

# **Open-Source Design of Medical Devices: A Useful Biomedical Engineering Tool for Developing Countries**

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There is a chronic need for medical devices to diagnose and treat patients in low- and middle-income countries (LMICs). The current medical device market is not providing affordable healthcare service to LMICs, as the price of a medical device is typically based on the costs and profit potential in high-income countries, decided by companies with intellectual property (IP) monopolies. In addition, only few public and private funds are available for healthcare in these regions.

Open-source technology development is based on sharing detailed technical descriptions of system designs or devices that are licensed to be fully open and thus allow unrestricted access. The design can be freely used, replicated or adapted without any patent restrictions or limitations. The open-source approach can be applied to medical device production, following the concept of frugal engineering, consisting on the conception and design of a device focused on its core functions, avoiding non-fundamental functionalities. Importantly, the combination of open-source and frugal design is applicable to routine medical equipment. Indeed, most commonly used medical devices are based on often simple technological principles, which originated decades ago and are no longer restricted by patents.

The production of open-source medical devices in LMICs can be stimulated by the global cooperation of biomedical engineers (e.g., [www.open-source-medical-devices.com](http://www.open-source-medical-devices.com)). Such programs should ideally include bidirectional collaborative co-creative and training activities with bioengineers in LMICs by adapting technological options to specific local needs in terms of medical device functions and servicing procedures. Importantly, biomedical engineers should closely collaborate with expert physicians to improve the design, implementation, and, crucially, the testing of the designed devices in humans<sup>6</sup> in addition to laboratory testing. Furthermore, the device needs to be approved by the relevant hospital, as well as regional or national ethical boards.

The open-source approach will substantially broaden global access to low-cost medical devices, and open-source hardware does not require large amounts of capital. Frugal design will further reduce device costs, and local manufacturing may empower communities and stimulate the creation of local industries. Addressing the global gap in healthcare is thus not facing a scientific or technological barrier, but rather a social responsibility challenge.