore, solved these failures. If training is conducted for C/Ps until they are able to carry out a highly specialised repair technique, adequate time to include the basics of science and technology will be required. If the person who receives the training does not have the basic engineering knowledge, the impact is not effective even if the training is continued for a long time. Because the ratio of failures that needs an advanced repair technology is about 5% among all failure cases, the cost-effectiveness is also low. In other words, training of the repair technique is in another category, and exceeds the capacity obtained on the site (OJT: On the Job Training). The training course in basic troubleshooting and repair technique is important, but those faults which cannot be repaired at a certain level need not be forced on the C/P side, and should be subcontracted.

Note 1.9 **In some developing countries, the importance of maintenance and inspection** is not clearly recognised due to the following reasons:

- People wonder why they should replace components or parts on working equipment;
 - The system of maintenance and management means repairing faulty equipment;
 - People think that because medical equipment never breaks down, it can be permanently used.
- Therefore, the medical equipment need not be maintained;

- Decreases in reliability and safety of equipment caused by the deterioration of accessories and required consumables are not recognised (see Figure below);
- Causes of equipment failures are seen as the responsibility of donors;
- The repair of equipment is also seen as being the responsibility of donors.

The system to maintain the reliability and safety of equipment should be established by overcoming the lack of recognition mentioned above.



Example of an anaesthesia apparatus:

In this case, a broken breathing hose is being mended using silicon tape. The anaesthesia apparatus being a type of 'Life- supporting Equipment', this is very hazardous for the patient. Vital components of the anaesthesia apparatus such as breathing hoses and breathing bags should not be repaired/ mended, but should be replaced by new ones.

Note 1.10 Development of technical potential of an ME section in a developing country—

Development of the medical equipment: Most medical equipment is manufactured in and exported from countries such as India and Pakistan. However, there is no technology in this field in many developing countries, and 100% of equipment is imported. Such a situation is surmountable to some degree if there is knowledge of medical equipment technologies at a certain level.

As one example, development of a phototherapy unit that consists of simple structure and brings reliable clinical effect was tried in Cambodia (see Photo below).

A comprehensive medical equipment development system was introduced to develop this equipment through:

- Market research and needs assessment (in a virtual situation);
- Specification as per industrial standard;
- Design of package & structure;
- Design of electric circuit;
- Calculation of electric circuit;
- Component layout design;
- Drawing of equipment;
- Production of equipment;
- Examination of performance, reliability and safety;
- Clinical trial conducted by doctors;
- Operating manual making.



Photo A phototherapy unit developed at the ME section of NMCHC, Cambodia

A C/P produced this equipment using parts and materials that were all obtained in the local market. This is, therefore, medical equipment which is 100% made in Cambodia. The specifications were brought close to the JIS standard of Japan. The cost to produce this equipment was approximately US\$90 while the price of the equivalent manufactured model is US\$1,300. The C/P introduced this equipment at the hospital steering committee, and the response was positive.

Besides the phototherapy unit, an ECG checker used to examine ECG equipment was designed and produced (see Photo 1.10). Additionally, infant weighting machines, infant warmers, infant incubators, laboratory incubators, etc. can be produced under supervision and clinical trials conducted by doctors. When producing this equipment, all of the components need not necessarily be procured in the local market. High-tech components such as infrared heaters and thermo-sensors would have to be imported.