

# Analysis of Patent Management on Health Care Product: Information of Electrocardiograph Devices

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## ABSTRACT

*Development of health care product nowadays becomes primer uses to support levelness of heart disease. A dynamic system of usefulness has referred to a potential market that occurs as a complementary effort in the health sector. Differentiation of product devices especially for electronic cardiograph has many impacts on technology innovation, in term of market-oriented. Analysis patent management is used as a tool to see technology that has already performed and is also used by industries, based on capturing market needs, to deliver more competitiveness model of the product. This paper aims to find relevant information through a database of an international patent on health care products for market orientation through the portfolio, licensing, status, competitor, innovation, and monitoring emerging market with the patent database that registered on World Intellectual Property Organization (WIPO). The methodology that applies in paper using software Total Patent to see more information related on the utilization of electronic cardiograph devices such as potential useful through leading patent-issuing authorities with composition results 247 documents of 113,612,014 patents that registered. The results showed that most of the inventions and patent applicants and beneficiaries are from the United States, Europe, and Asia-Pacific and the captive market distributed in Asian and South American area.*

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## 1. Introduction

Valuable patent document nowadays becomes sensitive if we can see from empowering the real data that exist inside the publication – many inventions found in order to enhance acceleration of technology through foresight from market demand. Instead of that argument and with the number of patents-patent technology is currently accessible through the patent information system that has been expanded with the help of information technology. The information of technology defines objective regarding invention-invention either in the status of published or have been exhausted the period of protection is accessible anywhere internet is available throughout the network – kind of information utilized to implement the technology that is in it for pioneering new industry. For developing countries like Indonesia, information on patents can be used as a reference for developing research (Wie, 2005).

Patents are representatives of the technological innovations of a country or an organization and are indeed an agreement between the inventor of the patent and government or any agency designated by the government (Ernst, 2003). Patent analysis is beneficial for organizations in determining the novelty of their inventions, as well as identifying the Intellectual Property (IP) and technological competitiveness (strengths and weaknesses) of the competitors (Abraham and Moitra, 2001). Besides the technological competitiveness, using IP information also helps in estimating the developments of a particular firm in a specific time interval (Ernst, 2003).

Diversification of product development especially technology in medical equipment devices kindly have many advantage order to support human interest in health sectors. Its meaning becomes essential thing due to supplement tools for emerging case in medical development. In the modern era, this cannot see that all complimentary product that exists need to appreciate in which capacity that is developing. The result of technological advances may lead to disruptive changes with social, economic, and political ramifications. Disruption causing global paradigm shifts in the commercial sector has been long recognized and extensively studied (Schumpeter, 1975). For instant case in the medical device, many products appear to support and variation useful in specification technology that being adopted to help the healing of the patient. For previous plan mean definitely to make sure that the robust system and to ensure access for safety reason, more productive uses, and have high quality in medical devices to prevent, diagnose, treat the disease with common goals is to offered services patient in their rehabilitation. On a particular case, it needs a legal document for clinical test and observation from the new product must base on health regulatory for medical devices to make sure protect the interest of patient safety.

Every day more than 50,000 different kinds of medical devices are estimated to be used in health care facilities and elsewhere all over the world. Most are quite simple, while others are complex and combine different technologies. The global medical

device market is worth over US\$ 150 billion, with the United States of America, European Union, and Japan has over 65% of the market share (Epsicom Business Intelligence, 2003). The trend of latest gained traction in this market is the integration of technologies to develop advanced electrocardiograph (ECG) devices. Meanwhile, the development of new monitoring technologies has helped improve disease diagnosis and treatment with allowed flexibility and portability of these systems. The reference on global ECG devices market shown by the rise in some lifestyle-related disorders, and aging demographic. In the other sides, the market is left behind because less of the skilled employee to handle monitoring devices and uncertain reimbursement policies.

This research paper used software Total Patent to elaborate user to know their development of technology for market orientation through the patent portfolio, licensing, status, competitor, innovation, and monitoring emerging market with the patent database. Linkage with innovative and economically promising technology fields and markets will see through technology control and technology foresight. And the most important thing was a strategic pathway to improve alignment in R & D and identified innovation processes at an early stage to secure significant competitive advantages. By entering the right keyword for the subject purpose, we can define the result of the registered patent with R & D development in World Intellectual Property Organization (WIPO) fields and also know possibility duration for year protection. Patent data can actualize the analysis of this knowledge network, i.e., through quantifying and structuring patent data, understanding of the knowledge development and construction becomes possible. The structure of data hidden in patents can play a critical role as a 'proxy meter' in understanding the structures of R&D activities and related knowledge. The aim of this paper was to define the strategic way to enhance the potential and prospecting market for ECG devices to support development in the health sectors.

## 2. Literature Review

### 2.1. *Electrocardiograph Devices to Support Health Sector*

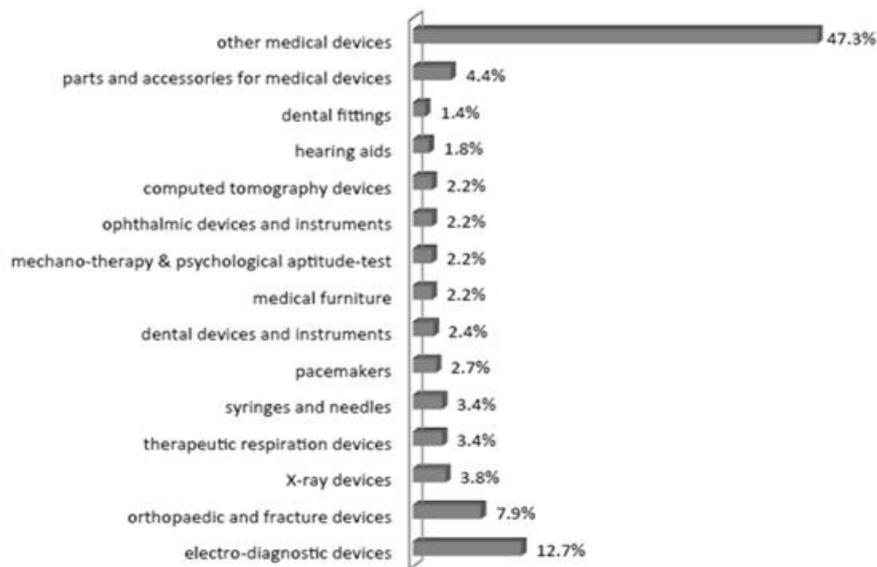
Development devices on healthcare sector in the modern era cannot be separated from dimension between people, product and process also service designed to promote health, and it can be considered a complex system that integrates (Tien and Goldschmidt-Clermont 2009). The use of the current medical devices when viewed from its function refers to equipment, software, materials, other instruments are used in actions of prevention, diagnosis, monitoring, treatment of even tackling the disease. For example, with the presence of the medical device, it is instrumental in supporting the development of medical science is mainly from the use of the supporting facilities and infrastructure. Medical devices are used to achieve the following intended objectives (EU SME Centre; 2015); (1) Diagnosis, prevention, monitoring, treatment or alleviation of disease; (2) Diagnosis, monitoring, treatment, alleviation of or

compensation for an injury or disabled patients; (3) Investigation, replacement or modification of anatomy or a physiological process; (4) Control of conception; (5) Support or maintenance of life; (6) Examination of samples taken from humans to provide information for medical treatment or diagnostic purposes.

From the description above, medical devices especially when it comes from a disease that has tremendous impact through popular symptoms in community environment needs to think as a practical problem to eliminate by providing a solution for humanity. For example, most signs in public health concerns caused by cardiovascular disease are the enormous and leading cause of death and disability in the world, for the kind result must be an alternative solution to preventing the needs of disease. Cardiovascular disease is a disease of the disorders of the heart and blood vessels are very dominant in the equipment utilization, through monitoring and diagnostic devices market is driven by the increasing need of measuring instruments which are practical. Much cardiovascular growth caused by a sedentary lifestyle, smoking and alcohol consumption, obesity and geriatric population forecasting period may cause medical equipment to the needs of technology-based diagnostic are assumed to be able to help monitor the patient's condition so that it can increase the investment in the field of manufacturing medical device by the manufacturer.

We can imagine that the largest medical device market was in the United States, valued at \$125.4 billion (Espicom, 2015). The U.S. market value represented approximately 38% of the global medical device market in 2012. The European medical devices market is the second largest, estimated at €58 billion. The leading EU markets are Germany, France, Italy, the United Kingdom and Spain (Klass Consulting, 2015). China has recently become the third largest medical device market, growing at an average of 20% annually since 2009 and valued at over \$48 billion (export, 2014). The global market share of medical devices illustrated in Figure 1, with electro-diagnostic devices accounting for 12.7% of the global market share (PRNewswire, 2014). Orthopedic and Fracture devices account for 7.9% of market share while dental fittings account for the smallest share of 1.4%.

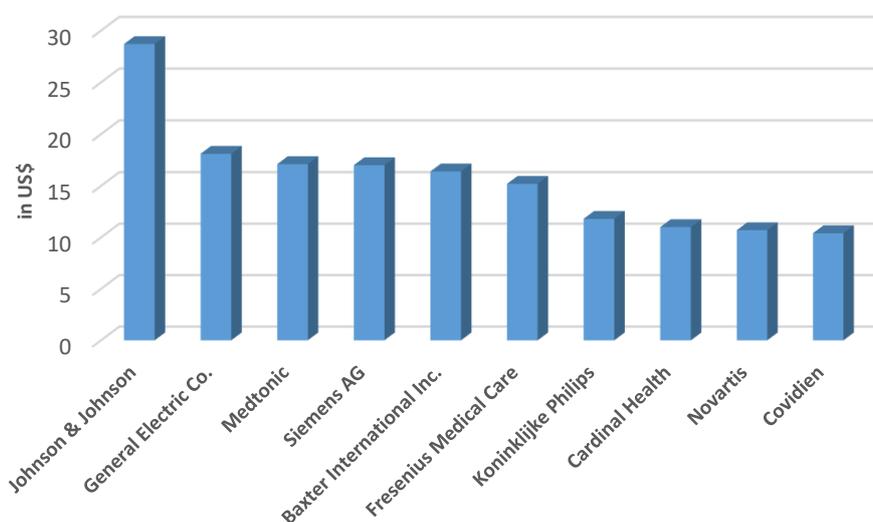
Figure 1. Global Market Share of Medical Devices (PRNewswire, 2014)



The essence of the message above mainly needs entry point with a breakthrough to robust dynamic capability in medical instrument devices. In the case of an electro-diagnostic-devices show the highest usage with 12,7% from the global market share of medical devices. That linked to the computerized in technically used as a simple method to screen for heart disease with most commonly as a diagnostic tool to measures and records the electrical activity of the heart in detail. Interpretation of these features enables the diagnosis of a wide range of heart conditions from minor to life-threatening.

From the user of electrocardiograph devices in the top ten leading company for global medical devices with their generated total revenues that accumulated to \$221.1 billion and total market capitalization to \$1.403,4 billion (MDDI, 2014) shown in figure 2. With illustrates.

Figure 2. Top Ten Leading Company for Global Medical Devices (MDDI, 2-14)

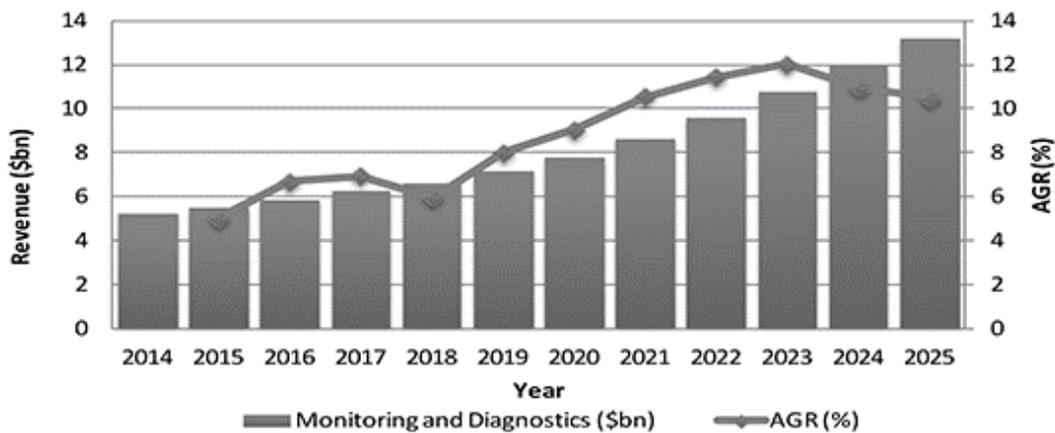


Development of electrocardiograph devices that connected with market forecast especially related to cardiac monitoring and diagnostic shown in figure 3 and table 1 with data description of recapitulation market forecast (%) and annual growth rate (%) from 2015 – 2025.

Table 1. Data Market Forecast, Annual Growth Rate, and CAGR Cardiac Monitoring and Diagnostic 2014 – 2025

<b>Monitoring and Diagnostic (\$bn)</b>	5.21	5.47	5.84	6.25	6.62	7.15	7.79	8.61	9.60	10.76	11.93	13.19
<b>Market Share (%)</b>	11.0	10.7	10.7	10.7	10.4	10.3	10.4	10.5	10.7	11.0	11.3	11.5
<b>CAGR (2014-2025)</b>	8.8											

Figure 3. Cardiac Monitoring and Diagnostic 2014 – 2025 (Visiongain, 2015)

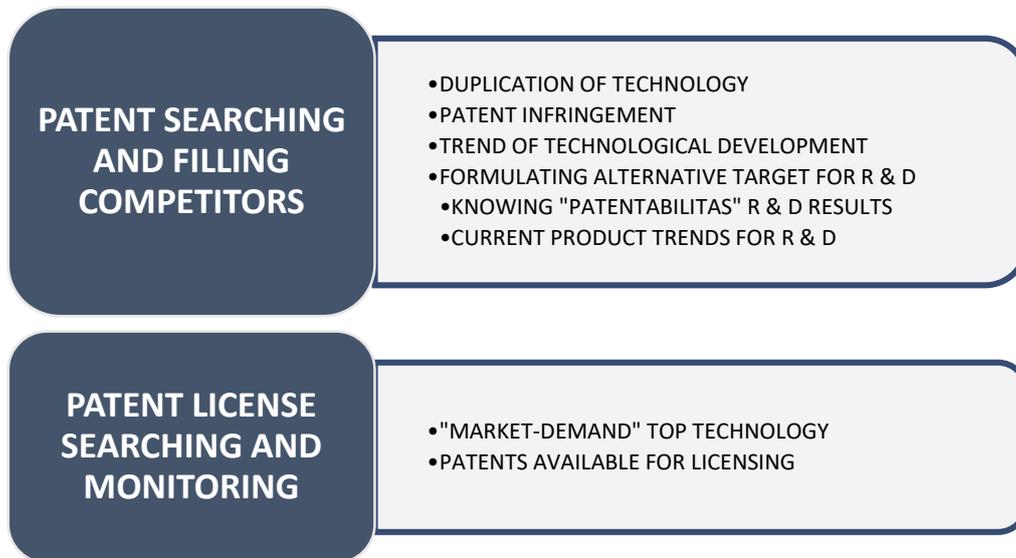


### 2.2. Analysis of Patent Management as Source Technology for ECG Devices

Implementation R & D technology cannot run well without the support of a creative and innovative culture of the society. Achievement of results against research and the current technological development tends to lead to the commercial stage. Before technology entered the stage of commercialization, it needs to register first through the protection of intellectual property right. With Know How (skills) in which defined as any information, data or knowledge engineering results from experience or skills that can use in practice, particularly in industry and allows the results of the research which have been patented for the applied and carried out the production process. At the level of the industry, the level of readiness of the technology to be used includes adaptability, assimilation, to create new technologies from existing technology (Gonsen, 1989). Besides, the technology development characterized by an increase in capacity and speed in an application that provides an extensive impact on the development of other industrial sectors in our life as well as thoroughly.

The needs of the development of the electrocardiograph devices to enhance development in health sectors can be seen from the many benefits and uses the result in implementation, one of can be known from patent potentialities useful through strategy, research, and development, analysis and collaboration (Hendrix, 2016). Also, describe methods of patent utilization searching as shown in figure 4.

Figure 4. Usefulness of Patent Searching



The analysis of patent management in the global era becomes complementary to develop many opportunities in completing source product of technology as part of process technology transfer and licensing – the spurred empowerment of R&D results that can use by the license in the form of technology transfer especially in using a patent as intangible asset based on R&D activities (Hendrix, 2014). With the ever-increasing volumes of patent information, the tasks of patent search and analysis have become vital from both legal and managerial perspectives (Liu, 2011).

The analyzing patent management, in general, gives us many opportunities in information for benchmarking product development mainly user from industry. For example, the needs information such as (1) monitoring scientific activity, (2) analyzing patent trend, (3) market trend, (4) technology development trend, (5) dynamic of a competitor, (6) road mapping technology, (7) strategic development planning. The variation of many obstacles that we have the face right now was how to synergize that becomes the needs of a customer, especially when it comes to market orientation. A patent represents an invention in a particular field of technology, and also previous studies portray that a considerable part of the information presented in patents is relatively new (Hunt et al., 2007). In other case patents as the database of source technology beneficial if we see from commercial like potential benefit from market demand especially from product diversification.

The process of patent analyzing with type providing maps and network provided us inside development of technology trends and also enable management policy makers to forecast potential competitor and future technology. Another useful application of patent analysis tools to support R&D tasks for strategic technology planning is called Technology Road Mapping (TRM), was a methodology that is used to support the strategic research and development tasks of an organization with the aim of mapping the technological developments with the product evolution and market opportunities (Phaal et al., 2003).

The global electrocardiogram (ECG) devices market is increasing in growth, due to many benign diseases of the cardiovascular and large population of geriatric. Related to product typing, seem to lead to the global ECG devices market. The enhancement R & D in the output of new product developments by the major players are supporting the demand for better and cost-effective ECG devices, thus fuelling the growth of the global ECG devices market. The source of data patent electrocardiograph devices gives us opportunity to collaborate to enhance innovation technology for technology devices in the health sector in Indonesia. Including the utilization, the results of research and development could have registered by other parties who are legally able to hold the patent rights so that the other party including those of us who find it must pay a royalty to the patent holder (Hilman and Romadoni, 2001). The main result of analysis patent management was to give a better direction and perspective for researcher or policymaker to determine R & D related to information technology electrocardiograph devices to enhance the development of the health sector.

### 3. Methodologies

This research employed a qualitative research methodology. With an approach to studying literature utilization on analysis patent management through R & D health care product (electrocardiogram). The documents database with data mining and information related to the topic of study by focusing on seeking the answers to the problems the study mainly on the utilization of information of electronic cardiograph devices to enhance the development of market demand. Data mining is one of the method or processes for extracting hidden patterns from a collection of particular data that emphasize data mining is the most important stages that transform data into patent information (Yanhong and Runhua, 2013). Data mining and the information used with three approaches, namely:

#### *a. Literature Study*

Browsing information related to the topics and issues from various sources, such as books, journals, articles or papers of other scholars.

#### *b. Patent Benchmark*

Analysis of patent management database through a document on utilization electrocardiograph devices, using software Total Patent which source in World Intellectual Property Organization (WIPO) field.

### *c. Interviews and focused discussion*

Interviews intended to deep up information on a research topic of experts associated with the object of investigation through a discussion. The discussion will be focused to obtain information patent database on development electrocardiograph devices, with the research study that has been and will be done to overcome these problems. The next stage is the extraction of the data and information obtained by each approach. The last step is to conduct the final analysis of the data and information analysis results obtained from the three methods mentioned above.

The purpose of this study is to find some information related to research topics through the international patent database (IPC) on WIPO fields that connected to research and development of prospecting utilization electrocardiograph devices in the health sector and to provide the readers with the latest research on a patent analysis in a unified form.

The target of searching and data analysis is to find the potential market and user that already apply for commercial interest and also to know the trends of technology and current research in progress. This paper is expected become the input for potential users of technology and useful source of information in the development of science and technology, as well as the nature of the modification process is implementation and reverse engineering of technological information sourced from the patent.

## **4. Results and Discussion**

The attractiveness from the mobility of ECG needs to be observed carefully regarding the development of product support, where the market will introduce with a broad range of diversification models. The source of data analysis appears by using software development called Total Patent that created by Lexis Nexis Team, due to the process held with entering the right keyword to determine the possibilities of a data requirement. With semantic based text mining techniques rely on domain knowledge and create a relationship among domain-specific concepts (Bonino et al., 2010).

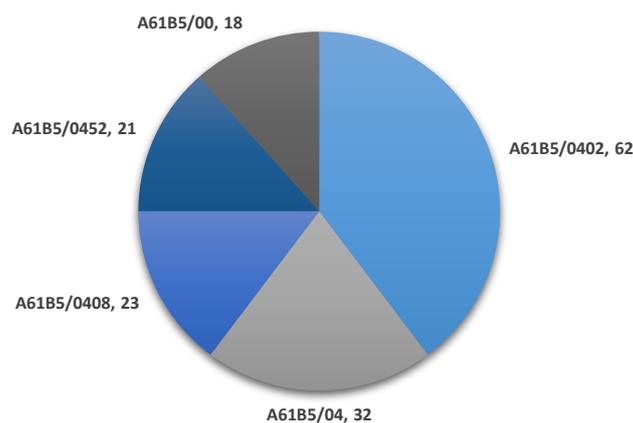
The keyword that used was “Electrocardiography” and found 247 patent document from 113,612,014 patent that being registered in WIPO fields. Description of data listed from Feb 28, 2007, until Feb 28, 2017, based on criteria as a single patent with validity period ten years. Primary authorities from the US, EP, WO, JP, KR, DE, FR, GB, and CA, including kind of document from Application and Granted file. With in-depth analysis and visualized from many components that inline into software, selected maximal patent document such as searching top 5 on the title, using a type of pie chart, we found data requirement as mention below;

### **4.1. International Patent Classification (IPC) on Electrocardiograph Devices**

Functional of variation from international patent classification on Electrocardiograph, means to provide the clustering system of independent symbols for the classification of patents and utility models according to the different areas of technology shown in

figure 5. The result IPC A61B5/0402 have 62 patent (39,8%) with description A (Section A Human Necessities); A61 (Medical Or Veterinary Science; Hygiene); A61B (Diagnosis; Surgery; Identification); A61B5/00 (Measuring for diagnostic purposes; Identification of persons); A61B5/04 (Measuring bioelectric signals of the body or parts thereof); A61B5/0402 (Electrocardiography, i.e. ECG), IPC A61B5/04 have 32 patent (20,6%) with description A (Section A Human Necessities); A61 (Medical Or Veterinary Science; Hygiene); A61B (Diagnosis; Surgery; Identification); A61B5/00 (Measuring for diagnostic purposes; Identification of persons); A61B5/04 (Measuring bioelectric signals of the body or parts thereof), IPC A61B5/0408 have 23 patent (14,8%) with description A (Section A Human Necessities); A61 (Medical Or Veterinary Science; Hygiene); A61B (Diagnosis; Surgery; Identification); A61B5/00 (Measuring for diagnostic purposes; Identification of persons); A61B5/04 (Measuring bioelectric signals of the body or parts thereof); A61B5/0402 (Electrocardiography, i.e. ECG); A61B5/0408 (Electrodes specially adapted therefor), IPC A61B5/0452 have 21 patent (13,5%) with description A (Section A Human Necessities); A61 (Medical Or Veterinary Science; Hygiene); A61B (DIAGNOSIS; SURGERY; IDENTIFICATION); A61B5/00 (Measuring for diagnostic purposes; Identification of persons); A61B5/04 (Measuring bioelectric signals of the body or parts thereof); A61B5/0402 (Electrocardiography, i.e. ECG); A61B5/0452 (Detecting specific parameters of the electrocardiograph cycle), IPC A61B5/00 have 18 patent (11,6%) with description A (Section A Human Necessities); A61 (Medical Or Veterinary Science; Hygiene); A61B (Diagnosis; Surgery; Identification); A61B5/00 (Measuring for diagnostic purposes; Identification of persons).

Figure 5. International Patent Classification in Electrocardiograph Devices

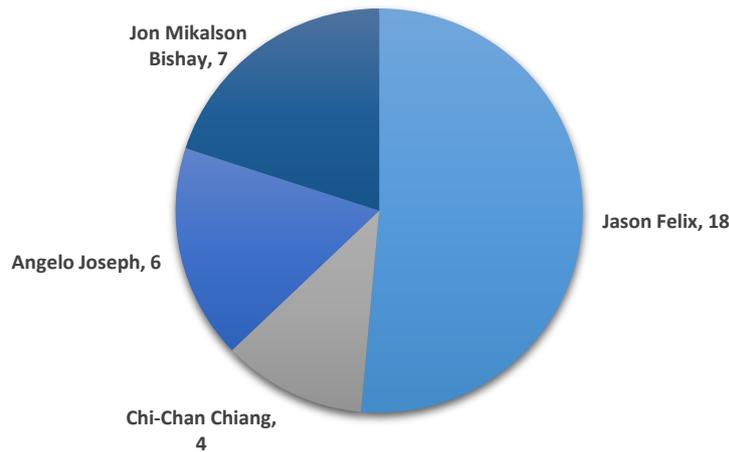


#### 4.2. Inventor on Electrocardiograph Devices

Inventor patent can define as an individual who made an inventive contribution to the invention and made an intellectual contribution as defined by the claims of the patent application. In this paper especially in a field of electrocardiograph shown in figure 6. Inventors most of them already joint in private corporate and university such;

Jason Felix with 18 patent (51,5%) that work at Bardy Diagnostic Inc. focus on providing an excellent quality atrial signal, or P-wave; Jon Mikalson Bishay with 7 patent (20,0%) that also work at Bardy Diagnostic Inc.; Angelo Joseph Acquista work at Peerbridge Health Inc. focus in leading healthcare providers of remote vital sign monitoring with 6 patent (17,2%); Chi-chan Chiang with 4 patent (11,5%) work as researcher and lecturer in Taiwan Medical University.

Figure 6. Inventors in Electrocardiograph Devices

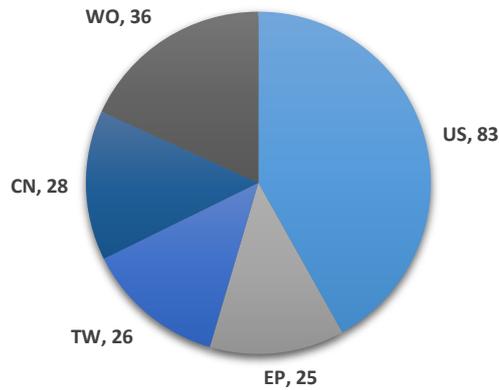


#### 4.3. Patent Authority on Electrocardiograph Devices

Patent authorities can mean as are government bodies that may grant a license or reject the patent application based on whether the application fulfills the requirements for patentability (European Commission, 2008). Authorities that in charge in filling patent registration mean statutes in different countries for own management patent office. Indeed need to apply when it comes to the Patent Cooperation Treaty (PCT) give us the opportunity from benefit and publication, the description shown in figure 7.

The authority spread in each country that has a Patent Office that consists of; United States linked with the United States Patent and Trademark Office (USPTO) with managed 83 patent (42,0%); World Intellectual Property Organization (WO) managed 36 patent (18,2%); China Patent and Trademark Office (CN) managed 28 patent (13,2%); Taiwan Intellectual Property Office (TW) led 26 patent (13,2%), and European Patent Office (EP) managed 25 patent (12,2%).

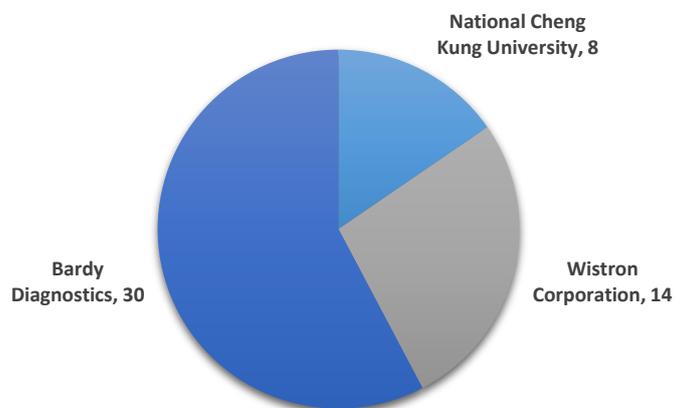
Figure 7. Patent Authority in Electrocardiograph Devices



**4.4. Patent Assignee on Electrocardiograph Devices**

Patent Assignee means a person who holds, valid assignment in writing, the whole interest of a patent, or any whole part of such overall interest including ownership rights of the intellectual property. The exclusive right to make, use, and vend the patented improvement during the term for which the patent granted. Figure 8 shows patent assignees distribution on electrocardiograph and almost entire patent already applied. Data demonstrated that the adoption of electrocardiograph define as; Bardy Diagnostic Inc. with total 30 patent (57,7%) this corporate deal with develops and delivers cardiac arrhythmia monitoring devices; Wistron Corporation Inc. managed 14 patent (27%) with focus on original design manufacturer (ODM) providing variety of support services related to design, manufacturing and after-sales services for ICT; National Cheng Kung University with total 8 patent (15,4%) and focus on research and developing instrument medical devices.

Figure 8. Patent Assignee in Electrocardiograph Devices

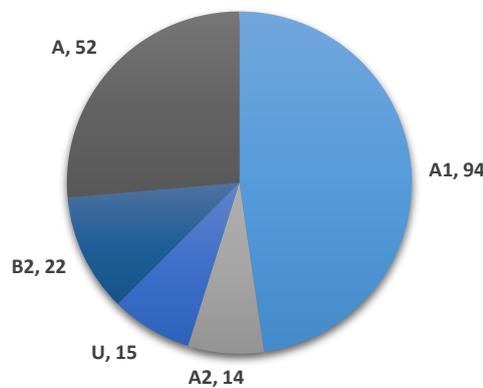


#### 4.5. Patent Kind Code on Electrocardiograph Devices

A patent kind code was used to identify the type of patent publication and help you to understand the history of the patent. Also help you figure out what's going on with a patent that represent expression “patent document(s)” includes the following documents: patents for invention, inventors’ certificates, medicament patents, plant patents, design patents, utility certificates, utility models, patents or certificates of addition, utility certificates of addition, and published applications therefore also all of codes registered in country authorities that have patent office. Data that appears as shown in figure 9 with description A1 Patent Application Publication - Utility Patent Application published with patent application registered 94 (47,8%); A Patent - Utility Patent Grant issued has registered 52 patent application (26,4); B2 Patent - Previously Published/Utility Patent Grant (with pre-grant publication) with 22 patent application registered (11.2%); U Granted Utility Model Patent with 15 patent application registered (7,7%) and A2 Patent Application Publication - Republication/Second or subsequent publications of a Utility Patent Application with 14 patent application disclosed (7,2%).

From data that describe above, can be defined that most of the patent information kind code on electrocardiograph devices still under process and review assessment by a patent investigator.

Figure 9. Patent Kind Code in Electrocardiograph Devices



## 5. Conclusion

Technology users have not much-exploited patent search results; this is due to the lack of socialization and user roles in conducting patent database searching. The need for intensive dissemination on empowered intellectual property that oriented to research and development activities related to electrocardiograph devices see the trend market that exists in the market today, through patent information from the internet so that the industrial sector used optimally.

The patent database was a valid document to define many substances of technology process that occur from R & D development. This kind of prospecting technology result to analysis and useful to determine potentials useful through strategy, research and development, patent analysis and patent collaboration among users. The arise from patent document preferable to trace the development of the technology, the relevant in patent documents there is prior art which is a technology earlier. Any technology that contained in patent documents have a novelty and the advantages of technology than its predecessor.

The analysis patent information on electrocardiograph devices to investigate the value of possible utilization and enrichment foresight technology that is used as a benchmarking from industries or stakeholder that needs to measure the level of their product output kind likes patent portfolio. From present knowing the leverage of electrocardiograph devices has a significant impact on health sectors and the public used also can play an important role in defining business strategies and support decision. Analytical from patent technology foresight represent information can use as a strategy for research and development of an organization. With expected to emerge results of studies in the field of electrocardiography devices and derivative product to enhance the development of health sectors that are innovative and highly competitive. The next stage, in patent analysis approaches for strategic technology planning developed so far, is capable of suggesting one strategy only. It would be worthwhile for the managers if the methods are made more efficient and flexible to offer various suggestions for devising strategies (Yu and Lo, 2009).

The result from analysis patent management database consists of number appropriate technology can be used with material transfer agreement (MTA) system that involves many users, industries, government and stakeholder that appear as a part of the work. Most common database on electrocardiograph devices has shown that utilization of patent from invention until commercialization done in Asia Pacific region and also based on a potential source for material and production assignee comes from China and Korea.

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