



## A REVIEW ON PUBLIC TRUST IN HOME MEDICAL DEVICES DURING THE COVID-19 OUTBREAK IN INDIA.

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**Abstract :** This is a fantastic accomplishment given the quick development of the COVID-19 medical device. The global population faces many challenges, including those related to production, distribution, deployment, and acceptability. As consumer awareness of and demand for home medical devices has grown, more manufacturers have entered the market. For international manufacturers of medical devices, India offers a large market opportunity. The existing low per-person expenditure rate for medical equipment is anticipated to fuel significant growth for the Indian medical device market.

Maintaining public confidence in home-use medical devices during COVID-19 would be crucial since the expansion of the medical device business in India poses difficulties with competition law (antitrust). The review article's objectives are to increase public awareness of frequently used medical devices during the COVID-19 epidemic and to gauge Indians' faith in home-useable medical equipment. Medical device makers would struggle to meet the needs of the health centre and have insufficient storage space in the event of a global epidemic. Since the quality of COVID-19 items is crucial in the current situation, the sale of some of the most important medical devices has increased, making it more challenging for the medical device industry to supply demand with high-quality goods.

Although it is challenging to supply enough medical supplies during a pandemic, they are working to adjust to the situation. After realising the necessity of raising awareness and gaining a thorough understanding of the handling, production, and sale of medical equipment during COVID-19 at home, this was done. Additionally, this situation is seen as a chance for medical equipment dealers and manufacturers to increase their profits.

This review article will help researchers at COVID-19 increase their understanding and boost public confidence in medical technology.

**Keywords** - Medical devices, COVID-19, Awareness, Trust, Quality equipment's, Regulations, Household devices.

### ❖ INTRODUCTION TO MEDICAL DEVICES :

The use of medical devices in the healthcare industry is becoming a more and more critical component of the treatment and diagnosis of various medical issues (2014).

The market for medical devices used to track various health indicators has seen growth, which has increased the possibility of risks associated with those equipment .

Due to the Indian government's lax enforcement of medical device rules, a large number of new manufacturers have joined the market and are now making money by selling subpar goods.

Sphygmomanometers, pulse oximeters, nebulizers, glucometers, and other devices are becoming more and more user-friendly nowadays, allowing people to manage their health conveniently and independently for a low cost.

Dialysis machines, ventilators, infusion pumps, and other complicated medical equipment are occasionally utilised outside of hospitals at home.

Any instrument, appliance, machine, equipment, apparatus, implant, or other comparable in-vitro reagent meant to be used singularly or in combination for at least the manufacturer's medicinal purposes is referred to as a medical device by the World Health Organization .

- diagnosis, follow-up, prevention, therapy, or sickness symptom relief;
- Treatment, relief, diagnosis, monitoring, or compensation for injuries
- modification, substitution, research, support for the physiological processes, or support for the anatomy
- bolster or maintain life
- design observation
- Cleaning medical equipment
- Examination of human body specimens in vitro yields information

Pharmacology, the immune system, or metabolism cannot carry out the main intended action on a human body, but they can aid it in doing so. WHO; medical supplies.

- **Classification Of Medical Devices :**

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Risk level	Classification(s)	Examples
Low	Class I	Surgical retractors Tongue depressors
Low to Medium	Class I—supplied sterile Class I—with a measuring function Class IIa	Sterile surgical gloves Medicine cup with specific units of measurement Dental drills; ultrasound machines; digital or infrared thermometers
Medium to High	Class IIb	Surgical lasers Diagnostic X-ray
High	Class III	Prosthetic heart valves Absorbable surgical sutures Hip prostheses (for example, replacement of hip joint)
High	Active implantable medical devices (AIMD)	Pacemakers Artificial heart

❖ **Function Of Medical Devices :**

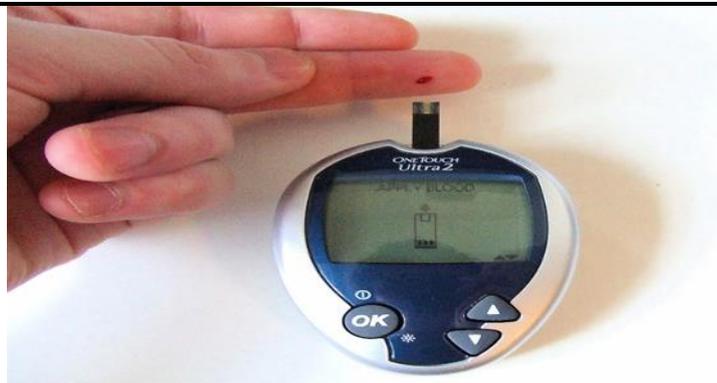
1. Screening and diagnosis: These processes are becoming more precise and
2. intricate. Home care is offered by point-of-care and mobile diagnostic technologies, which also facilitate external treatment and increase access to care both within and outside of encompassing and remote locations.
3. Treatment/care: Advanced surgical technology not only greatly shortens hospital stays but also enables doctors to manage extremely critical and challenging patients. Gradually, it enables patients to select risky procedures like knee replacement, bariatrics, pain management, etc.
4. Restoration: By utilising contemporary assistance and rehabilitation technology, hospitals and physiotherapy-rehabilitation centres today enable patients to quickly regain their health and resume their normal lives.

Health tests make it possible for people to monitor their health at home and run routine checks on key performance markers.

- **Publicly accessible, frequently used medical equipment :**

Medical electrical equipment is active medical gear whose operation depends on an energy supply or other power source other than that produced directly by the human body or gravity and which operates by converting such energy.

➤ **Blood Sugar Gauges :** People who have type 2 diabetes or prediabetes symptoms need to check their blood sugar levels frequently. Using a device known as a blood glucose monitor, it can be completed at home. In this approach, diabetic patients can promptly alert their doctor to extreme fluctuations in the level of glucose in their blood and receive corrective medicine.



➤ **Pulse Oximetres :** This instrument measures the blood's oxygen content because the body's organs receive enough oxygen through blood cells to function normally. Hypoxemia, or low blood oxygen levels, can make it difficult for vital organs like the heart and brain to function properly. The pulse oximeter is useful in these situations to ensure that the injured person receives prompt medical care.



➤ **A blood Pressure Device :** This gadget is very important for people who have high blood pressure (hypertension) or low blood pressure (hypotension), as it is advised that you check your blood pressure frequently and let your doctor know the results. To standardise someone's blood pressure, the immediate effects of prescription drugs are also assessed. Usually, a person's normal blood pressure ranges from about 110/70 to 120/80.



➤ **Pedometers And Scales for Weight Loss :** A pedometer is a simple device that counts your steps and calculates your caloric expenditure. A scale that measures your weight is very helpful because it might flag serious underlying illnesses like hormone imbalance or faulty lipid metabolism. Having a body mass index (BMI) between 18.5 to 24.9 identifies a healthy weight for an individual.



**PEDOEMETER  
WITH BEST  
PERFORMANCE**

➤ **Thermometers :** When a fever, cold, or influenza outbreak occurs, these basic equipment should be present in every home, especially in the highlands and during the winter. This thermometer can determine whether the body temperature is higher or lower than normal, enabling the appropriate course of prescription medication to be chosen and ensuring a speedy recovery. The average body temperature of an adult is 36 to 37.5 degrees Celsius, or 97 to 99 degrees Fahrenheit.



- **Medical technology's role in the COVID-19 epidemic :**

Medical device industries are dealing with a rise in demand for some medical equipment as a result of the COVID-19 global health crisis. Professionals that work with medical devices are essential in meeting the demand for high-quality products. Whereas many nations have restricted the export facilities due to the rising demand for medical gadgets on a global scale. This has exacerbated the problem for nations that rely on imports to meet their needs and has damaged the supply chain. In addition to the COVID-19 pandemic, India has experienced a serious medical equipment shortage. The Indian government made the decision to become "atam-nirbhar," or self-sufficient, in order to meet the demand. The large-scale production of the necessary products was started with help from the medical device companies and from the government.

- **The approach of the Indian government regarding medical device regulation :**

The COVID-19 pandemic and subsequent rise in demand for diagnostic kits, ventilators, and other medical devices have centred the Indian medical business. The Drugs and Cosmetics Act of 1940's The Regulations on Medical Devices 2017 (Rules of Procedure) of the Indian Medical Devices Industry (the Act). The Rules become effective on January 1st, 2018.

Surgical staples, blood, ligatures, operative sutures, blood component bags, and bandages covered by Section 3(b) of the Act, with or without anticoagulants covered under Subclause I. Mechanical contraceptives including disinfectants (condoms, tubal rings, and intrauterine devices), disinfectants, and insecticides notified under (ii) of Section 3(b) of the Act.

- **Medical product registration:**

In order to be marketed in India for import, medical equipment that is designated as a medicinal product needs to be registered with the health ministry. Medical devices classified as medicinal items are subject to the current Drugs and Cosmetics Act and the regulations for the manufacture and import of medical devices. Although there are no quality control procedures for medical equipment, it is preferred that products be of the same calibre and performance as those recognised by the CE or FDA. Manufacturers of medical devices that are classified as medicines are required to follow Good Manufacturing Practices (GMP) and do the necessary tests to prove product quality. It should be the responsibility to create quality systems through their design, development, and manufacturing. For this kind of equipment, risk management according to ISO 14971 is also required.

Form 40 will be submitted along with the registration in accordance with Rule 24A of the Cosmetic Drugs Act. In India, the applicant could be an importer, manufacturer, or agency.

General Controller of Drugs India (DCG (I)) requests applicant information such as name and address. The Department also needs to know the name and location of the factory, importer, local official, and producer if there is one in the area. A duplicate of the Plant Master File is included with the application. The information required in the Plant Master File is outlined in the Clarification of Guidelines for Manufacture and Import of Medical Devices.

- ✚ **Effects of the medical device industry:**

Medical devices are crucial in providing a range of healthcare services. Medical devices fall under the broad definition of "devices used in the diagnosis, treatment, mitigation, therapy, or prevention of sickness" and are neither absorbed nor metabolised by the body. This statement is true for all medical equipment, from basic supplies like syringes and latex gloves to high-tech imaging and implanted devices like cardiac defibrillation. The medical equipment industry contributes significantly to a larger healthcare system by creating innovative medical technology that improve disease detection and treatment. The majority of medical equipment is employed as an input rather than as a standalone service while providing health care.

- ✚ **Effect of COVID-19 on the production and supply of medical devices:**

The world has come to a standstill because to the COVID-19 epidemic. The worldwide epidemic had a significant impact on businesses and industries. Hospitals are lacking in beds, masks, fans, and testing equipment. In order to meet the public's need, the medical equipment business is disturbed due to a sharp increase in demand for certain medical equipment. For makers of medical devices, the need for PPE kits, fans, test kits, and other items is becoming more and more difficult.

- ✚ **Pricing plans for medical equipment during a pandemic:**

To keep medical equipment costs under control and provide the public with equipment during the epidemic at a fair price. The NPPA requested pricing verification information from importers and manufacturers. The general public is currently asking the medical device sector and importers to lower the retail costs for medical devices.) The National Pharmaceutical Pricing Authority (NPPA) of India gives producers and importers three weeks to supply price information for all 24 categories of medical devices. According to a directive issued by NPPA on February 16, it is required to keep track of the maximum retail price (MRP) for medical equipment classified as pharmaceutical by the government.

- ✚ **Environment for medical devices used at home:**

Healthcare is increasingly migrating from a clinic to the patient's house, where it is possible to monitor patients' signs and symptoms via television using smartwatches, apps, and other technologies that can be connected to a wireless network. Both professionals and laypeople are employing a variety of technology and home healthcare devices to monitor their own health because it has become incorporated in their daily lives. Digital displays are included with home healthcare equipment to make them easier for consumers to use. Consumer-friendly versions of these gadgets are now available at reasonable prices.

- **Medical equipment used in homes during COVID-19:**

The current COVID-19 pandemic has also accelerated the rate at which healthcare workers' exposures are being reduced by technology and artificial intelligence. Through social segregation and quarantine measures, the number of COVID-19 patients in need of urgent medical assistance was reduced. Vital sign assessments supported by technology, such as those of pulse rates, body temperatures, blood pressure, and respiration rates, can be used to assess and isolate homeless people, provide basic care for others, and determine when home care is no longer appropriate. Mobile applications could potentially help policies like contact tracking and required insulation that are aimed at improving the overall health of people who test positive for SARS-CoV-2.



**Medical equipment preserved at home :**

- Pulse oximeter
- Incentive spirometer
- Oxygen cylinder
- Patient monitor multi-parametric

**List of Medical Devices commonly used during Covid-19 :**

Type of equipment's	Medical Device name
Personal protective equipment's	Respirators
	Surgical Masks(2-ply,3-ply, N-95 masks etc.)
	Face shield
	Gloves
	Protective goggles
	Surgical gowns
Medical Equipment's	Infrared thermometer
	Pulse oximeter
	Digital sphygmomanometer

❖ **Public's trust in medical technology:**

Technology trust is the conviction that a tool, machine, or device won't break down. Trust is the foundation of the connection between patients and doctors. Deeply personal information is frequently provided and that is trusted to be kept private. The clinic has faith in its clients to accept their diagnoses and recommended treatments, even if they are undergoing invasive surgery or taking chronic medications on an ongoing basis . Physicians and healthcare organisations must first persuade people that patients' needs come before their own financial or non-financial interests in order to achieve this degree of trust. Healthcare trust, however, has drastically declined over the last 50 years .

❖ **Trust in medical devices during a pandemic :**

The coronavirus sickness causes new issues with trust (COVID-19). This may not have been possible due to the new disease pathogen that defied expectations (such as transmission through asymptomatic carriers) and sped up the understanding of the sickness in the scientific community. Contradictory signals, questionable research practises, political influence over health recommendations and therapy effectiveness, pseudoscience, and conspiracy theories, aside from the general lack of faith in science, are all problems . Further endangering the trust of Black and Latino populations in doctors, the healthcare system, public health, and sciences were inadequate testing, prohibitively expensive treatment barriers, and overly high levels of COVID-19 cases and fatalities.

❖ **Issue statement and purpose :**

Medical equipment for home usage have assimilated into our way of life. It has become increasingly important for manufacturers to provide simple-to-use devices as people use healthcare equipment at home to monitor their health. Over time, the introduction of a tracking system has made it simpler for manufacturers to track products throughout the product cycle and recall products with flaws. By scanning barcodes, QC codes, and embedded chips, medical device tracking has made it simpler to verify product authenticity.

**Conclusion and future forecast:**

Manufacturing companies for medical equipment have been harmed by the COVID-19 pandemic's continuous spread. The need for home-use medical equipment is rising as more people choose for home healthcare. The medical equipment market in India is expected to reach \$50 billion by 2025. Device producers all around the world are keeping an eye on this quickly developing demand and concentrating on better meeting it. Medical equipment used in domestic healthcare during COVID-19 should be appropriate for the individuals and the environment in which they are employed. The ability of governments to convey the advantages of medical technologies and to deliver them safely and effectively is crucial for maintaining public trust in them.

People's reliance on clinical support, pathology, and diagnostic facilities for all needs is being reduced because to the spread of home medical equipment. Since patients and their families still pay the majority of healthcare costs out of their own pockets in India. Economically disadvantaged people can save a lot of money using medical devices. India is a market with competitive prices that primarily produces low-to mid-tech goods. This study found that Indians are more interested in home medical equipment and self-health monitoring than ever before.

The development of new, cutting-edge techniques to increase the robustness and safety of medical equipment in the home setting might also be the main topic of this review. Future technological advancements will come from new devices like improved pacemaker medication systems and cochlear implants. A variety of medical devices for both official and informal health care applications will be made possible by the miniaturisation of numerous components, including microprocessor and nanotechnology, for the benefit of improvements. In order for medical equipment for people who trust in-home health care to be safe and effective, all these custom considerations must be taken into account. This review emphasises how crucial public trust is to the health care system's and society's overall functioning.

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