‘IITB INNOVATE’ PROGRAMME APPLICATION

PROJECT CHARTER DOCUMENT

Title	**Health era solutions**
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1. Project Executive Summary

- **1.1 Project goals**

  Our principal aim lies in setting up state of the art R&D facility in India in the field of bio-medical electronics. The Indian medical industry still depends mostly on western market for fulfilling its need for diagnostic equipment, making the basic health care facilities duly overpriced and inaccessible to the common man. The equipment is imported paying huge import duties burdening the end user. Most of the diagnostic equipment we use in the basic healthcare industry can be indigenously developed at a cost decrement index of at least 10 times.

  We will be concentrating on innovative diagnostic designs with simpler interface upholding patient support products like the "epilepsy prediction system" which helps epilepsy patients to lead a normal life by predicting and alerting the occurrence of epilepsy in the pre-ictal stage. For the innovative idea of epilepsy prediction, our team member Ananthakrishnan was awarded by Motorola for the best innovative project in India in 2008. All these research requires satisfactory funding and state of the art support technologies. So to begin with we have planned to reverse engineer, design customization, develop and market some of the very useful, but costly products in India thereby supporting the 'Make in India' Campaign.

- **1.2 Objective**

  Our objective is to indigenously develop some of the very commonly used equipments. Primarily , we have engineered a few products. The following list gives the products we intent to market.

  1. **Vein detector (Simple version):** This product is very common in developed nations and is used by medical practitioners to access the right vein for administering Intravenous (IV). The device emits light of a specific wavelength spectrum which is absorbed by hemoglobin thereby projecting veins as darker streaks compared to the surrounding area. Fig.1 is the existing device in foreign markets. The gap in Indian market can be filled easily with a suitable alternative with greater technical supremacy and ergonomics of the same product. This device helps medical practitioners to avoid tourniquets, reduced failed attempts of vein access.

Fig.1 – Veinlite LED

2. **Vein Detector (Projection Type):** This is the advanced/upgraded version of the early described. This uses IR rays of a specific wavelength spectrum to scan the body surface. The scanned image is captured by a camera to project back the image of underlying venous network after a complex image processing algorithm by a digital signal processor. The utility of this device is mainly harvested by doctors attempting complex surgeries on veins like the treatment of varicose veins (sclerotherapy). The device is complex but gives a more accurate and clear picture of the underlying venal network. Fig.2 is an existing device in foreign markets.

Fig.2 – Accuvein AV400 and its image

3. **Automation of Microscope:** Apart from the other devices explained above, this is a novel technique jointly developed with the labs of IIT Kanpur. For the detection of cancer and its degree in a tissue sample from biopsy, expert diagnosis by a professional is required. It is often very difficult to get experienced histologists and quite unaffordable for small labs and hospitals, leading to a compromise on the quality of diagnosis result they produce for patients. Hence the chances are more that the diagnosis results going wrong mainly due to the lack of any golden standards for the differentiation of a healthy tissue from a tumor. Our aim is to standardize this by automating a microscope and in building enough intelligence so that the microscope can itself differentiate a cancerous tissue from a healthy one. This helps in standardizing and automating the procedure followed generally by the histologists under oncology. The intelligence was developed in the bio-photonic labs of IIT K and the technology has been applied for a patent in India. An understanding has been reached by IIT K and our team for commercialization of the developed product. The technology will be transferred to our team for further development.

- **1.3 Scope**

In hospitals and clinics medical practitioners struggle to access the right vein to infuse IV injections and attempts multiple trials putting the patient in utter discomfort. They use old techniques like the tourniquets to view the vein. In neonates, the veins are tiny strands and are very difficult to trace one.

The device developed here bridges this gap. Marketing targets include all hospitals and clinics. Indian medical facility still uses the old technique of tapping and tourniqueting for identifying the right vein. Even though this product exists in foreign markets, due to the heavy cost involved in imports, Indian medical industry still refrains from the use of such a useful product.

When marketed at a reasonable cost, we are confident enough to get a broad market in India. Apart from hospitals and clinics the device will also find its use among geriatrics who are advised by doctors to take IV at home by themselves. It will be very useful for nursing and medical students to learn IV infusion with the help of these devices. Also these devices will be very useful for emergency wards and ambulances where IV infusion is done urgently and frequently.

The projection type of vein detector is required for sclerotherapy for viewing the complete venal network beneath the skin and will be preferred over other equipments in the market. Automated microscope avoids the requirement of trained professionals in cancerous tissue detection.

- **1.4 Approach**

The team will primarily focus on the design and development of the simple and the advanced versions of the vein detectors. This will help the team to raise fund for future R&D activities and also gain experience on the Indian Bio-medical Industry market

1. Vein Detectors(simple and projection type):
    - Technology, proof of concept
    - Understanding the market and its readiness to accept the product, competitors, approximate cost of production etc..
    - 1st phase Prototyping
    - Testing the product on patients to analyze its veracity
    - Corrections and modifications before finalizing the bill of materials
    - 2nd phase prototyping
    - Product sample distribution in selected markets and collecting feedback
    - Prototype Refurbishment, if required
    - Final casing design aesthetically and ergonomically
    - Getting necessary certifications and licensing (the ICAC mark) from the Ministry of Health / Certifying , Legalizing and Licensing
    - Fixing the final cost of the product
    - Final production

2. Microscope Automation :
    - Doing a thorough market research on the usability of the product, analyzing the surveys done to get an understanding about the marketability of the product
    - Applying for the transfer of technology for the already developed and proven product from IIT Kanpur
    - 1st phase prototyping
    - Field test
    - 2nd phase prototype with necessary modifications
    - Planning a market strategy
    - Getting necessary certifications and licensing (the ICAC mark) from the Ministry of Health
    - Fixing the final cost of the product
    - Final casing design aesthetically and ergonomically
    - Final production

Our approach would be to hit the market with one product at a time. We plan to keep the Projection type vein detector and the automated microscope in pipeline. The above are a few pointers related to the development of the product. In parallel, we will also be registering ourselves as a company and establishing ourselves.

- **1.5 Risks**

The following risks are involved in business plan

1. Once the market is familiar with the product, much economical, compromised on quality Chinese equipment can hijack the market
2. Risk as a result of lack of funding at the adequate time
3. Risk of other Indian companies copying the business model

- **1.6 Time line:**

The business plan includes development of three products. The vein detector (Simple version), Vein detector (projection type) and automation of microscope. The development of Vein detector (simple version) began in December 2013 and is almost in its final prototyping stage. We expect to launch this product after a small final tuning. The projection type vein detector is expected to roll out in june- july 2015. The automated microscope is planned to launch late 2015. Please refer to section 13 '*Timeline*' for the breakup of activities

- **1.7 Costs**

Our team approximately expects around INR 3.22 lakh for the equipment and components and around INR 90,000 towards prototyping and for other outsourced services. INR 1,75,000 for patent expenses of automated microscope and INR 15,000 towards miscellaneous expenses. Please refer to the section 12 *'Budget'* for split up of costs involved

2. Market Opportunity

In India we have not seen any clinic or hospital using this technique to image vein for intravenous drug delivery. To confirm this we had done a survey 4 months back in some of the nearby hospitals and interviewed some doctors, which thoroughly confirmed the absence of any such products and shed light on the requirement of this product. We were able to understand the reason for its absence, as the huge cost these products are tagged with for they need to be imported from the US and other European countries. Since this product can be made at an affordable rate and lucrative specifications compared to its competitors; we are quite confident to capture the market all over India. A small variation to the form factor of this product can help pediatrics to image vein on neonates. This product is a must for doctors performing sclerotherapy. This product is a boon for geriatrics who are advised to take IV at home more frequently. This assists them in situations where the absence of a nursing professional to

administer IV. Studies on the use of such products in western countries have proven the improvement of first attempt to vein access up to 90% to 95% shooting up the patient satisfaction index.

3. Novelty

In US and other advanced countries commonly use these vein detectors in clinics and hospitals. Some of the commercially available vein detectors are Veinlite PEDI, Veinlite LED, Veinlite EMS, Veinlite and V600. These are different variants of the same product. They use the red and orange visible light spectrum imaging technique for vein detection. Philips has recently come up with a vein detector for the neonates called the 'wee sight'. The cost of Veinlite products vary from USD 179 to 1600. The paediatric version is cheaper. Cheaper Chinese versions are also available in the market. But in India Jolly Technocrats has the distribution for Veinlite^{TM}. A company from Kerala (ibis medicals) which is incubated at NIT Calicut has recently started manufacturing vein detectors for neonates along with other bioelectronic products. Accuvein manufactures the advanced model of Veinlite LED ie, system with image projection back on patient's body. The cost of the current product (the simple one itself) in the market is well above INR 10000 and the advanced model may go upto INR 4 lakh.

Associated Patents in India :

3.1 Patent Application No: 1525/DEL/2012 : In India a patent filed by Prof. Harshawardhan wanare of IIT Kanpur is very near to our concept. He has patented a specific band of wavelength (575nm- Yellow color) for vein imagining. The patent will be held jointly by the professor and IITK.

How we are different *: Our product will be saved from this patent since we use approximately 650nm (Red color) wavelength light for vein transillumination*.

3.2 Patent Application No: IN-MUM-2012-01448 : Patent which can be close to our advance level vein imaging device is by AASHUTOSH SHARMA. In this patent he has claimed 'a blood vessel visualization apparatus comprising of high intensity and low intensity lighting along with Near Infra Red (NIR) camera for visualizing blood vessels comprising of veins, arteries and capillaries' The said invention illuminates the body part of the patient using an NIR camera and visible red light which helps in easily identifying the blood vessels.

How we are different*: In our idea we are using only NIR wavelength light source for vein trans illumination and NIR camera to capture image of vein and project it back on the skin surface*.

3.3 Patent Application No: IN-KOL-2010-00249 : This Patent claims an apparatus Integratable with mobile phone having camera to form a cost effective alternative for viewing veins. The said apparatus of the present invention comprises array of at least 3 to 4 near infrared light sources of 780 nm wavelength; a mounting means on which the array of near infrared light sources are mounted in a certain pattern; and a means for providing power to said infrared light sources for their illumination. The said vein viewing apparatus embedded with the said mobile phone when placed above the skin of human subject at a distance of approximately 4 cm, vein is viewed.

***How we are different**: We are developing a standalone device which works using camera, infrared LEDs, projector and computing ICs.*

4. Project Scope

Goal 1.

Objectives	**Methodology/ Activities**	**Alternate strategies**	**Milestone**	**Date of end of activity (mm/dd/yy)**
1.Vein Detector (simple Version)	1. Proof of concept		Completed	10/01/2014
	2. Design of prototype		1. PCB design, component finalization and testing 2. Designing of outer casing (Rapid prototyping)	10/10/2014 11/15/2014
	3. Creating at least 10 to 20 sample products		Industrial design of prototype	11/25/2014
	4. Send samples to medical practitioners and collect feedback		1. Contact with medical practitioners 2. Collect feedback	12/10/2014 01/15/2015
	5. Getting certifications and licensing done			03/31/2015
	6. Production and Marketing			04/30/2015

2. Vein Detector (Projection Type)	1. Proof of concept		1. Purchase of equipment 2. Matlab and DSP programming 3. final hardware	10/15/2014 01/15/ 2015 02/10/2015
	2. Design of prototype		Outsourcing outer case design (Industrial design prototype)	02/28/2015
	3. Creating at least 10 to 20 sample products		Manufacturing samples	03/30/ 2015
	4. Send samples to medical practitioners and collect feedback		1. Contact with medical practitioners 2. Collect feedback	04/10/2015 04/30/2015
	5. Getting certification			Mid 2015
	6. Production and Marketing			Mid 2015

Goal 2.

Objectives	**Methodology/Activities**	**Alternate strategies**	**Milestone**	**Date of end of activity**
1. Microscope automation	1.a) Proper market analysis about the product utility b) Getting the technology transferred from IITK		Company registration for technology transfer	11/30/2014

	2. Building the prototype		1. Purchase of Instruments/components 2. Technology learning 3. Final Hardware prototype	12/30/2014 02/28/2015 03/31/2015
	3. Creating at least 10 to 20 sample products		Manufacturing samples	04/30/2015
	4. Market testing and strategy planning		1. Connect with various labs and doctors 2. Collect feedback	05/31/2015
	5. Getting certification			Late 2015
	6. Production and Marketing			Late 2015

5. Project Structure Approach

The team plans to Develop and market the products one at a time and pipelining others for the immediate release. For the development of products, the following steps would be followed:

Step - 1 : Testing the proof of concept and primary prototype development (already done to this date)

Step - 2 : Finalizing the electronic circuitry and fixing the second prototype (In the process)

Step - 3 : Processing the feedback from medical practitioners and nurses. The feedback will also be useful in designing the advanced version of vein detector. In parallel to this the technical team will work on developing prototype of Projection based vein viewer

Step - 4 : Registering as a company and business development team will initiate the transfer of technology from IIT-K. Certification of the simple vein detector equipment with final casing design of the product

Step - 5 : Construction of first prototype, testing and construction of final prototype of the projection based vein detector. Depending on feedback we received for the simple circuitry, the requirements can be altered in this also.

Step - 6 : Market testing and design of final prototype. Marketing team will develop a proper strategy to put the device in market along with the simple vein detector and will start contacting various nursing Institute, Hospital chains, and Individual doctors for the same. Marketing team to do intense research on product distribution and brand value creation

Step - 7 : Constant feedback generation and processing to fine tune to develop second generation of the product already marketed

Step - 8 : Technical team to start working with prof. Asima Pradhan, IIT Kanpur to develop automated microscope

Step - 9 : The Marketing team to analyze the market for UV based oral cancer screening light, product feasibility etc.. for indigenizing the product and pipelining it as the next product

6. Project Team

Project Team Role	Project Team Member(s)	Responsibilities
Market Analyst	Anantha Krishnan C S	Identify Health care industry market, requirements and building marketing strategies. His main responsibility is to create a broader vision for the company, a business and a revenue model, identifying market gap, new products for development and to drive the technical team for R&D of products. He also keeps a tab on production cost and works on marketing flexibility
Technical Analyst	Girish Nayak	Designing of product, technical assistance to product developer and also working with Marketing team to build product as per Market requirement. His responsibility is to bridge the marketing team and the technical team and to ensure the development is on track and all the deadlines are met. He takes additional responsibility of company incubation, registration etc.. He is also involved with the product development team for aesthetic and ergonomic design of product casing
Product Developer	Arun M P	Converting the engineering design into an consumer-oriented product with maximum reliability and cost effectiveness, aligning with the business model. He takes responsibility of the technology robustness.

7. Risk factors

#	Risk Area	Likelihood	Project Impact-Mitigation Plan
1	IP infringement	Medium	Vein detector which we discussed above may face IP infringement from US patents. Currently we are sure that patents are not protected in India. Most of them are related to Device shapes and wavelength, which can be tweaked as per convenience. This can be sorted out by discussing with patent consultants.
2	Inadequate funding	Low	We are trying to incubate our company in IIT-Bombay incubation center "SINE". They have good past track record in creation of successful companies. They will help us to get grants from govt./private organizations and also give exposure to VCs

8. Constraints

1. Unavailability/Scarcity and expensive shipment of proper industrial standard integrated circuits for the development
2. LEDs at the required wavelength spectrum not available directly in the market
3. Requirement of costly lab equipment like the spectrometer to understand the directionality, spread and the spectrum of the emitted light .
4. Unavailability of monochromatic projectors, as a result, dependence on the costly DMD projectors inevitable .
5. Higher charges for casing design if outsourced
6. Higher charges for DSP programming if outsourced

9. Preliminary work & intellectual property

1. Testing proof of concept and designing the initial prototype of the vein detector (simple version)
2. First prototype casing design and 3D printing
3. Testing the proof of concept for projection type vein detector
4. The work related to microscope automation has been applied for patent jointly by Prof. Asima Pradhan with IIT Kanpur

10. Relevant references

1. https://www.veinlite.com/media/downloads/Feature-Veinlite-Transillumination-Pediatric.pdf
2. https://www.youtube.com/watch?v=l8Zn1GntRXU
3. Nandan Das et. al Probing multifractality in tissue refractive index: prospects for precancer detection,January 15, 2013 / Vol. 38, No. 2 / OPTICS LETTERS
4. Panigrahi.K et. al, Multilevel thresholding for image segmentation through a fast statistical recursive algorithm, Pattern Recognition Letters 29 (2008) 119–125, elsevier publication
5. Madhur et. al, A Fast Statistical Method for Multilevel Thresholding in Wavelet domain, elsevier pub, Vol 28, page 268

11. Future plan of commercialization

The Vein detector (simple version) is almost in the final phase of prototyping and can be introduced in market after some more adjustments based on the feedback we collect from medical practitioners. Just next to the launch we also plan to introduce the projection type vein detectors in the market. This will be followed by the automated microscope.

12. Budget

Equipment & accessories	(INR)
1. Digital storage oscilloscope	45K
2. Multipurpose advance Soldering station	8K
3. Multi-meter	2K
4. Variable voltage source	2K
5. Controllers and Processors ICs along with Programmers	8K
6. Pico projector (For prototyping advanced vein detector)	20K
7. Spectrometer	100K
8. IR camera	8K
9. DMD chip for making handheld projector	6K
10. DMD driver IC	3K

11. Texas Instrument DLP Light crafter Evaluation module 12. Clinical Microscope 13. Stepper motor and total cost for designing Assembly line	40K 70K 10K
Human resources 1. DSP circuit design and programming	 30K
Consumables 2. Patent consultation 3. Patenting the microscope automation	 25K 150K
Out-sourcing PCB Making (For multiple iterations of prototyping) Product design and rapid prototyping	 20K 40K
Other recurring heads	5K
Other financial detail Travelling (To reach medical practitioners)	 10K
TOTAL (INR)	602 K

13. Timeline

Date Estimate	Project Milestone	Funds required	Deliverable(s) Included
11/05/2014	Start (Prototype of simple vein detector)	20K	1. Industrial design of prototype for simple vein detector 2. Distribution of samples to medical practitioners and collecting feedback
11/10/2014	Purchase of components / equipment / evaluation kit For projection type advanced vein detectors Matlab and DSP programming	227K	Proof of concept (Advance vein detector)
12/30/2014	Purchase of Component to design stand alone projector based vein detector Circuit designing BB testing and finalizing PCB level testing	150K	Proof of concept (Advance vein detector)
02/20/2015	Outsourcing outer case design (Industrial design prototype) Microscope automation patent fee Purchase Required instrument to make automated microscope	205K	Design of prototype (Advance Vein detector) Building the prototype for Automated Microscope