MASTERS THESIS

TOPIC: Разворотка модульной системы для скрининговой диагностики состояния человека

(DEVELOPMENT OF A MODULAR SYSTEM FOR PATIENT AND CONDITION SCREENING)

Student

Supervisor

Academic Advisors

PhD of engineering Sc., Docent

PhD of engineering Sc., Associate professor

PhD of engineering Sc., Associate

Doctor in engineering, Professor

Saint Petersburg

2018

Okoroji G. E.

Yuldashev Z.M

Ivanov A.N

Semenova E.A.
TASK FOR THE MASTER’S THESIS

Student Окороджи Г.Э (Okoroji G.E) Group 2500
Topic: Development of a Modular system for Patient and Condition Screening
Institution: Saint Petersburg Electrotechnical University (ETU)
Initial data (technical requirements): The graduate qualification work demands for a suitable modular system and automated software for screening and diagnosing Patient health condition.
Contents of the thesis: This research work includes, Introduction, Problems and the actuality of developing a patient screening system, biosensors, electrical requirements, results, special aspects of safety and conclusions.
List of report materials: Articles, Journals and various publications from PubMed, Wikipedia, google scholar, etc.

The task given Submitted for defense
« » 20 « » 20

Student Окороджи Г. Э. (Okoroji G.E.)
Supervisor Doctor in engineering, Professor Yuldashev Z.M.
# PROJECT TIMELINE FOR THE MASTER’S THESIS

Approved

Head of the department BES

________________ Yuldashev Z.M.

«___» ________ 2018

Student Оégorоджи Г.Э (Okoroji G.E)  Group 2500

Topic: Development of a modular system for patient and condition screening

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Student Оégorоджи Г.Э (Okoroji G.E)  

Supervisor Doctor in engineering, Professor  Yuldashev Z.M.
SUMMARY

Explanatory note 81; 28 figs; 02 tables; 70 sources.

KEYWORDS: Point of care, diagnosis, ECG, development, challenges.

The subject of the research is Development of a modular system for patient and condition screening. Designing a diagnostic and monitoring system for patient healthcare.

The target of the GQW

This research work is aimed at carefully developing a portable and cost-effective device that can diagnose and monitor several psychological parameters. With special emphasis on its portability, power consumption and ease of use.

Driven by burgeoning developments in sequencing technologies, and other progresses in biological sciences, new diagnostic tests are expected to play a leading role in medicine as well as in tailoring medical treatments to specific patients. This general qualification work examines the barriers that exist in the introduction of new diagnostic investigations into routine medical practice. These barriers are manifold and include the burden of proof in establishing the scientific validity and clinical usefulness of a new test; regulatory hurdles; issues surrounding costs, coverage, and ensuring appropriate compensation for the work that goes into the development and delivery of a new test; a preference amongst physicians for traditional diagnostic methods that are often less formal and require a higher degree of expert analysis and interpretation. However, various steps were taken to develop an economically efficient diagnostic device that alleviates some of the initial problems highlighted. With the increased cost of care, preventive and proactive care has come to stay coupled with the advancement in technology. There would always be challenges, but when the benefits and gains outweigh these hurdles, then preventive medicine has come to stay.
АННОТАЦИЯ

Ожидается, что в результате развития событий в технологиях секвенирования и других достижений в области биологических наук новые диагностические тесты будут играть ведущую роль в медицине, а также при индивидуальном лечении конкретных пациентов. В этой общей квалификационной работе рассматриваются барьеры, существующие при введении новых диагностических исследований в рутинную медицинскую практику. Эти барьеры являются многообразными и включают бремя доказывания в установлении научной достоверности и клинической пользы нового теста; нормативные барьеры; вопросы, связанные с расходами, охватом и обеспечением соответствующей компенсации за работу, которая идет на разработку и сдачу нового теста; предпочтение отдается врачам для традиционных методов диагностики, которые часто менее формальны и требуют более высокой степени экспертного анализа и интерпретации. Однако были предприняты различные шаги для разработки экономически эффективного диагностического устройства, которое облегчает выявление некоторых из начальных проблем. С увеличением стоимости медицинской помощи превентивная и проактивная помощь пришла в себя вместе с развитием технологий. Всегда будут проблемы, но когда выгоды и выгоды перевешивают эти препятствия, тогда превентивная медицина стала оставаться.
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DEFINITIONS, DESIGNATIONS AND ABBREVIATIONS

This explanatory note utilized the following abbreviations listed below;

ECG – Electrocardiography
EWH – Engineering World Health
ESD – Electrostatic Discharge
FDA – Food Drug Administration
IAQ – Indoor Air Quality
IEC – International Electrotechnical Commission
ISO – International Standard Organization
IT – Information Technology
NPV – Negative Predictive Value
POC – Point of care
PPV – Positive Predictive Value
RDT – Rapid Diagnostic Test
SCG – Seismocardiography
WHO – World Health Organization
WPM – Wearable Patient Monitor
PCB – Printed Circuit Board
LED – Light Emitting Diode
LCD – Liquid Crystal Display
SCR – Silicon Controlled Rectifier
INTRODUCTION

A State of wellbeing is the capacity of a biological framework to acquire, change over, dispense, circulate, and use energy with the greatest proficiency. The World Health Organization (WHO) characterized human wellbeing in a more extensive sense in its 1948 constitution as "a condition of finish physical, mental and social prosperity and not only the nonattendance of ailment or infirmity"[1, 2]. This definition has been liable to debate, specifically as lacking operational esteem, the equivocalness in creating durable health methodologies and in view of the issue made by utilization of "complete", which makes it for all intents and purposes difficult to achieve [3-5]. Other definitions have been proposed, among which a current definition that connects wellbeing and individual satisfaction [6, 7].

The meaning of health has developed after some time. With regards to the biomedical point of view, early meanings of wellbeing concentrated on the topic of the body's capacity to work; health was viewed as a condition of typical capacity that could be disturbed every now and then by infection. A case of such a meaning of health is: "a state described by anatomic, physiologic, and mental honesty; capacity to perform by and by esteemed family, work, and group parts; capacity to manage physical, organic, mental, and social pressure [8]. The Figure 1 in the next page, illustrates a state of health
However, the absence of diseases does not always signify a perfect state of health in humans. The significance of random diagnosis and screening plays a vital role in forestalling any eventualities through early detections of signs and symptoms of impending ailments and adverse conditions.

Screening, in solution, is a methodology utilized as a part of a populace to distinguish the conceivable nearness of a so far undiscovered sickness in people without signs or side effects. This can incorporate people with pre-symptomatic or unrecognized symptomatic sickness. All things considered, screening tests are to some degree strange in that they are performed on people clearly healthy. Screening mediations are intended to distinguish infection in a group early, in this way empowering prior intercession and administration in other to diminish mortality and experiencing an ailment. In spite of the fact that screening may prompt a prior conclusion, not all screening tests have been appeared to profit the individual being screened; overdiagnosis, misdiagnosis, and making an incorrect conviction that all is well with the world are some potential antagonistic impacts of screening. Also, some screening tests can be improperly overused. [8, 9] For these reasons, a test utilized as a
part of a screening program, particularly for an ailment with low frequency, must have great affectability notwithstanding worthy specificity.

A few sorts of screening exist: widespread screening includes screening of all people in a specific classification (for instance, all offspring of a particular age). Case finding includes screening a little gathering of individuals in view of the nearness of hazard factors (for instance, on the grounds that a relative has been determined to have an innate sickness). Screening intercessions are not intended to be indicative, and frequently have critical rates of both false positive and false negative outcomes. The Figure 2 below, depicts an example of a screening test.

![Screening Test Diagram](image)

Figure 2 – A diagram illustrating a screening test
1 PROBLEMS OF DEVELOPMENT OF PATIENT HEALTH STATE SCREENING SYSTEMS

Driven by vast improvements in sequencing advancements, proteomics and different advances in biological sciences, new demonstrative tests are required to assume a developing part in prescription and also in fitting medical medications to specific patients. The focal role played by testing in deciding the general course of patient treatment features the basic significance of the necessity that symptomatic tests be precise, dependable, and effective [10].

Nevertheless, regardless of the potential usefulness of new analytic systems and methods of conveyance, numerous challenges still exist as regards the widespread reception of creative diagnostic systems within a routine medical practice. Some of these barriers include:

- unavailability of spare parts,
- high cost of product development,
- biocompatibility,
- proof of establishing usefulness of a new test,
- miniaturization of biosensors and signals,
- technological security issues,
- international and local regulatory compliance,
- hardware and software integration,
- administrative obstacles etc.

Obstruction among doctors to new symptomatic techniques (i.e. a predisposition toward conventional, highest quality level, diagnostic methods that are often less programmatic than new tests and require more expert analysis and understanding); and social and ethical issues, including protection from more expansive based hereditary testing by the overall population. The accompanying areas in this article will look at
every one of these boundaries, drawing on cases of new symptomatic tests with applications inside a scope of therapeutic works on and other issues.

1.1 The unavailability of spare accessories
The lack of spare parts for the repair of medical equipment can present a serious barrier to continuous use. Most devices put into operation generally function effectively at first, but some components will inevitably need replacement after a certain period of use. Data from an Engineering World Health (EWH) study of medical equipment in developing world hospitals point to some main reasons for this shortage of spare parts [11]. They include:

- The spare parts are no longer produced;
- Health staff members believe that purchasing of spare parts is a poor use of resources (e.g. requesting a new device altogether as a better option than meeting the cost of acquiring spare parts).

As regards the non-availability of adequate spare parts for the repair and overall maintenance of diagnostic and various medical systems, it poses some grave dangers which includes;

- Decrease of performance;
- Deterioration of the equipment;
- Detrimental effects on the health of the patient, the user or other persons;
- Contravention of any laws and regulations that may exist.

1.2 High Cost of product development
The medical device industry faces an assortment of estimating issues: Governments and back up plans need to control costs; social insurance offices are getting lower reimbursements, and medical facilities have tight spending plans. These issues influence how medical devices are estimated, valued, and acquired. Purchasing
decisions have moved from doctors to regulators, hospital administrators in acquiring offices, and non-healthcare services experts.

The cost involved in acquiring medical gadgets represents a noteworthy snag to their utilization in some countries. For instance, a single MRI scanner can cost in excess of a million US$ to buy, and together with working expenses can take up a critical chunk of a nation's health insurance spending plan. The cost of capital, be that as it may, is just the tip of the iceberg, with numerous intermittent costs covered up underneath, for example, benefit contracts, spare parts, depreciation, consumables (e.g. needles), training, and so forth. Such expenses inhibit the development of patient healthcare systems [12]. The diagram of Figure 3 below, illustrates the hidden costs in developing medical devices.

Fig 3– The hidden costs in development and procurement of medical devices

1.3 Biocompatibility

Biocompatibility is identified with the conduct of biomaterials in different settings. The term alludes to the capacity of a material to perform with a fitting host reaction in a particular situation. [13] The obscurity of the term mirrors the continuous
improvement of experiences into how biomaterials collaborate with the human body and in the long run how those cooperations decide the clinical achievement of a medical device, (for example, pacemaker, hip substitution or stent).

Present day medical devices and prostheses are regularly made of in excess of one material so it may not generally be adequate to discuss the biocompatibility of a particular material [14].

Since the resistant reaction and repair works in the body are so convoluted, it isn't satisfactory to depict the biocompatibility of a solitary material in connection to a solitary cell write or tissue. Once in a while one knows about biocompatibility testing, that is a vast battery of in vitro test [15] that is utilized as a part of agreement with ISO 10993 (or other comparative guidelines) to decide whether a specific material (or rather biomedical item) is biocompatible. These tests don't decide the biocompatibility of a material, [16] yet they constitute a critical advance towards the creature testing lastly clinical trials that will decide the biocompatibility of the material in a given application, and consequently, medical devices, for example, embeds or sedate conveyance devices [17].

All these definitions deal with materials and not with devices. This is a drawback since many medical devices are made of more than one material. Much of the pre-clinical testing of the materials is not performed on the devices itself but rather the on the material. But at some stage the testing will have to include the device since the shape, geometry and surface treatment etc. of the device will also affect its biocompatibility.

1.3.1. Proof of establishing usefulness of a new test

For another diagnostic test to be acknowledged by the medical foundation and broadly received inside a normal medical practice, specialists must show that the strategy it utilizes is substantively better than officially existing techniques. The Royal
College of Pathologists isolates the helpfulness of a symptomatic test into 3 particular segments:

- analytical legitimacy (i.e., specialized performance),
- clinical legitimacy (i.e., the energy of the test to foresee the presence of clinical illness), and
- clinical convenience (i.e., the likelihood that utilization of the test will bring about enhanced patient outcome) [18].

Most importantly, the analytical legitimacy of a test is estimated by its sensitivity (i.e., the likelihood that an example from a person with a specific illness will test positive) and specificity (i.e. the likelihood that an example from a healthy individual will test negative), and in addition by its opposite measures, to be specific, the positive predictive value (PPV) and negative predictive value (NPV). PPV is the "likelihood that those testing positive by the test are really infected," and NPV is "the likelihood that those testing negative by the test are genuinely uninfected" [19]. These 4 measures are commonly decided with respect to a reference standard test, or gold standard test, that is utilized to figure out which people really harbour a specific sickness or ailments and which don't. Another essential property, precisely, reproducibility, measures the degree to which similar test outcomes are acquired from a similar example by various laboratorians over the span of different tests.

It is conceivable that the net helpfulness of another indicative test will include trade-offs between various measures of its execution. An agent case is Rapid Diagnostic Tests (RDTs), which are utilized to recognize infectious sicknesses. The value of RDTs exists essentially in the promptness with which test results can be gotten. The estimation of RDT strategies in general wellbeing settings including a crisis reaction to epidemiological episodes is clear. Notwithstanding, current RDTs are hampered by the way that healthcare experts have generally believed these tests to be less accurate than the gold-standard reference tests against which they are assessed.
1.3.2 Technological security issues

Medical devices, for example, pacemakers, insulin pumps, operating room monitors, defibrillators, and surgical instruments, including profound cerebrum stimulators, can incorporate the capacity to transmit essential health data from a patient's body to medical professionals [20]. Some of these devices can be remotely controlled. This has caused worry about privacy and security issues [21] human mistake, and specialized glitches with this innovation. While just a couple of studies have taken a look at the vulnerability of diagnostic devices to hacking, there is a risk [22-24]. In 2008, PC researchers demonstrated that pacemakers and defibrillators can be hacked remotely by means of radio hardware, a receiving wire, and a personal computer [25].

These analysts indicated they could close down a combination heart defibrillator and pacemaker and reinvent it to convey possibly deadly shocks or run out its battery. Jay Radcliff, a security specialist interested in the security of medical devices, raised fears about the safety of these systems. He shared his worries at the Black Hat security conference [26]. Radcliff fears that the devices are defenseless and has discovered that a deadly assault is conceivable against those with insulin pumps and glucose monitors.

Some medical manufacturers make light of the danger from such assaults and contend that the assaults have been performed by talented security scientists and are probably not going to happen in reality. In the meantime, different creators have requested that software security specialists explore the safety of their devices [27]. Not quite long ago in June 2011, security specialists demonstrated that by utilizing promptly accessible hardware and a client manual, a researcher could both take advantage of the data on the information of a wireless insulin pump together with a glucose monitor. With the PIN of the device, the researcher could remotely control the dosage of the insulin [28]. Anand Raghunathan, a scientist in this research, clarifies that medical devices are getting miniaturized so they can be worn with ease.
The drawback is that extra security features would put an additional strain on the battery and size and drive up costs. Dr. William Maisel offered a few insights on the motivation to take part in this action. Motivation to do this hacking may include the purpose of obtaining private data for monetary benefit or competitive advantage; harm to a device maker's notoriety; disrupt; plan to incur money related or individual damage or just satisfaction for the assailant.

1.3.3 International and local regulatory compliance

The importance of regulation as regards medical devices is undeniable in terms of providing assurance for safety and total wellbeing. This view supports measures put in place by major international associations, for example, The Global Harmonization Task Force, the World Trade Organization and the International Organization for Standardization [29]. Such benchmarks can be useful in giving valuable directions to the governments of various nations, particularly those that need medical device-specific regulations.

While the advancement of measures and control of medical devices is without a doubt very paramount, excessive regulations, especially one that is inhumane to the domestic settings, can act as a hurdle to local innovation. It can conceivably upset domestic development by subjecting new technologies to extensive and costly licensing processes, thereby resulting to increased costs and time that local manufacturers need to put resources into expansion. As a result, advancements with moderately low development costs, for example, immune-diagnostics, may become unreasonably expensive. A few items that are of critical value to low-income nations might be removed from the market because of risks associated with their use, based on of elevated standards in highly industrialized nations (where rules generally originate) [30]. For instance, as the EWH study has discovered, original replacement batteries for a defibrillator can cost between US$ 200 and 300. It may be workable for a local
producer in a developing nation to produce a less expensive alternative, yet which is probably not going to meet global norms, (for example, working at 0º C) [11]. In summary, by forcing powerful benchmarks and regulatory standards, the universal body in medical device regulation and control appears to deflect as opposed to empower local innovation and content, thus hindering the chances of local manufacturers being able to flourish.

1.4 Diagnostic errors associated with medical devices and testing

Misdiagnosis is a huge, unexplored part of patient well-being, with wildly ranging rates of delays and mistaken conclusion. Our ignorance stems from the troubles of concentrating on the issues and the perplexing causes and outcomes of diagnostic errors. For more clarifications on the area of diagnostic errors, emphasis is placed on some determining factors in diagnostic testing. They include

- Sensitivity
- Specificity
- Validity

**Sensitivity**

Sensitivity refers to the test's capacity to effectively recognize sick patients who do have the condition. [4] In the case of a medical test used to distinguish an illness, the sensitivity of the test is the extent of individuals who test positive for the ailment among the individuals who have the ailment. Scientifically, this can be calculated in the next page as

\[
\text{Sensitivity} = \frac{\text{number of true positives}}{\text{Number of true positives} + \text{number of false negatives}} \\
= \frac{\text{number of true positives}}{\text{Total number of sick individuals in a population}} \\
= \text{Probability of a positive test given that the individual has the disease}
\]
A negative result in a test with high sensitivity is valuable for ruling out disease [4]. A high sensitivity test is solid when its outcome is negative since it once in a while misdiagnoses the individuals who have the infection. A test with 100% sensitivity will perceive all patients with the infection by testing positive. A negative test outcome would completely preclude the nearness of the infection in a patient.

A positive outcome in a test with high sensitivity isn't helpful for ruling in disease. Assume a 'bogus' test pack is intended to demonstrate just a single reading, positive. At the point when utilized on sick patients, all patients test positive, giving the test 100% sensitivity. Be that as it may, sensitivity by definition does not consider false positives. The bogus test likewise returns positive on every single sound patient, giving it a false positive rate of 100%, rendering it pointless for recognizing or "ruling in" the infection.

Sensitivity isn't the same as the accuracy or positive predictive value (proportion of genuine positives to combined genuine and false positives), which is as much an announcement about the extent of real encouraging points in the populace being tried as it is about the test.

The calculation of sensitivity does not consider uncertain test outcomes. On the off chance that a test can't be repeated, uncertain examples either ought to be prohibited from the examination (the number of rejections ought to be expressed while citing sensitivity) or can be dealt with as false negatives (which gives the most pessimistic scenario esteem for affectability and may, in this way, think little of it).

**Specificity**

Specificity refers to the test's capacity to effectively reject healthy patients without a condition. Think about the case of a medical test for diagnosing an illness. Specificity of a test is the extent of healthy patients known not to have the disease or ailment, who will test negative for it. Mathematically, this can likewise be composed as:
Specificity = \frac{\text{number of true negatives}}{\text{number of true negatives + number of false positives}}

= \frac{\text{number of true negatives}}{\text{total number of healthy individuals in a population}}

= \text{Probability of a negative test given that the patient is healthy}

A positive outcome in a test with high specificity is helpful for decision in sickness. The test once in a while gives positive outcomes in healthy patients. A test with 100% specificity will read negative, and precisely prohibit sickness from every single healthy patient. A positive outcome connotes a high likelihood of the presence of disease [31].

1.5 Challenges of using modern medical electronic components

As the interest for medical equipment and gadgets keeps on growing worldwide, electronic innovations are progressively vital segments of these items and as more electronic medical devices are made portable, wearable, or even implantable, medical device manufacturers will battle with the hurdle of getting more functionality and longer lasting power into their creations. Miniaturization of these devices is a regular challenge for manufacturers, and their supply and service partners. Empowering these devices to accomplish more while consuming up less space is a huge task.

Greater globalization also implies more prominent difficulties with respect to component traceability and reliability.

All these challenges often result in the failures of these electronic components. Electronic components have an extensive range of failure modes. These can be classified in different ways, for example, by time or cause. These failures can be caused by excessive temperature, excess current or voltage, ionizing radiation, mechanical
shock, stress and numerous causes. In semiconductor devices, issues in the device package may cause disappointments because of defilement or contamination, mechanical stress of the device, or open or short circuits. Failures most times happen close to the start and close to the consummation of the lifetime of the parts. Below are some electronic component failures due to modernization of these components [32].

Packaging failures

The majority of electronic parts faults are package-related [33]. Packaging, as the hurdle between electronic parts and environment, is exceptionally defenseless to environmental variables. Thermal expansivity on components results in mechanical stress that may cause material fatigue and this happens mostly when the thermal expansivity coefficients of the various integrated components are different. Humidity and forceful synthetic substances can cause corroding of the packaging materials and leaks, potentially breaking them and resulting in their internal parts being damaged, which in turns leads to electrical failure. Surpassing the permitted environmental temperature range can cause a blowup of wire bonds, thus tearing the connections loose, breaking the semiconductor dies, or causing packaging leaks. Moistness and consequent high-temperature heating may likewise result in cracking, as well as mechanical harm or shock. During encapsulation, holding wires can be disjointed, shorted, or touch the chip die, usually at the edge.

Contact failures

Bounded or soldered joints can fail in varying instances like in electromigration and arrangement of weak intermetallic layers. A few failures become noticed only at outrageous joint temperatures, upsetting troubleshooting. Heat-induced mismatch between the printed circuit board material and its packaging strains the part-to-board bonds; while leaded parts can absorb the strain by bending, leadless parts depend on the solder to absorb stresses. Thermal cycling may prompt fatigue cracking of the welded joints, particularly with flexible solders; different methodologies are utilized to
alleviate such occurrence. Free particles, such as holding wire and weld flash, can form in the device cavity and move into the packaging, causing frequently irregular and shock-sensitive shorts.

Corrosion of its components may cause the development of oxides and other nonconductive items on the contact surfaces. Whenever shut, these then show unsuitably high resistance; they may likewise migrate causing shorts [34].

Metal whiskers which is a phenomenon that occurs in electrical devices can be formed on tin-covered metals like the internal side of the packaging; free stubbles at that point can cause discontinuous short-circuits inside the devices. Cables also may fail by fraying and fire harm. The figure 4 below depicts a corroded component.

![Figure 4. A printed circuit board with its components being corroded](image)

Printed circuit board failures

Printed circuit boards (PCBs) are susceptible to environmental impacts; for instance, the traces are erosion-prone and might be improperly etched thus leaving incomplete shorts, while the vias might be deficiently plated through or loaded with solder. The traces may break under mechanical loads, often bringing about unreliable PCB activity. Buildups of weld flux may encourage corrosion; those of different materials on PCBs can cause electrical leaks. Polar covalent compounds may likely
cause dampness like antistatic agents, forming a thin layer of conductive moisture between the traces; some ionic compounds like chlorides have a tendency to encourage corrosion. Soluble base metal ions may move through plastic packaging and impact on the functioning of semiconductors. Chlorinated hydrocarbon deposits may hydrolyze and discharge corrosive chlorides; these are issues that happen after years. Polar particles may dissipate high-frequency energy, resulting to parasitic dielectric losses

Relay failures

Each time the contacts of an electromechanical relay or contactor are opened or shut, there is a sure measure of contact wear. An electric arc happens between the contact points (anodes) both amid the change from closed to open (break) or from open to closed (make). The arc caused during the contact (break curve) is likened to arc welding, as the broken curve is normally more active and more destructive. [35]
The heat and current of the electrical arc over the contacts create particular cone and crater formations from metal migration. Added to the physical contact damage, there's also a coating of carbon and other matters. This degradation radically constrains the general working capacity of a relay or contactor to a scope of maybe 100,000 tasks, a level that represents 1% or less than the mechanical life expectancy of the same device. [36]

Electrical overstress

Most stress induced semiconductor fails are electrothermal in nature infinitesimally; locally expanded temperatures can prompt quick failures by liquefying or vaporizing metallization layers, dissolving the semiconductor or by vaporizing metallization. Diffusion and electromigration have a tendency to be quickened by high temperatures, shortening the lifespan of the device; damage to joints not prompting immediate failure may show up as altered current-voltage characteristics of the joints. Electrical overstress failures can be termed as thermally-initiated, electromigration-related and electric field-related failures; cases of such failures include:
• Thermal runaway, where groups in the substrate cause confined loss of thermal conductivity, prompting damage to the component and thus creating more heat; the most widely recognized causes are voids caused by incomplete soldering, electromigration effects, and Kirkendall voiding. Clustered dispersion of current density over the junction or current fibers prompt current swarming confined problem areas, which may develop into a thermal runaway.

• Reverse bias. Some semiconductor devices are diode junction-based and are normally rectifiers; nonetheless, the reverse breakdown mode might be at a low voltage, with a direct reverse voltage causing quick degradation and tremendously quickened failure. 5 V is a maximum reverse-bias voltage for common LEDs, with a few kinds having lower figures.

• Extremely over-burden Zener diodes in reverse bias shorting. An adequately high voltage causes torrential slide breakdown of the Zener junction; that and a vast current being passed through the diode causes outrageous localized heating, melting the junction, metallization and as a result a residue of silicon-aluminum is formed which shorts the terminals. This is at times purposefully utilized as a strategy for hardwiring connections by means of fuses [37].

• Latchups (when the device is subjected to an over-or-under voltage pulse); a parasitic structure in form of an activated SCR at that point may cause an overcurrent-based failure. In ICs, latchups are grouped as internal (like transmission line reflections and ground bounces) or external (like signals introduced by means of I/O pins and cosmic beams); outer latchups can be activated by an electrostatic release while internal latchups cannot. Latchups can be activated by charge bearers infused into chip substrate or another latchup; the JEDEC78 standard tests defenselessness to latchups [38]. The Figure 5 below, depicts an overstressed electronic component.
Metallization failures of electronic components

Metallization failures are more typical and genuine causes of FET transistor degradation than material procedures; indistinct materials have no grain boundaries, obstructing interdiffusion and corrosion [39]. Examples of such disappointments include:

• Electromigration moving atoms out of active areas, causing disengagements and point defects as in nonradiative recombination centres emitting heat. This may happen with aluminum gates in MESFETs with RF signals, causing sporadic drain current; electromigration for this situation is called gate sinking. This issue does not happen with gold gates [39]. With structures having aluminum over a refractory metal obstructor, electromigration essentially influences aluminum however not the refractory metal, making the structure's opposition to increase erratically. Displaced aluminum may result in shorts to neighboring structures; 0.5-4% of copper in the aluminum increases electromigration resistance, the copper amassing on the alloy grain
boundaries and expanding the energy expected to displace atoms from them [37]. Asides that, indium tin oxide and silver are liable to electromigration, causing current leaks and (in LEDs) nonradiative recombination along chip edges. In all cases, electromigration can result to variations in dimension and parameters of the transistor gates and semiconductor junction.

- Mechanical stresses, high currents, and corrosive situations, forming of whiskers and short circuits. These impacts can happen both inside packaging and on circuit boards.

- Formation of silicon nodules. Aluminum interconnects might be silicon-doped to saturation amid deposition to forestall alloy spikes. During thermal cycling, the silicon particles may move and glue up together forming nodules acting as voids, thus resulting in local resistance which lowers device lifespan [38].

- Ohmic contact degradation amongst metallization and semiconductor layers. With gallium arsenide, a layer of gold-germanium alloy (a times with nickel) is utilized to accomplish low contact resistance; an ohmic contact is formed by dissemination of germanium, forming a thin, highly n-doped region under the metal thereby assisting in the connection, leaving gold stored over it. Gallium molecules may move through this layer and get caught up by the gold above, making a defect-rich gallium-deficient zone under the contact; gold and oxygen at that point move oppositely, bringing about expanded obstruction of the ohmic contact and consumption of viable doping level [39]. Formation of intermetallic compounds likewise assumes a part in this failure pattern. The figures 6 and 7, below show examples of metallization effect failures in components.
Figure 6 – An illustration of metallization effects on components

Figure 7 – A faulty electrical component failure due to wrong input voltage and overheating on the chip
1.6 The problems of power supply in the development of diagnostic devices

The expanding intricacy of medical device setups is causing worry in the medical industry. As more health experts utilize an assortment of electrical equipment as a major aspect of their diagnosis and assessment, there seems to be a knock-down effect on the stability of the mains control supply. Be that as it may, the increased needs for the electrification of these devices puts more burdens on the mains control supply. AC to DC conversion brings about voltage distortion, electrostatic discharge, power surges and electromagnetic interference (EMI). These power quality issues can influence the calibration and sensitivity of diagnostic devices utilized by specialists and medical services experts. Mistaken test outcomes can bring about misdiagnosis and possibly unsafe treatment plans for patients.

The increasing use of smaller and more minimal power supplies in electronic devices and controlled motors has to a great extent been influenced conceivable using switch-mode to power supplies (SMPS) in individual use and variable speed drives (VSDs) in commercial and mechanical use. This is accomplished by controlling the mains control supply, utilizing components in rectifier and chopper circuits, in a procedure of high-frequency modulation, or pulse width modulation (PWM).

Despite the fact that PWM accomplishes low power losses, the procedure results in harmonic current inflow into the supply. Harmonics are basically products of the fundamental 50Hz frequency and are in basically responsible of various issues, especially in modern conditions. The most immediate issue is increased energy consumption. The distortion caused by harmonic brings about a non-linear, non-sinusoidal waveform. For instance, if the major current drawn is 70A, this capacity may comprise of 20A of harmonic frequencies, implying that the aggregate current the framework needs to supply is really 72.8A.
This increased consumption is regularly underestimated and goes unchallenged. It's just when harmonic current prompt more discernible component damage that worries are raised.

By and large, these issues can start to influence both the nearby framework inside and the more extensive supply framework remotely. Internally, electromagnetic interference (EMI) can start to influence telecommunication hardware and metering mechanical apparatus. Noteworthy distortion of the current waveform locally can start to distort the voltage supply externally, creating symptoms, for example, flash on open low voltage networks. The table 1 below, shows example of electrical failures and their probable causes.

<table>
<thead>
<tr>
<th>Failure</th>
<th>Probable causes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Package breakdown</td>
<td>Electrical and or thermal overload</td>
</tr>
<tr>
<td>Electrical breakdown</td>
<td>Electrical overload, excessive moisture</td>
</tr>
<tr>
<td>Mechanical damage</td>
<td>Deformation due to differing thermal expansion coefficients</td>
</tr>
<tr>
<td>Chip separation</td>
<td>Chip to substrate bonding defects</td>
</tr>
<tr>
<td>Breakdown of metallization layers</td>
<td>Electrostatic discharge, corrosion, electric/ thermal overload</td>
</tr>
<tr>
<td>Electromigration</td>
<td>Flowing current</td>
</tr>
<tr>
<td>Damage to oxide layers</td>
<td>Electrostatic discharge, pores</td>
</tr>
<tr>
<td>Deformation</td>
<td>Mechanical stress during heat cycling</td>
</tr>
<tr>
<td>Chip defects</td>
<td>Defects in bulk semi-conductors</td>
</tr>
</tbody>
</table>

1.7 Actuality of the development of systems for screening patient health conditions
With rising technological advancements in healthcare, including smartphone applications, biosensors, lab-on-a-chip, and wearable devices; all of which offer a closer association with the patient point-of-care (POC) technologies are rapidly taking over in transforming the healthcare terrain. The driving force behind the innovation of point-of-care testing (POCT) is to bring diagnosis and the results conveniently and rapidly to the patient to facilitate analysis and ensuing treatment. POCT considers quicker clinical choices in hospitals, doctors' offices, ambulances, patient's home, and in the field. The College of American Pathologists (CAP) characterizes POCT as "testing that is performed close or at the site of a patient with the outcome prompting a conceivable change being taken care of by the patient." Because of its comfort, time sensitiveness, and potential to enhance patient's outcome, POCT's fame has been on the ascendancy [40]. Empowering patients to settle on the best possible choices at the patient's side can possibly altogether affected healthcare delivery positively and to help address difficulties of health variations. Bringing the test to the patient improves the probability that the patient, doctor, and care group will get the outcomes speedier, taking into consideration prompt clinical administration choices. Moreover, improvement, usage, and availability of portable diagnostic and monitoring devices for POCT will play its part as a paradigm shift towards a more pragmatic approach from corrective medication to predictive, customized, and preemptive medicine.

Explosion of POC Technology in Modern healthcare

Various elements, for example, the expanding predominance of infectious illnesses in developing nations, the rising occurrences of lifestyle diseases, for example, heart diseases and diabetes, the rising use of home-based POC gadgets, and technological progressions concerning improvement of cutting edge, faster, and easy-to-utilize devices are stimulating the interest for POCT [41]. While POCT is a standout amongst the most dynamic fragments inside the diagnostic world, the innovative
capacities far dwarf the rate of POCT adoption [42]. The Figure 8 below, shows the network pattern of POCT system.

Figure 8— A structural representation of point-of-care-technology

In light of the numerous elements expanding the inquest for POCT, manufacturing organizations are angling to every known limit to make POCT devices quicker, less demanding, and more reliable. The worldwide POC diagnostics market is anticipated to develop at a compound annual growth rate (CAGR) of 9.3% from 2013 to 2018, and to reach $27.5 billion by 2018 [41, 43]. The market accounts both professional and patient self-monitoring tests and incorporates testing packs for the following below

- Blood gases/electrolytes,
- Cardiac markers,
- Cholesterol/lipids,
- Coagulation monitoring,
- Drugs of abuse testing (DAT),
- Fecal occult blood,
• Food pathogens,
• Glucose monitoring,
• Hematology,
• Infectious diseases,
• Pregnancy and fertility,
• Tumor/cancer markers,
• Urinalysis testing.

**Elements Driving the POCT Market**

POCT can be a powerful avenue for enhancing proficiency and results and reacting to fundamental healthcare services needs among large populaces and in rural territories. POCT is most beneficial when patient treatment can be moved forward by fast outcomes. The maximum capacity of POCT is best realized in circumstances or in an ailment state where having the outcome or result as speedily as possible is vital to treatment, and in so doing, leads to diminishing downstream expenses. Additionally, in a circumstance where the patient can get real-time counseling based on the test results (e.g., Hgb A1c testing for diabetic status or PT/INR testing to monitor coagulation treatment), POCT turns out to be very beneficial [44].

**Healthcare reforms- Patient centered care**

Healthcare reforms, presently being sought after in the U.S and other parts of the world, is encouraging the provision of a better and more easier access to medical services for all patients, especially those with debilitating diseases [45]. The potential for POCT to be part of patient-driven healthcare services is evident in light of the fact that speedier outcomes encourage quicker clinical decisions. As the healthcare scope shifts (e.g., clinics solidify into local systems with profoundly specialized healthcare care performed in its facilities), more services can be offered at the point of patient contact [46]. The Figure 9 below, shows a Multipsychological monitoring device.
Figure 9 – A mobile Multipsychological parameter monitoring device

Diagnostic facility testing is experiencing a comparable change. Complex, non-pressing tests are performed in center research centers or in reference sites; normal, intense diagnostic tests are performed in center labs or in satellite medical center offices; and POCT is performed in outpatient facilities, doctor office labs, retail centers, and in-patient homes. Patients are looking for treatment at nearby doctor offices and retail facilities at a higher rate than any time in recent memory before now.8 With the attention on giving cost-effective, convenient medical attention to mobile patients, POC lab testing has turned out to be one of the quickest regions of development in the medical field, with the number of tests expanding at an estimated 10% to 12% annually [46]. The creation of the patient-centered medical home (PCMH) placed a renewed
accentuation on essential care and made a commitment to patient-oriented care. POCT can bolster PCMHs in their endeavors to:

- Enhance access to care
- Enhance patient experiences
- Enhance care quality
- Improve disease understanding and awareness by the patient

**Increase in Older Population and Chronic Disease**
A rising interest for home healthcare services and the ever-increasing need to deal with a larger populace of elderly patients with numerous chronic health conditions is required to drive POC diagnostics market request in the coming years. This reality, together with government activities to cut short hospital length of stay (LOS) by setting up out-patient care models, is altogether estimated to impact on the POC diagnostics market [47].

**Advances in Technology**

The POCT scope is driven by technological progressions and by preference of patients. Producers are making persistent advancements towards research, innovative work, and developments to make products with more up to date technologies. The innovation associated with POCT has advanced by and large in terms of quality and satisfaction of patient’s medical needs comparable to the centralized laboratories. Progressions have additionally been made that makes testing sufficiently straightforward and accurately performed by moderately trained staff due to its ease of use. Numerous tests that before now required a research center for testing would now be able to be precisely tested at the point of care. Significantly more complex molecular diagnostic devices are being produced directly for the POC market [44].
Current POCT Market Status

Several tests once considered excessively complex for POC are currently routinely performed outside the laboratory [48]. Sensor innovations empower the fast investigation and analysis of blood tests for most critical assays, including chemistries, electrolytes, blood gases, and hematology. Biosensors are utilized for toxicology and drug screens, estimation of platelets, coagulation, detection of cardiac markers, and glucose self-testing.

Glucose: Largest Market Segment

The hospital glucose market is the largest POCT market fragment on account of the high predominance of diabetes and the need for steady checking of blood glucose levels. According to statistical records made public by the International Diabetes Federation, the worldwide prevalence of diabetes is required to go up from 382 million in 2013 to 592 million in 2035 [41]. Moreover, increasing interest in demand for home medical care to address the rising frequency of diabetes is another market driver. The blood glucose monitoring device market is an exceptionally lucrative business with tremendous future potential; estimated at more than $2 billion out of 2012 [47]. Figure 10 below, shows how portable and accurate in measurements blood glucose monitors have become as a result of major advancements in healthcare technology.
Heart: Fastest-developing Segment

While glucose testing is the biggest market section in POCT, heart POCT is viewed as the quickest developing fragment. The global ECG Market was estimated at $4,516 million in 2016, and is likely to reach $6,637 million by 2023, registering a CAGR of 5.6% from 2017 to 2023. Electrocardiograph (ECG) is a non-invasive diagnostic device that records the electrical movement of the heart pulse over some undefined time frame. ECG monitoring devices, for example, resting ECG, stretch ECG, and Holter monitors assist in sorting out and give data about unusual workings of the heart. Cardiovascular defect is gradually becoming of the most common diseases across the world today, with high death rate representing around 370,000 individuals dying yearly in the U.S. alone. This drives the interest for ECG market as the increase in number of ECG tests performed by individuals, vulnerable to heart ailments. The
other key factors that lift the development of electrocardiograph (ECG) market include innovative technological progressions in ECG devices, for example, portable and handheld, an upsurge in frequency of cardiovascular diseases worldwide, increase in the geriatric populace, and some favourable government controls with respect to monitoring devices. Be that as it may, certain aspects, for example, unfavourable reimbursements approaches alongside the increase in market saturation hinder the market growth [49]. The Figure 11 below, shows how modernized and portable ECGs have become and they play a major role in early diagnosis of various heart ailments which have been on the rise globally.

![Figure 11 - Graphical statistics showing the steady increase in ECG usage globally](image)

1.8 Objectives and tasks of the graduate qualification work

The main goal of this graduate qualification work is to develop a suitable and portable diagnostic system that can perform the purposes of diagnosis, registration of vital signals and monitoring of patients multipsychological conditions with precision. In other to achieve these set goals, some certain targets need to be met that accomplishes the needs of the end users, and these design goals include;
• Affordability- Low cost
• Sensitivity– minimization of false negatives
• Specificity– minimization of false positives
• User-friendly– Ease of use
• Rapid and precise– Short turnaround time and precision in results
• Equipment-free– No complex equipment
• Delivered– to end users

Aside these objectives listed above, other desires the research work should fulfil includes the longevity of the device as a long-term usage of the device would be beneficial to the end users. Also, its portability and userability is paramount to the end users deriving maximum satisfaction. The Figure 12 below, shows the trend of a basic diagnostic device in our everyday living

Figure 12 – A systematic trend of preventive healthcare
1.9 Conclusion

With the advancements in technology and the rapid growth of patient medical devices, the future looks bright. Preventive health screenings are an affordable, efficient and effective way to identify hidden disease risk. For most people, getting screened is the first step in early intervention to prevent potential health events later in their lives. It helps people understand their risks so that they can consult with their doctor and take proactive steps towards a healthier future. Inasmuch as it faces some challenges, the benefits outweigh the obstacles thus making it a breakthrough worth embracing.
2 DEVELOPMENT OF A MODULAR SYSTEM FOR PATIENT AND CONDITION SCREENING

2.1 The development of a generalized structure of the system

The main target of this research work is to develop a bioengineering system for the purpose of enhancing preventive health screening through the use of a diagnostic device that can diagnose, process the signals, monitor, and receive psychological signals when interfaced with the patient and these bio signals are visualized either on

This graduate qualifying work widely investigates building up a perfect diagnostic framework that can be considered to be perfect. A great deal of planned steps was being taken to realize the set objectives and goals of this task. The system is intended to work as a heartbeat monitor, pulse oximeter, a temperature sensor, and a non-invasive blood pressure analyzer with it being portable and user-friendly and it could be connected to a PC or with a more advanced technology of a smartphone using Bluetooth connectivity for visual display of its volumetric signals. The device is a hardware-software integrated system that must leverage on the ever-improving technology to meet demands for improvements in accuracy, functionality, and size, as well provide advances in data capture, transmission, storage, and compatibility, ultimately empowering improved healthcare and enhanced patient outcomes.

The next approach is to give a clearly defined structure of how a suitable diagnostic device should look like, bearing in mind that its compatibility with the patient is very vital to solving critical health problems before it becomes fully blown. The electronic components and all other modules for signal acquisition and processing are highlighted in this research work. A well-defined structure of the interface between the patient and the device is shown in Figure 13 below.
Figure 13 – A generalized structure of a patient screening system displaying the interface of the patient with the device to the display of the probable health condition

The intended approach was to design a diagnostic device circuitry using discrete electronic components. This is certainly a valid approach that could be cost-effective depending on parts selection. Some of the electrical components used in the development of this work include a microcontroller unit, Microprocessors, Input amplifiers, analog/digital units, amplifiers, UART, ECG sensors, temperature sensors, pulse rate sensors, a non-invasive blood pressure sensor, a 16×2 LCD, a GSM module, jumper wires etc.

2.2 Development of the structure of the microprocessor unit

The microprocessor is a multipurpose, clock driven, enlist based, advanced integrated circuit that acknowledges binary data as information, processes it as per directions put away in its memory, and gives out results as output. Microprocessors contain both combinational logic and successive digital rationale. Microprocessors operate on numbers and images spoke to in the binary gig framework.
The integration of an entire CPU onto a solitary chip or on a couple of chips extraordinarily diminished the cost of handling power, expanding effectiveness.

Integrated circuit processors are created in substantial numbers by profoundly robotized forms, therefore it is low for every unit cost. Single-chip processors increase unwavering quality on the grounds that there are numerous less electrical associations with fall flat. As microchip designs improve, the cost of assembling a chip (with smaller components built on a semiconductor chip) by and large remains the same.

Before microprocessors, little PCs had been fabricated utilizing racks of circuit boards with numerous medium-and little scale ICs. Microprocessors merged this into one or a couple of larger scale ICs. Later increases in the capacity of microprocessors have since rendered it totally old (check out the history of computing equipment), with at least one microprocessor utilized in almost everything from the littlest implanted frameworks and handheld gadgets to the biggest centralized computers and supercomputers. The Figure 14 below, depicts the bus structure of an 8085-microprocessor model.

![Figure 14 – A Bus structure of an 8085 microprocessor](image-url)
Some basic terms of the Microprocessor unit (MPU)

**Bus** - A bus, as been described of a microprocessor is a heap of wires that are assembled together to fill a solitary need. For instance, in memory interfacing, the microprocessor communicates with outer memory device through a collection of wires. Some pass data, some pass address, and others go about as control lines. These lines are "daisy-chained" starting with one device then onto the next. For instance, Figure 15 beneath, demonstrates A19 of the chip associated with A19 of Memory Device 1 which is associated with A19 of Memory Device 2. This is valid for every one of the address and data connections [50].

![Diagram of bus structure showing memory interfacing](image)

Figure 15 – A bus structure showing the memory interfacing of microprocessors

**Register** – A register is a gathering of D flip-flops that have been assembled together for a solitary reason. For instance, Figure 16 below, shows how the individual flip flops merge into an 8-bits chip that would form an integer.

![Diagram of register displaying groups of flip-flops](image)

Figure 16 – A register displaying the groups of flip-flops forming an integer
In an MPU chip, envision every cell representing a flip-flop that would contain a solitary bit. An 8-bit integer may be held temporarily in one of these groupings. Two groupings of flip-flops may contain two numbers to be included, the outcome at that point going into a third grouping of flip-flops. Every one of these groupings of flip-flops would be known as registers.

 Registers may contain:

- **data** - values to perform mathematical or logical capacities on
- **addresses** - bits, when joined together, point to a location in memory
- **instructions** - the numeric substitute of command orders, i.e., what to do to the data
- **flags** - singular bits gathered together to represent the status of a group of procedures

**Latch** - A latch is a register with a more precise different reason. This gathering of D flip-flops is to hold values to be used as output to different devices. For instance, you needed to control various LEDs say for a level meter, a latch would hold the appropriate 1's and 0's to drive those LEDs while the processor heads off to perform other functions [50].

**Buffer** - Hardly does a microprocessor work alone in a device, for example, a PC. There will be various processors notwithstanding the fundamental processor, for example, processors to control the video output, processors to control communication interfaces (USB, Firewire, Ethernet, and so on.), or processors to keep up the DRAM. These processors are working autonomously, and in this way may complete a procedure a long time before another processor is prepared to receive the results. Different processors may likewise convey from PC to PC as in a system.

**CPU** - The CPU is the brain of the microprocessor, it tells other devices what to do and when to do it. Figure 17, shows the block diagram of a microprocessor with the CPU pulling all the strings.
1. Arithmetic Logic Unit (ALU) performs all of the arithmetic and logic.

2. All instructions are stored as binary values. The instruction decoder reads that value and tells the ALU which computational circuits to energize in order to perform the function.

3. The registers are used for all calculations and for maintaining addressing information.

Input/Output: I/O chips are utilized in connecting the microprocessor to an assortment of devices (called peripherals). The most widely recognized of these include memory disks, printers, data links to different PCs (forming systems), instrumentation controlling gear, and so forth.

The most widely recognized of I/O chips are either Parallel Input/output (PIO), Serial I/O (UART, or Universal Asynchronous Receiver/Transmitter), CTC (Counter Timer Circuit) and FDC (Floppy Disk Controller). You will regularly discover depictions of PCs disclosing to you what number of parallel-ports and serial-ports it gives. This gives you a sign of what number of peripherals you can connect specifically to your PC.

PIO: The PIO chip sends information through 8 pins (or lines) between devices. An ordinary PIO chip schematic is shown in Figure 18 below.
Figure 18 – A Parallel I/O chip, with pin functions

2.3 The Microcontroller unit

Microprocessors and microcontrollers are majorly used in embedded systems products. Microcontroller is a programmable device. A microcontroller has a CPU in addition to a fixed amount of RAM, ROM, I/O ports and a timer embedded all on a single chip. The fixed amount of on-chip ROM, RAM and number of I/O ports in microcontrollers makes them the best bet for most applications in which cost and space are of importance. The Intel 8051 is Harvard architecture, single chip microcontroller (µC) which was developed by Intel in 1980 for use in embedded systems. It was popular in the 1980s and early 1990s, but today it has largely been superseded by a vast range of enhanced devices with 8051-compatible processor cores that are manufactured by more than 20 independent manufacturers including Atmel, Infineon Technologies and Maxim Integrated Products [51].
2.4 Amplifier and Filter Design

Filtering process is often required to expel the bothersome disturbances. The weak nature of the IR signal and the noise interference influencing on it requires the execution of a scope of channels and differential amplifiers. The signal conditioning circuit comprises of two indistinguishable dynamic low pass filters with a cut-off frequency of around 2.5 Hz.

\[
\text{Cut Off Frequency} = \frac{1}{2\pi R_f C_f} = \frac{1}{2\times3.1416\times68K\times1\mu F} = 2.34 \text{ Hz};
\]

where, \( R_f = R_1 = R_4 = 68K\Omega \) and \( C_f = C_1 = C_3 = 1\mu F \).

This shows that the greatest maximum quantifiable heart rate is around 150 bpm. The gain of each filter stage is set to 11, giving the aggregate amplification of around 121.

\[
\text{Gain of each stage} = 1 + \frac{R_t}{R_i} = 1 + \frac{680K\Omega}{68K\Omega} = 11;
\]

where, \( R_t = R_2 = R_5 = 680K\Omega \) and \( R_i = R_3 = R_6 = 68K\Omega \).

A 1 \( \mu \)F capacitor at the input of each stage is utilized to hinder the dc component in the signal. The conditions for computing gain and cutoff frequency of the active low pass filter. The two-phase amplifier/filter gives adequate gain up to help the weak signal which is 3-4 mV and originating from the IR sensor unit and converts it into a pulse. This heartbeat is tallied by microcontroller. At that point, a LED is used which flickers each time when the heartbeat is detected [50]. Figure 19, shows a pulse amplifier that filters noise and displays a typical heartbeat waveform.
A Liquid-crystal display (LCD) is a flat-panel display or other electronically regulated optical device that makes use of the light tweaking properties of liquid crystals that uses the light-tweaking properties. Liquid crystals don't emit light in a direct form, rather it uses a backlight or reflector to create images in colour or monochrome [52]. Its low electrical power consumption and less heat generation during operation makes it very suitable for battery-powered medical devices. Figure 20, shows a typical 16×2 LCD.
The electrocardiogram (ECG) has become a standout amongst the most normally utilized diagnostic devices in our current health care scope. Its utility in the diagnoses of a whole lot of cardiovascular pathologies running from myocardial ischemia and infarctions to syncope and palpitations has been very vital to clinicians for a considerable length of time [53]. The ECG sensor is connected to the patient utilizing dispensable electrodes on the left and right half of the chest. The signal gotten from the body is amplified and filtered. The sensor yields a simple signal which is then converted over by the analog to digital converter (ADC). The serial-to-Bluetooth module transmits the digital output of the ADC to the smartphone or display unit where it can be visualized. Figure 21 below, displays a typical ECG sensor.
Pulse oximeter sensor

Pulse oximetry is a noninvasive strategy for checking a man's oxygen saturation (SO2). It is a safe, advantageous, noninvasive, cost-effective pulse oximetry technique for estimating oxygen saturation in clinical sphere and its most normal (transmissive) application mode, a sensor device is set on a thin piece of the patient's body, more often than not a fingertip or ear cartilage, or on account of a baby, over a foot. The device passes two wavelengths of light through the body part to a photodetector. It gauges the changing absorbance at every one of the wavelengths, enabling it to decide the absorbances because of the beating blood vessel blood alone, barring venous blood, skin, bone, muscle, fat, and (as a rule) nail polish [54].

A pulse oximeter sensor A heartbeat oximeter sensor is a diagnostic device that indirectly screens the oxygen saturation of a patient's blood (instead of estimating oxygen saturation specifically through a blood test) and changes in blood volume in the skin, delivering a photoplethysmogram. The pulse oximeter might be joined into a multiparameter patient screen. A pulse oximeter sensor can be seen in Figure 22 below.
A temperature sensor is precisely what it sounds like—a sensor used to gauge ambient temperature. This specific sensor has three pins—a positive, a ground, and a signal. This is a direct temperature sensor. An adjustment in temperature of one degree centigrade is equivalent to a difference in 10 millivolts at the sensor output.

1.3 Development of the schematics of the diagnostic system unit

Beyond the fundamental lead II ECG (electrocardiogram), medical practice demands a speedy examination of an ever-expanding cluster of crucial signs—both continuous and trending; to better comprehend a patient's present condition, change, or deterioration. A typical multiparameter device at the same takes a cursory look at an ECG monitor, oxygen saturation (SpO₂), CO, hemoglobin, temperature, noninvasive blood pressure, and respiration. It regularly screens ECG, pulse rate, pressure rate and IR (infrared) temperature. Below in Figure 23 and 24, are schematic circuitries of diagnostic devices for screening patient condition.
Figure 23 – A schematic diagram of a patient ECG device

Figure 24 – A schematic circuitry of a patient monitoring system
2.5 Minimization of power consumption

Regardless of how great the battery is, regardless of how to a great degree the processor is, regardless of how effective other components are, for competitive reasons companies need to give portable medical devices so much performance, features, and such a small (battery/gadget) size that the battery life is as yet diminished to the negligibly satisfactory level. In a nutshell: power consumption matters and will stay essential. The patterns in power consumption for the different components demonstrate that they may bring about a power emergency. Keeping in mind the end goal to finding a solution, scientists are chipping away at different approaches to diminish the power consumption. There are as of now three directions in control management.

- Reduce the power consumption of the hardware components
- Improve the procedures to utilize the sleep modes of hardware components
- Improve the efficiency of the cooperation between components.

The principal direction focuses on the individual hardware components. positive changes on power efficiency at, for instance, the transistor level utilizes techniques, for example, clock gating, parallel hardware, state machine modifications, and adjusted memory organization [55]. Reduction of feature size in semiconductor innovation provides the pathway for more advances. This research direction gets noteworthy consideration. The primary research direction is complemented by the second research direction: which involves turning off unused hardware components. For instance, if the hard disk has not been in use for one minute, it should be put into a deactivated state with less power consumption. The rule that chooses when to utilize these deactivated states is known as a power management policy. The deactivated states of hardware components have different names, for example, rest mode, snooze mode, hibernate mode, sleep mode, or essentially inert mode. Hardware parts can support more than just one single deactivated state. Each state has an alternate power consumption and wake-up time. The wake-up time is the time it takes an equipment component to come back
to the active state. It ranges from 1 µs to a few seconds. Exploiting deactivated states has been the theme of numerous research work. Dougli and Li connected the system to hard disks and published their papers in 1994 [56, 63]; numerous different productions took after, for example, [57, 59, 60, 61, 62]. The Advanced Power Management (APM) standard characterizes the BIOS interface for power administration [58]. The third research direction to solving the power situation is enhancing the proficiency of how the various components cooperate. In this research bearing, applications are incorporated into the power management of the various segments. The manner by which components are consolidated and interface with each other is a vital factor in the total power consumption. Enhanced collaboration between components (the applications inclusive) can yield noteworthy savings as indicated by [64]. Figure 25 below, depicts the block diagram of a health monitoring system

![Block diagram of the patient diagnostic and monitoring device](image)

Figure 25– Block diagram of the patient diagnostic and monitoring device

2.6 Software development of the device
The Arduino program software was used in developing the prototype of this device because it can be composed in any programming language with compilers that deliver binary machine code for the objective processor. Atmel gives a well-developed
environment to its 8-bit AVR and 32-bit ARM Cortex-M based microcontrollers: AVR Studio (more established) and Atmel Studio (newer).

MATLAB Support Package for Arduino lets you communicate over USB to your Arduino and connected devices such as Adafruit motor shield, I2C, and SPI devices. Because MATLAB is a high level interpreted language you can see results from I/O instructions immediately without compiling. MATLAB includes built-in math, engineering, and plotting functions that you can use to analyze and visualize data from your Arduino. Figure 26 below, shows a typical and well labeled Arduino hardware device with its various components.

![Figure 26 – A typical Arduino uno hardware](image)

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Below is a detailed script of the software development written to further support the signals it got from the Arduino hardware.

```java
void setup () {
    // set the window size:
    size(1000, 400);

    // List all the available serial ports
    println(Serial.list());
    // Open whatever port is the one you're using.
    myPort = new Serial(this, Serial.list()[2], 9600);
    // don't generate a serialEvent() unless you get a newline character:
    myPort.bufferUntil('\n');
    // set initial background:
    background(0xff);
}

void draw () {
    // everything happens in the serialEvent()
}

void serialEvent (Serial myPort) {
    // get the ASCII string:
    String inString = myPort.readStringUntil('\\n');

    if (inString != null) {
        // trim off any whitespace:
        inString = trim(inString);

        // If leads off detection is true notify with blue line
        if (inString.equals('!')) {
            stroke(0, 0, 0xff); // Set stroke to blue (R, G, B)
            inByte = 512; // middle of the ADC range (Flat Line)
        }
    }
```
}  
// If the data is good let it through  
else {  
    stroke(0xff, 0, 0); //Set stroke to red ( R, G, B)  
inByte = float(inString);  
}  

//Map and draw the line for new data point  
inByte = map(inByte, 0, 1023, 0, height);  
height_new = height - inByte;  
line(xPos - 1, height_old, xPos, height_new);  
height_old = height_new;  

// at the edge of the screen, go back to the beginning:  
if (xPos >= width) {  
    xPos = 0;  
    background(0xff);  
}  
else {  
    // increment the horizontal position:  
    xPos++;  
}  

}  
}
Below in Figure 27, is the heartbeat sensor and the ECG display on a serial plotter using Arduino. Here, we can easily observe the readings of the heart and detect any abnormalities to the individual been screened.

![Heartbeat Sensor and ECG Display](image)

**Figure 27** – The heartbeat sensor displayed on a serial plotter using Arduino

Monitoring and control is the center of the real-time monitoring for patient physical states, and it can arrange, show, save, inquiry and examine the information from every patient. To know the physical conditions of inpatient, the physical parameters should be monitored real-time. With the increase in the number senior citizens and ceaseless illnesses, the quantity of elderly patients who require steady help has expanded. One key purpose of all basic elderly patient is the constant observing of their crucial signs. The outcomes demonstrate that the versatility, ease of use and execution of our proposed framework have impacts on the client's demeanor, and there
is a critical positive connection between the client's state of mind and the expectation to utilize our proposed framework. This proposed framework is expected to monitor the electrical movement of heart of the patient under diagnosis are all the more helpfully and precisely to diagnose which can be interfaced with PIC 16F877 to bring it under a system framework broadly for the specialist to screen the patient's condition sitting in his own office without being physically present close to the patient’s bed. Remote – organized implanted gadget incorporates flag molding hardware, sensors and a PIC controller with a remote Transceiver module. To quantify or screen human developments or exercises, a graphical LCD show is chosen at its minimal effort, little size, ability of persistent estimation, and simplicity of combination. Figure 28 below, shows a prototype of a patient condition screening and monitoring system.

Figure 28 – A patient diagnostic device prototype
3 SPECIAL ASPECTS OF SAFETY [SAS]

The definitions to safety are numerous and that tells us the importance of safety with respect to so many factors as it concerns us today. Safety could be defined as a state of being safe, or the condition of being protected from harm or other non-desirable outcomes. Safety can also refer to the recognition of any risk or hazardous effects in and around us in order to achieve the best suitable state.

This research is concerned with developing a system that screens and tests patients with varying health conditions. The health and safety of the individuals being subjected to these diagnoses is very paramount in ensuring an all-round safety and wellbeing of the end users. Therefore, the biocompatibility of such medical devices must meet with all health standards and regulations. However, certain factors come to play in ensuring maximum working capacity of such devices, for example environmental and physical factors, temperature, and other latent factors. The early identification of these factors would further ensure the safety and wellbeing of the end users.

3.1 Descriptions of environmental Factors
Environmental safety has become been given its been as a high priority issue all around the world and thus ensuring the safety of an environment is very paramount and key to optimum productivity in a work setting.

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. More so, 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 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.

The workplace is an environment where most adults spend a bulk fraction of their time. It has the potential to have both positive and negative influences on their health and well-being – sometimes with long-lasting effects. Factors influencing health include the following listed below.

- **Temperature and humidity**
  Adequate (indoor) heating is very vital to providing thermal comfort in cold weather (normally or at least 16°C if work is mainly sedentary or to at least 13°C where physical manpower is required). Particularly cold stresses may occur in certain occupations, for instance Food preparation, and open-air working. Protection and greater emphasis is also needed against heat stress from ambient temperature, high thermal radiation and higher levels of humidity for such occupational workers. For example, workers in foundries, laundries etc.

- **Atmospheric pressure ranges**
  Ventilation is the movement of air between the environment through the respiratory organs. Adequate air movement and rate of its exchange is very vital in ensuring stability. Poor ventilation is a hazard. And like all hazards, it poses a risk to your employees’ health and you must eliminate or control it at all costs. If this not done, it’ll slow down productivity in your workplace. That’s why you must ventilate


your workplace either by natural means (through adequate vent outlets) or by mechanical means (through fans). Failure to do so will increase health and safety risks to employees. Below are some health consequences resulting from poor ventilation.

1. High levels of carbon dioxide and low levels of oxygen can cause fatigue and affect your employee’s ability to concentrate.

2. Buildup of chemical and biological contaminants that cause poor indoor air quality. Poor indoor air quality can lead to employees suffering from headaches, fatigue, hypersensitivity and allergies, sinus congestion, dizziness, shortness of breath, coughing and nausea.

3. Extreme temperature in the office causes fatigue, discomfort and distraction and can increase accidents in the workplace as a result.

4. Low humidity can cause a dry throat, dry skin and static electricity build-up. High humidity contributes to bacterial and mould growth. This can make your employees very sick.

5. Excessive and irritating workplace odours cause discomfort and affect concentration. For example, ammonia and chlorine.

6. Poor ventilation causes Sick Building Syndrome (SBS). The symptoms include irritation of eyes, nose and throat, headaches and fatigue.

Indoor and outdoor operations

As regards to this research, which involves human and machine interface, the test environment is very important. This test condition incorporates the space in which the test is regulated, the instruments used to manage the test, and particular conditions under which the test is directed.

This examination in a perfect world requires a chamber which adequately disconnects the testing region from the wave and electromagnetic influences of the room. It should be devoid of noise or environmental pollution as minimally as possibly. Unwanted noise can cause annoyance and aggression, increase stress levels, disturb
sleep, and in severe cases damage hearing. Traffic, construction, industrial, and some recreational activities are the most common sources of outdoor environmental noise. Noise pollution can also occur indoors, but the sources of indoor noise are different (house alarms, music, home appliances, animals, and family conflict). Indoor noise pollution may also be subject to different regulations, depending on the use of that indoor location (for example, occupational health and safety). Noise regulations restrict the amount of noise, the duration of noise, and the source of noise. The permitted noise level can also be dependent on the time of day and the location of the noise: at nighttime or in very quiet locations the permitted noise levels are much lower than during the daytime in other areas.

While outdoor air quality and industrial air quality are well regulated at a federal level, there are few regulations for indoor air quality. This is surprising considering how much time we spend indoors, sleeping, working, traveling, or engaging in indoor sporting or leisure activities. Indoor air quality (IAQ) is the term used to describe the concentrations of air pollutants that are known or suspected to affect people’s comfort, health, or performance at work or school.

3.2 List of harmful factors and risk analysis

Identifying a risk and proper assessment helps to forestall any impending dangers. Harmful factors could include Fire outbreak, electrical shock, environmental hazards, radioactive hazards, electrostatic discharge(ESD) medical device malfunctioning in the case of this research and a whole lot more. As clearly stated above, a proper risk analysis helps a great deal in forestalling impending dangers. Below are some useful ways.

Fire safety. Causes of a fire can be an impact on the equipment of external causes. Possible local ignition of a component or gas (reagents), which heat the electrical elements of the apparatus. As well as ignition can occur due to the closure of live parts
on the body; Such currents, which in the smallest amount of time, release a large amount of heat in the conductors, which causes a sharp increase in temperature and ignition of combustible insulation, melting of metal conductors followed by a powerful release of electrical sparks into the environment that can cause ignition.

**Electrostatic discharge**

Electrostatic discharge (ESD) is the sudden flow of power between two electrically charged particles caused by contact, an electrical short, or dielectric breakdown. A development of friction-based electricity can be caused by tribocharging or by electrostatic induction. The ESD happens when in an unexpected way charged items are united close or when the dielectric between them separates, frequently making a noticeable spark.

ESD can create fantastic electric sparkles (lightning, along with the sound of thunder, is an expansive scale ESD occasion), also less vigorous forms which are less visible and audible can sufficiently cause significant harm to electronic devices.

**Short circuiting**

Short-circuits occur most often due to a breakdown in the insulation of conductive parts because of mechanical damage, aging, exposure to moisture and corrosive media, as well as improper actions of people. In the event of a short circuit, the current increases, and the amount of heat released is known to be proportional to the square of the current. So, if the current increases 20 times during a short circuit, the amount of heat released will increase approximately 400 times.

**Ventilation Level of testing room.** This research was carried out under an enclosed room and hence ventilation is a risk factor as users can suffocate in this closed room if proper ventilation is not enhanced. The ventilation system of the testing room meets the standard below.

Windows in a spacious room in opposite direction to the door for cross ventilation which is enough to ventilate the test chambers after each test is performed.
This was tactically made in order not to electrically or technically connect the rooms ventilation system to the chambers ventilation system.

3.3 Technical means to prevent harmful impacts

There are various technical means to forestall harmful and hazardous effects, but firstly the risk has to be assessed and analyzed in order to ensure the most suitable solution is met. Risk Assessment is where the severity of the Hazard and its potential outcomes are considered in conjunction with other factors including the level of exposure and the numbers of persons exposed and the risk of that hazard being realized. There are a number of different formulae used to calculate the overall risk from basic calculations using high, medium and low categories to complicated algorithms to calculate risks at nuclear power stations and other high-risk work locations.

It is important to ensure that the residual risk following implementation of control measures is ‘as low as is reasonably possible (ALARP). For a risk to be ALARP it must be possible to demonstrate that the cost involved in reducing the risk further would be grossly disproportionate to the benefit gained.

3.4 General electrical safety requirements

All electrical work practices must comply with applicable sections of the Occupational Safety and Health Administration (OSHA), National Fire Protection Association (NFPA), National Electrical Code, National Electrical Safety Code, and State adopted electrical codes.

1. Approval Required. Use only electrical wire, conduit, apparatus, and equipment for the specific application that is approved or listed by Underwriters Laboratories (UL), or Factory Mutual Corporation (FMC). Install and use listed, labeled, or certified equipment according to the instructions included in the listing, labeling, or certification.
2. Qualified Persons. Only qualified personnel familiar with code requirements, safety standards, and experienced in the type work may work on electrical circuits and equipment. NFPA 70E and OSHA 29 CFR 1910.269 contain references for training requirements. See attachment at the end of this section.

3. Safety Requirements Before Performing Electrical Work. The employer will determine, by inquiry, direct observation, or instruments, the location of any part of an energized electric power circuit, exposed or concealed. If the work may cause any person, tool, or machine to penetrate the boundaries set forth in the de-energize the circuit(s) and ground them, as appropriate. Additionally, all of the following must be required:

a. Underground Lines. Protect all underground lines with surface signs and a longitudinal warning tape buried 12 inches to 18 inches above the lines. Do not perform drilling, auguring, or material excavating operation within 6 feet of underground lines unless the lines have been deenergized

Personal Protective Equipment (PPE). Provide and use the appropriate PPE needed to accomplish the job safely. Use flash-protection clothing in accordance with NFPA 70E if the job requires operating, racking, circuit breakers with the doors open, or, working within reaching distances of exposed energized parts. Employees working on energized lines and equipment rated at 440 volts or greater must use rubber gloves, hard hats, safety boots, and other approved protective equipment or hot-line tools that meet ASTM standards.

Other Procedures. Perform procedures related to electrical work in accordance with the following:

• FIST 1-1, Hazardous Energy Control Program
• FIST 5-1, Personal Protective Grounding, and
• Written Standard Operating Procedures (SOPs) of each area office
3.5 Electromagnetic disturbances to medical devices

The risk management requirements of EN/IEC/ANSI/AMIEE 60601-1-2 Edition 3 (2007) and IEC 60601-1-2 Edition 4 (2014) are mostly either ignored or misunderstood by manufacturers, their EMC test labs, and medical regulatory assessors (other than in Germany). In any case, it has long been impossible to fully test any microprocessor or the software that runs on it, in any reasonable period of time (for example, less than 10 years of 24/7 testing). This means that, where errors, malfunctions or mishaps in a digital system can result in an unacceptable safety risk, it is impossible by testing alone to prove that it can be safe enough over its intended operational lifecycle (except in very special and very limited circumstances).

This is more accurate for EMC testing, because to prove EMI couldn’t cause excessive safety risks we would have to test digital systems by enough (which is impossible) for all reasonably foreseeable:

- Electromagnetic disturbances that could occur over the entire lifecycle;
- Effects of physical and climatic stresses, aging, etc.;
- Degradations/faults in filtering, shielding, surge suppression, and circuits;
- Angles of incidence and polarization, modulation types/frequencies, transient waveshapes and repetition rates, etc.;
- Combinations of any/all of the above independent variables.

This understanding that microprocessors and software can never be tested sufficiently to prove they are safe enough for the vast majority of safety-related applications gave rise to IEC 61508 [2], the IEC’s basic standard on Functional Safety, first published in 2000, with Edition 2 published in 2010.

The concept of functional safety is concerned with managing the risks that could be caused by any reasonably foreseeable errors, malfunctions or failures in hardware or software, [65] describes well-proven Techniques and Measures (T&Ms) in system, hardware and software design, verification and validation, and how to use them to
ensure that digital equipment and systems could not cause excessive safety risks. Many product-family functional safety standards have been developed, based upon [65], but IEC medical standards based their risk management requirements on ISO 14971 [66] instead.

Although ISO 14971 has the same general, overall functional safety/risk management requirements as IEC 61508, it uses totally different terminology and does not include any of 61508’s well-proven T&Ms, with unfortunate consequences that I will discuss later on. IEC 60601-1-2 [67] applies to medical electrical equipment and medical electrical systems, which it calls me equipment and me systems respectively, using small capital letters which makes reading it very difficult. So in this article I will just use “medical devices, equipment and systems” to mean the same thing. Please note that “devices” includes all modules, products, etc., and “systems” includes installations too.

3.6 Compliance with the rules of safety


The testing, marking and documentation changes that Ed.3 made with respect to its previous version (Ed.2.1:2004) However, they didn’t tend to write much about the requirement to risk manage the effects of electromagnetic disturbances; [67] requires medical devices, equipment or systems to achieve the defined terms “Basic Safety” and “Essential Performance”, despite the effects of electromagnetic disturbances. Note that it is not concerned at all with any other, non-safety-related, EMI effects on functional performance.
The terms Basic Safety and Essential Performance are not specified in [67], so we turn to the definitions used in its base standard – IEC 60601-1 [70]. This defines Basic Safety as the: 'freedom from unacceptable risk directly caused by physical hazards when the equipment is used under normal condition and single fault condition.’

This definition includes such physical hazards as those caused by excessive touch temperatures, electrical shocks, fire, radiation, sharp edges, etc. EMI cannot generally affect these, other than by interfering with the correct operation of electronics that control them.

Essential Performance (EP) is the new concept that was introduced into IEC 60601-1 at Edition 3 to deal with risk management due to the inability to fully test programmable digital systems. For this new term, [70] borrowed the definitions given in ISO 14971, to define it as the:

“…performance of a clinical function, other than that related to basic safety, where loss or degradation beyond the limits specified by the manufacturer results in an unacceptable risk…”

“…most easily understood by considering whether its absence or degradation would result in an unacceptable risk combination of probability of occurrence of harm and the severity of that harm…”

[70] goes on to warn that performing a risk analysis, as required, might find that the actual EP for a certain medical device, equipment or system might need to go beyond its definition above. It is worth noting that some of [70]’s “particular standards”, such as IEC/ISO 80601-2-72 for ventilators, can extend its rather woolly, generic definition of EP by including some very specific requirements. [67] allows us to choose whether to do immunity tests on all of the functions of our medical device, equipment or system; or just on those that provide its EP. Each function associated with EP must be tested in its most critical mode (from a patient outcome perspective). The most critical mode must be based upon a risk analysis which takes into account equipment
build-options, cable layout, and accessories, in a typical configuration consistent with normal use (an example might be Figure 1), including the use of a patient simulator where one is needed to verify normal operation. Of course, each different type of immunity test could have a different “most critical mode”. It is worth mentioning here – because it is so often overlooked – that any protection or warning functions such as alarms, which help ensure that faults, damage, incorrect use, etc., do not cause excessive safety risks, must be tested to make sure that they do not operate when they should not, and then tested again to make sure that they do operate when they should, which of course requires simulating the conditions they are protecting/warning against.

Because [67] requires electromagnetic disturbances not to prevent the medical device, equipment or system from achieving EP, and because EP is defined in terms of Risk, it is clear that 60601-1-2 Ed.3:2007 requires what is sometimes called the risk management of EMC. But it only actually mentions risk management in its Forward, and again in an Informative Annex, so this important new requirement is very easy to overlook.

Immunity to ESD.

EC 61000-4-2 outlines the global immunity standard for electronic hardware capacity to withstand ESD produced from a human body or metal articles with a built-up static charge. The standard accepts that the source is an electrified human body release, and testing mimics the present waveform created in those conditions. The table 2 below, visualizes the varying test voltages discharged in these ESD test levels
ESD test levels (IEC/EN 61000-4-2)

Table 2 – Various levels of ESD test and their test voltages

<table>
<thead>
<tr>
<th>Level</th>
<th>Contact discharge</th>
<th>Air discharge</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>±2kV</td>
<td>±2kV</td>
</tr>
<tr>
<td>2</td>
<td>±4kV</td>
<td>±4kV</td>
</tr>
<tr>
<td>3</td>
<td>±6kV</td>
<td>±8kV</td>
</tr>
<tr>
<td>4</td>
<td>±8kV</td>
<td>±15kV</td>
</tr>
</tbody>
</table>

Electromagnetic compatibility and its effects

Electromagnetic compatibility (EMC) is the branch of electrical engineering burdened about the accidental generation, propagation and gathering of electromagnetic energy which may cause undesirable impacts, for example, electromagnetic interference (EMI) or even physical harm in an operational device. The objective of EMC is the right operation of various equipment in a typical electromagnetic condition.

EMC focuses on 3 main classes of issue which include; Emission which involves the release of electromagnetic properties into the environment be it intentionally or accidentally. The second issue interwoven in EMC is the issue of susceptibility which is the process whereby an electrical equipment breaks down due to exposure from these emissions. The ability to withstand the exposure and function optimally is known immunity. The third class is called coupling which is mechanism by which an emitted interference reaches its victim.
Conclusion

The benefits of safety cannot be overemphasized as it involves the continued existence of everything within and around us and the environment devoid of harm or risk. The various forms of safety need to be adhered to strictly to ensure and reduce the possibilities of hazardous occurrences. As regards this research work, there is the need for more precautions to be taken as medical devices have interfaces with people and the environment. As innovations and advancements are on the increase, there is the heightened need for more safety as the inappropriate use and insufficient monitoring of these devices can result in hazardous effects. For this reason, greater focus and emphasis on the safe use of medical products is very vital to sustainability. As we experience a robust and dynamic growth in the number and complexity of medical devices, greater awareness needs to be placed on safety. Therefore, a great need for increased awareness of safety rules and practices is essential for not just healthcare practitioners alone, but also to their families and even the environment. Patients and user’s education on the risk associated with medical devices and appropriate use of medical devices will contribute immensely to the reduction of medical devices occurrences.
GENERAL CONCLUSION

This research work highlighted the challenges facing the healthcare industry in terms of rising cost, power consumption, regulatory restrictions, portability and ease of use by the end users. The device has a less complex structure with high accuracy, low power consumption and the issue of portability was tackled. Its ability to diagnose and monitor multi-psychological parameters like body temperature, blood pressure rate invasively and pulse rate in real time makes it a suitable point of care device. However, further improvement is needed to deal with more prevalent health concerns. The future of health care is being shaped dramatically by a number of significant trends. And with the cost of care on the increase, the industry is experiencing a paradigm shift toward preventive and value-based care. At the same time, technology like wearable devices, point of care testing services and telemedicine are empowering patients to be more engaged with and proactive about their own health.
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