ASSIGNMENT

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On

5 Medical Devices

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$_{2}$ INTRODUCTION

A medical device is an instrument ,implant or other similar o related article, which is intended for use in the diagnosis of disease or other condition, or in the cure, treatment or prevention of diseases or intended to affect the structure or any function of the body and which does not achieve any of its primary intended purposes through its chemical action within or on the body.

THE 5 MEDICAL DEVICES ARE:

- Lab Incubator
- Mobile MRI
- Needle Free Injector
- Oxygenator

 \bullet The rapeutic Intravascular Ultrasound

3 Lab Incubator

3.1 What is Incubator?



Figure 1: Interior of a CO2 incubator used in cell culture

An incubator is a device used to grow and maintain microbiological cultures or cell cultures. The incubator maintains optimal temperature, humidity and other conditions such as the CO2 and oxygen content of the atmosphere inside. Incubators are essential for much experimental work in cell biology, microbiology and

molecular biology and are used to culture both bacterial and eukaryotic cells.



Figure 2: A Bacteriological incubator

3.2 History of the laboratory incubator

From aiding in hatching chicken eggs to enabling scientists to understand and develop vaccines for deadly viruses, the laboratory incubator has seen numerous applications over the years it has been in use. The incubator has also provided a foundation for medical advances and experimental work in cellular and molecular biology.

An incubator is made up of a chamber with a regulated temperature. Some incubators also regulate humidity, gas composition, or ventilation within that chamber. While many technological advances have occurred since the primitive incubators first used in ancient Egypt and China, the main purpose of the incubator has remained unchanged: to create a stable, controlled environment

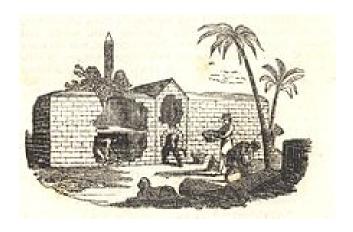


Figure 3: Egyptian Egg oven

conducive to research, study, and cultivation.

3.3 The earliest incubators

The earliest incubators were found thousands of years ago in ancient Egypt and China, where they were used to keep chicken eggs warm. Use of incubators revolutionized food production, as it allowed chicks to hatch from eggs without requiring that a hen sit on them, thus freeing the hens to lay more eggs in a shorter period of time. Both early Egyptian and Chinese incubators were essentially large rooms that were heated by fires, where attendants turned the eggs at regular intervals to ensure even heat distribution.

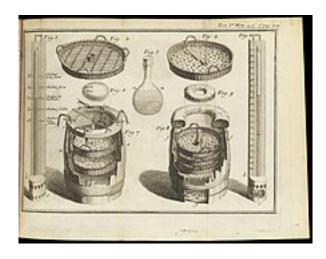


Figure 4: Method for incubation of poultry eggs

3.4 In the 16th and 17th century

The incubator received an update in the 16th century when Jean Baptiste Porta drew on ancient Egyptian design to create a more modern egg incubator.



Figure 5: Old Réaumur scale thermometer

While he eventually had to discontinue his work due to the Spanish Inquisition, Rene-Antoine Ferchault de Reaumur took up the challenge in the middle of the 17th century.[2] Reaumur warmed his incubator with a wood stove and monitored its temperature using the Reaumur thermometer, another of his inventions.

3.5 In the 19th century

In the 19th century, researchers finally began to recognize that the use of incubators could contribute to medical advancements. They began to experiment to find the ideal environment for maintaining cell culture stocks. These early incubators were simply made up of bell jars that contained a single lit candle. Cultures were placed near the flame on the underside of the jar's lid, and the entire jar was placed in a dry, heated oven.



Figure 6: Incubator invented by hess

Incubator invented by Hess In the late 19th century, doctors realized another practical use for incubators: keeping premature or weak infants alive. The first infant incubator, used at a women's hospital in Paris, was heated by kerosene lamps. Fifty years later, Julius H. Hess, an American physician often considered to be the father of neonatology, designed an electric infant incubator that closely resembles the infant incubators in use today.

3.6 In the 20th century

The next innovation in incubator technology came in the 1960s, when the CO2 incubator was introduced to the market.[4] Demand came when doctors realized that they could use CO2 incubators to identify and study pathogens found in patients' bodily fluids. To do this, a sample was harvested and placed onto a sterile dish and into the incubator. The air in the incubator was kept at 37 degrees Celsius, the same temperature as the human body, and the incubator maintained the atmospheric carbon dioxide and nitrogen levels necessary to promote cell growth.

At this time, incubators also began to be used in genetic engineering. Scientists could create biologically essential proteins, such as insulin, with the use of incubators. Genetic modification could now take place on a molecular level, helping to improve the nutritional content and resistance to pestilence and disease of fruits and vegetables.

3.7 Today

Incubators serve a variety of functions in a scientific lab. Incubators generally maintain a constant temperature, however additional features are often built in. Many incubators also control humidity. Shaking incubators incorporate movement to mix cultures. Gas incubators regulate the internal gas composition.



Figure 7: Shaking incubator for culture tubes

Some incubators have a means of circulating the air inside of them to ensure even distribution of temperatures. Many incubators built for laboratory use have a redundant power source, to ensure that power outages do not disrupt experiments. Incubators are made in a variety of sizes, from tabletop models, to warm rooms, which serve as incubators for large numbers of samples.

4 Mobile MRI

4.1 What is MRI?

Magnetic resonance imaging (MRI) is a medical imaging technique used in radiology to form pictures of the anatomy and the physiological processes of the body. MRI scanners use strong magnetic fields, magnetic field gradients, and radio waves to generate images of the organs in the body. MRI does not involve X-rays or the use of ionizing radiation, which distinguishes it from CT and PET scans. MRI is a medical application of nuclear magnetic resonance (NMR) which can also be used for imaging in other NMR applications, such as NMR spectroscopy.

4.2 What is Mobile MRI or Portable MRI?

Portable magnetic resonance imaging (MRI) is referred to the imaging provided by an MRI scanner that has mobility and portability. It provides MR imaging to the patient in-time and on-site, for example, in Intensive care unit (ICU) where there is danger associated with moving the patient, in an ambulance, after a disaster rescue, or in a field hospital/medical tent.



Figure 8: Mobile MRI

4.3 Types of MRI

4.3.1 Superconducting-magnet-based portable MRI

The superconducting magnet is one of the main sources to supply a homogeneous main static magnetic field (B0) for MR imaging. Normally it ranges from 1 T to 7 T. To obtain mobility for a conventional MRI scanner that uses a superconducting magnet to supply B0, it is placed in a trailer.

The magnetic field strength of such a mobile MRI scanner is within the range of 1.5 T to 3 T. The weight

of the scanner is the same as one sited in a hospital and the price is higher than a traditional one in the hospital, which is due to the mobility added to the scanner. It can be sited by a medical tent by a battlefield.

4.3.2 Electromagnet-based portable MRI

The electromagnet is another source to supply homogeneous B0 for MR imaging. It offers mobility to MRI as electromagnet is relatively light and easier to move around compared to a superconducting magnet. Moreover, an electromagnet does not require a complicated cooling system. Matthew Rosen and his colleagues from Massachusetts General Hospital have developed a 6.5 mT (65 Gauss) electromagnet-based system. The scanner has a 220 cm diameter and is sited in a copper-mesh enclosure where it has been used mostly for human head imaging, although the system was originally designed to perform hyperpolarized 3He lung imaging with subjects in both upright and horizontal orientations. Magritek has a table-top system using an electromagnet to supply B0. The imaging volume is a cylinder with a diameter of 1–2 cm. The downside of using an electromagnet for MRI us the field strength. It is usually below 10 mT if the field of view (FoV) is relatively large, e.g. a diameter of spherical volume (DSV) of 20 cm for head imaging.

4.3.3 Permanent-magnet-based portable MRI

A permanent magnet array (PMA) can supply B0 field for MRI.[8] It does not require power nor a cooling system, which helps to simplify the hardware of a scanner favoring portability. To supply a homogeneous B0 within an FoV of 40–50 cm for a body scan, a PMA, usually in a C-shape or an H-shape, goes up to a room size and is heavy. The field strength is usually below 0.5 T. Siemens has a product, MAGNETOM C, which has a magnetic field of 0.35 T for a body scan. The scanner is a room-sized, 233×206×160 cm, and has a weight of 17.6 tons. Its FoV can go up to 40 cm with a homogeneity of less than 100 ppm. When the concept of body dedication is applied to a PMA-based system where the magnet and other apparatus are built around a targeted body-part under imaging (e.g. the angle, the knee, the shoulder, the arm), the size of the scanner can be reduced to half of a room-size [10][11][12] for a homogeneous field for a DSV of around 10–15 cm. A C-shaped PMA was reduced to a table-top size to have a homogeneous field within a DSV of 1–2 cm for imaging.

Using a PMA to supply a homogeneous B0 and relying on linear gradient fields supplied by gradient coils cannot give us a PMA with portability and a relatively large imaging volume simultaneously. Allowing magnetic field that has non-linear gradients to encode the signal for imaging leads to the possibility of having a relatively light PMA (tens to hundreds of kgs) and a relatively large FoV (15–25 DSV) at the same time. A Halbach array supplies a magnetic field that points in the transversal direction and has a quadrupolar pattern . An Inward-outward (IO) ring pair array supplies a magnetic field that points in the longitudinal direction which allows the application of the advancement of RF coils to the system. The pattern supplied by the latest designed IO ring pair array can be very close to a linear pattern, which leads to an efficient signal encoding and a good image quality.

5 Needle Free Injector

5.1 INTRODUCTION

Needle free injection technology (NFIT) is an extremely broad concept which include a wide range of drug delivery systems that drive drugs through the skin using any of the forces as Lorentz, Shock waves, pressure by gas or electrophoresis which propels the drug through the skin, virtually nullifying the use of hypodermic needle.

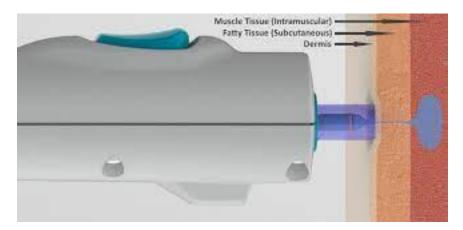


Figure 9: Needle free injector

5.2 How it is useful

This technology is not only touted to be beneficial for the pharma industry but developing world too find it highly useful in mass immunization programmes, bypassing the chances of needle stick injuries and avoiding other complications including those arising due to multiple use of single needle. The NFIT devices can be classified based on their working, type of load, mechanism of drug delivery and site of delivery. To administer a stable, safe and an effective dose through NFIT, the sterility, shelf life and viscosity of drug are the main components which should be taken care of. Technically superior needle-free injection systems are able to administer highly viscous drug products which cannot be administered by traditional needle and syringe systems, further adding to the usefulness of the technology.

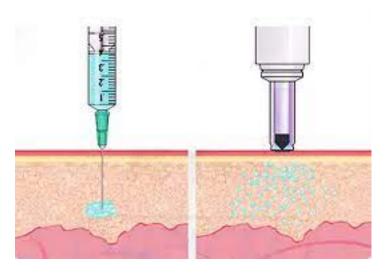


Figure 10: Normal injection versus Needle free injection

NFIT devices can be manufactured in a variety of ways; however the widely employed procedure to manufacture it is by injection molding technique. There are many variants of this technology which are being marketed, such as Bioject® ZetaJetTM, Vitajet 3, Tev-Tropin® and so on. Larger investment has been made in

developing this technology with several devices already being available in the market post FDA clearance and a great market worldwide. This technology is being backed by organizations as World Health Organization, Centers for Disease Control and Prevention and various groups including Bill and Melinda Gates Foundation. This technology is not only touted to be beneficial for the pharma industry but developing world too find it highly useful in mass immunization programs, bypassing the chances of needle stick injuries and avoiding other complications including those arising due to multiple uses of single needle. Better patient compliance has been observed.

6 Oxygenator

6.1 what is oxygenator?

An oxygenator is a medical device that is capable of exchanging oxygen and carbon dioxide in the blood of human patient during surgical procedures that may necessitate the interruption or cessation of blood flow in the body, a critical organ or great blood vessel. These organs can be the heart, lungs or liver, while the great vessels can be the aorta, pulmonary artery, pulmonary veins or vena cava.

6.2 How it is useful?

An oxygenator is typically utilized by a perfusionist in cardiac surgery in conjunction with the heart-lung machine. However, oxygenators can also be utilized in extracorporeal membrane oxygenation in neonatal intensive care units by nurses. For most cardiac operations such as coronary artery bypass grafting, the cardiopulmonary bypass is performed using a heart-lung machine (or cardiopulmonary bypass machine). The heart-lung machine serves to replace the work of the heart during the open bypass surgery. The machine replaces both the heart's pumping action and the lungs' gas exchange function. Since the heart is stopped during the operation, this permits the surgeon to operate on a bloodless, stationary heart.

One component of the heart-lung machine is the oxygenator. The oxygenator component serves as the lung, and is designed to expose the blood to oxygen and remove carbon dioxide. It is disposable and contains about 2–4 m² of a membrane permeable to gas but impermeable to blood, in the form of hollow fibers. Blood flows on the outside of the hollow fibers, while oxygen flows in the opposite direction on the inside of the fibers. As the blood passes through the oxygenator, the blood comes into intimate contact with the fine surfaces of the device itself. Gas containing oxygen and medical air is delivered to the interface between the blood and the device, permitting the blood cells to

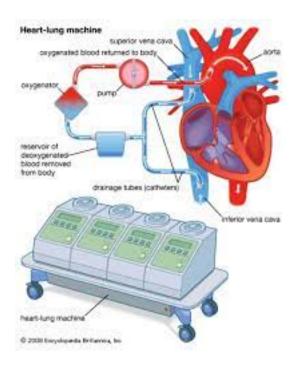


Figure 11: O xygenator

absorb oxygen molecules directly.

7 Intravascular Ultrasound

7.1 What is Intravascular ultrasound?

Intravascular Ultrasound (IVUS) is a catheter-based diagnostic procedure used to view the inside of a coronary artery, providing a real-time view. IVUS shows the degree of narrowing or thickening (stenosis) of an artery by providing a visual image of the inside of the artery (the lumen) and the atheroma (membrane/cholesterol loaded white blood cells) that are hidden within the artery wall.

7.2 Advantages of Intravascular Ultrasound

IVUS enables a physician to get inside the artery with a camera-like device. IVUS can quantify the percentage of narrowing and give insight into the nature of the plaque. It also may reveal what in the past has been referred to as "re-stenosis" (a recurrence of the plaque buildup that may have previously been removed). There is evidence that this is not a re-stenosis but rather the IVUS's ability to see buildup that may have been missed during an angiogram and angioplasty.

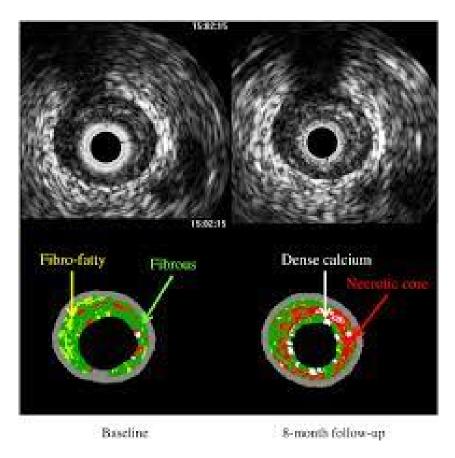


Figure 12: Intravascular Ultrasound

7.3 How does it work?

IVUS is an invasive procedure and, as such, comes with the risks associated with any invasive procedure.

The entire procedure might take less than an hour or as long as several hours:

An area around the groin will be shaved and cleaned in preparation for the insertion of a catheter (a thin tube).

1. A mild sedative is administered to aid in relaxation.

- 2. A local anesthetic is injected into the catheter site.
- 3. The imaging physician directs this catheter, painlessly, through arteries until it reaches the area to be studied. 4. A guide wire with an ultrasound probe on its tip is inserted into the catheter and guided to the furthest position to be imaged. 5. Sound waves are emitted from the probe. The probe also receives and returns the echo information, sending images to a computer. 6. The guide wire is held in place and the probe is slid backwards - usually under steady, smooth, motorized control - sending and receiving ultrasound images along the way. 7. After the catheter is reomoved, patients must lie flat for two to six hours. 8. If a patient lives more than an hour's drive from the hospital, they may need to stay overnight. Due to the administration of a mild sedative, patients will not be allowed to drive themselves home. If a patient arrives without a companion to take them home—and they are not staying overnight—the procedure will be cancelled and rescheduled.

7.4 Results of the Intravascular Ultrasound

The blood vessel wall inner lining, atheromatous disease within the wall, and connective tissues are echogenic (they return echoes making them visible on the monitor). Blood and healthy muscular tissue are echolucent (they return no images, just black spaces on the monitor).

Heavy calcium deposits are very echogenic, which means they reflect sound, and are distinguishable by shadowing. Heavy calcifications are reflected as bright images with shadowing behind it.

Patients need to meet with their physician to discuss their test results and any recommended treatment plans.

References-

 $wikipedia, Cedars\ Sinai, britannica, lab compare.$
