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Biomedical Device Design

Investigation report

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1 Introduction/Strategic Focus

Our startup company, BEsol Limited, we are dedicated to improving the healthcare industry with our new ideas. As undergraduates, we want to push ourselves to meet the needs and requirements of the medical industry. This investigative report is to select a device to design that falls under our company's acceptance criteria. A few of them are provided below.



Figure 1: Acceptance Criteria

1.1 Our mission

Our mission as a startup is to invent and innovate modern-day healthcare equipment and accessories to help medical personnel be more efficient and productive.

1.2 Our Strength and Capabilities

As 2nd-year undergraduates, our expertise lies in a constricted section of the biomedical industry. Medical electronic equipment (bioelectronics) is the field we specialize in and are comfortable with. However, we are capable of doing biomechanical designs, up to a certain extent. As a company founded by a biomedical undergraduate and an electronic and telecommunications undergraduate, we are quite capable of handling any kind of electronic-related problem.

1.3 Consumer Population

The projects that we are planning to do must have a significant audience. As a startup, doing a project that only benefits a few individuals is quite out of the question for us. We would consider such a project only if those groups of

potential consumers are a special group of people with a special need for that kind of equipment. Moreover, we are looking forward to a project that can benefit the vast majority.

1.4 Market

Since we are a new company, the market is a crucial factor when choosing the project. Predicted growth of the product market and Similar products already in the market are thoroughly researched before getting into a project. If we could pull a major change toward betterment than the competitive products already in place, those projects will be given more focused

1.5 Time and Resources allocation

Because most of our projects must be completed in a single semester, the time allocated per project from the start until a working prototype is created will be limited. Also, as a company in a third world country, resources are also limited to go for a bigger project. So when selecting our next project, we'll thoroughly look at its complexity.

1.6 Affordability

The products we develop must be in a considerable price range. Production costs will also be considered since we are a startup company in a third-world country. However, if the product can generate sponsorships and opportunities, we will be obligated to create them.

2 Need Finding

2.1 Problem : Non Invasive Intracranial pressure measurement / Neurovascular monitoring in the head

Source: Neurosurgeon from Colombo National Hospital (7/Nov/2022)

The base idea is that complications may occur in patients who underwent an injury or surgery in the head. In those patients there is a high probability of occurring an internal hemorrhage causing variations in intracranial pressure. Currently the intracranial pressure is measured by an invasive method by inserting an intraventricular catheter. But this method is currently used only in extremely severe cases due to the invasive nature of the procedure and the risk of complications. It would be more beneficial if a device is produced to real time monitor the vascular activities of the brain that could automatically detect and alert complications such as hemorrhages. Approximately 13 million people undergo brain surgery worldwide. which suggests that there is a significant market for such a device. [1]

2.1.1 Need statement1

- **Problem :**Non Invasive Neurovascular monitoring in the head
- **Population :**Patients who underwent head trauma/surgery
- **Outcome :**Real-time detection of hemorrhages before complications

"The way to address Non-invasive Neurovascular monitoring of the head in Patients who underwent trauma/head surgery to Real-time detection of hemorrhages before complications"

2.1.2 Disease state foudamentals

Rupture of blood vessels in the brain leads to a hemorrhage in the brain that would immediately damage the functional tissues of the brain due to the hematoma. Mechanical forces occurred due to the raised pressure, which disrupt signaling pathways around the hematoma. More than one fourth of the patients would undergo a considerable expansion of the hematoma within an hour. Degeneration of the blood-brain barrier, as well as the mass effect, would significantly raise intracranial pressure and disrupt blood flow to other areas. Secondary complications may occur due to inflammatory reactions and the edema associated with those reactions. As brain tissue damage is irreversible, this would lead to the loss of cognitive functions associated with the affected region and would probably be fatal if the brain stem were affected.

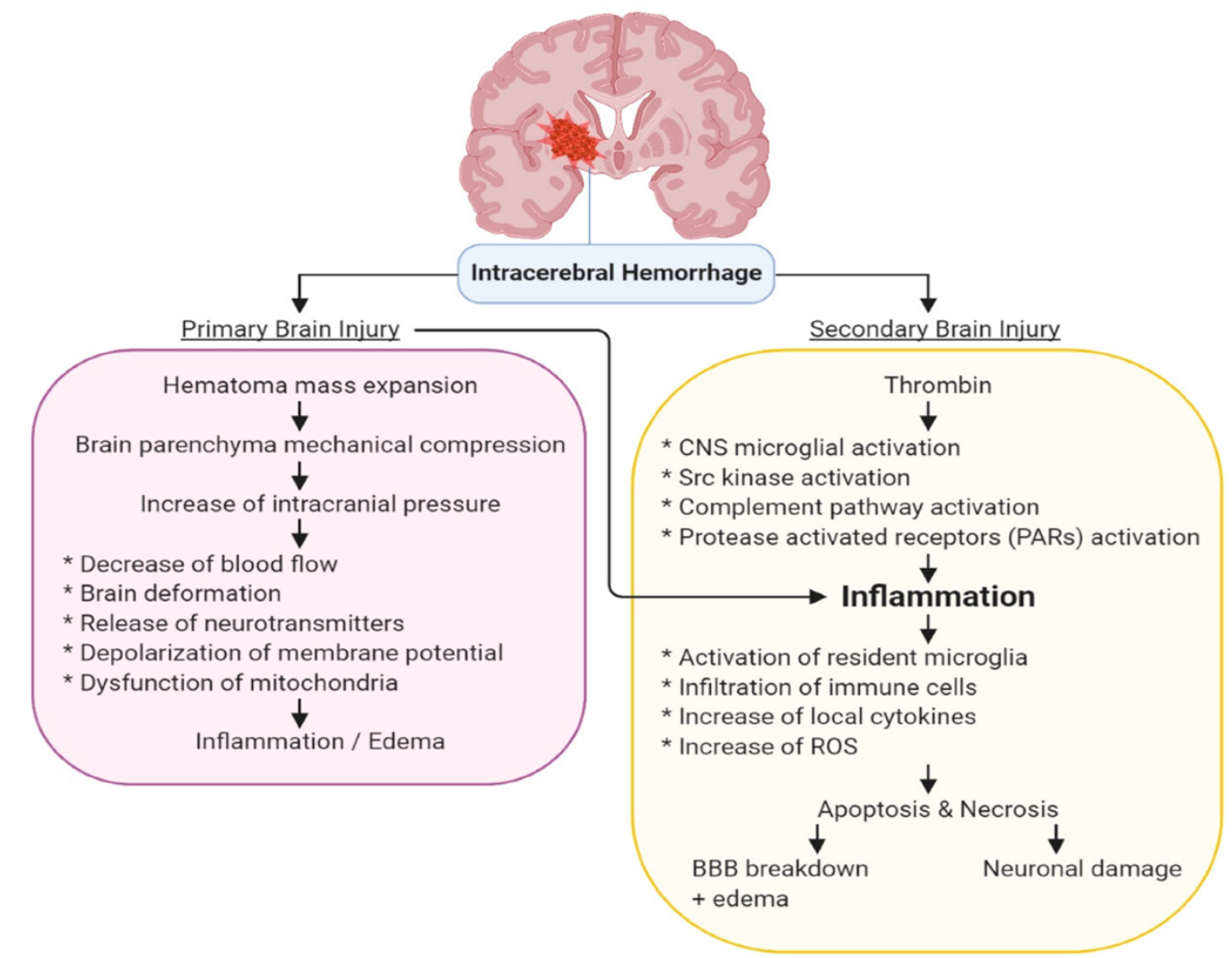


Figure 2: Intracerebral Hemorrhage

2.1.3 Existing Solutions

CT or MRI scans could be used to detect a slowly progressing hematoma, but they would not be useful in cases of sudden and drastic ruptures because a patient could not be continuously placed inside a scanner of that scale. The best existing solution is to measure the intracranial pressure, but as it is an invasive procedure done by inserting an intravascular catheter, Due to the invasive nature of the procedure, this method is only used in high-level trauma centers and in severe cases. The EEG could warn by sounding an alarm, but only after damage has occurred and the electrophysiology has changed.

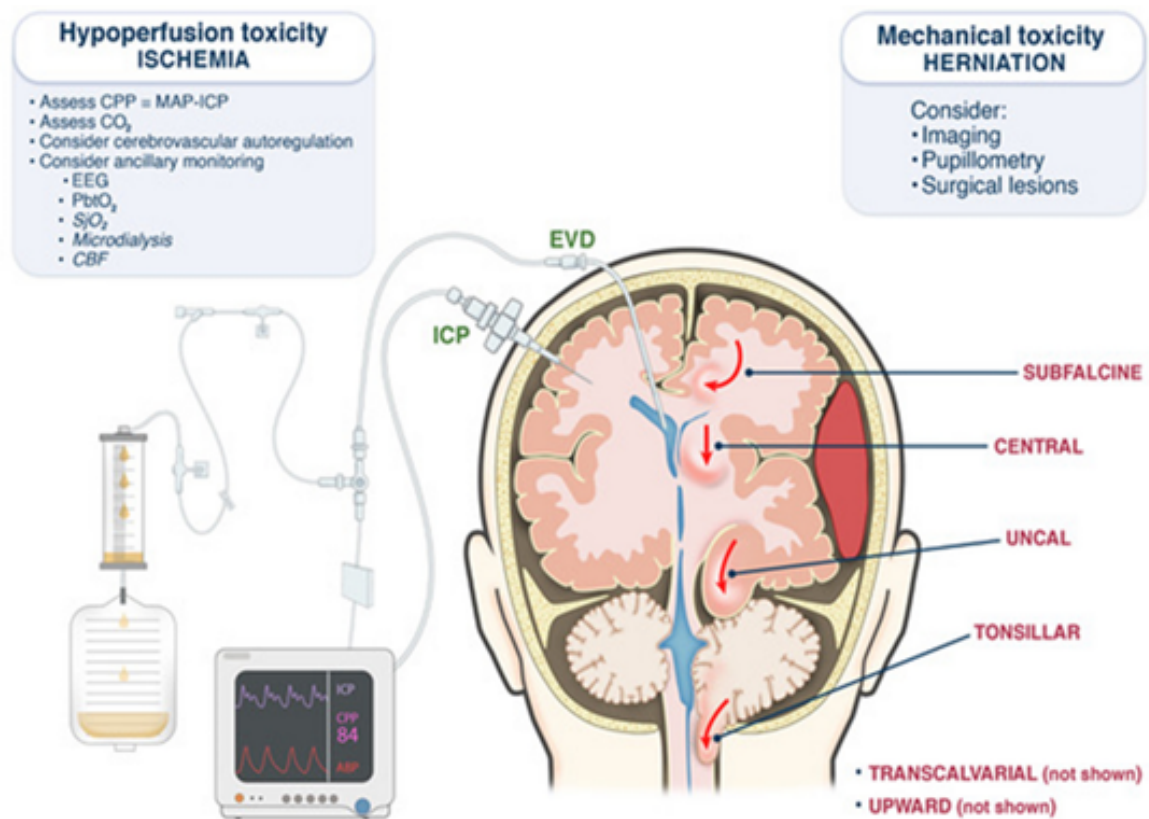


Figure 3: Invasive ICP measurement

2.1.4 Stakeholder Analysis

Patients : With a new non invasive method Patients will be more comfortable undergoing or agreeing to give their consent for the ICP measurement, resulting in fewer post-operative complications.

Doctors & Nurses: The preparations and the procedure will be efficient and with the cotinuous hands off monitoring they will be able to guarranty the safety of the patient to not go to critical states.

Government and general public : ICP machines are expensive and hard to replace. As stated in the market analysis below, a method to reduce the expense of ICP monitoring systems would be more effective for many countries.

2.1.5 Market Analysis

The ICP monitoring devices market was worth 1.5 billion USD in 2021 and was expected to grow at approximately 7% CAGR by 2030.[III]

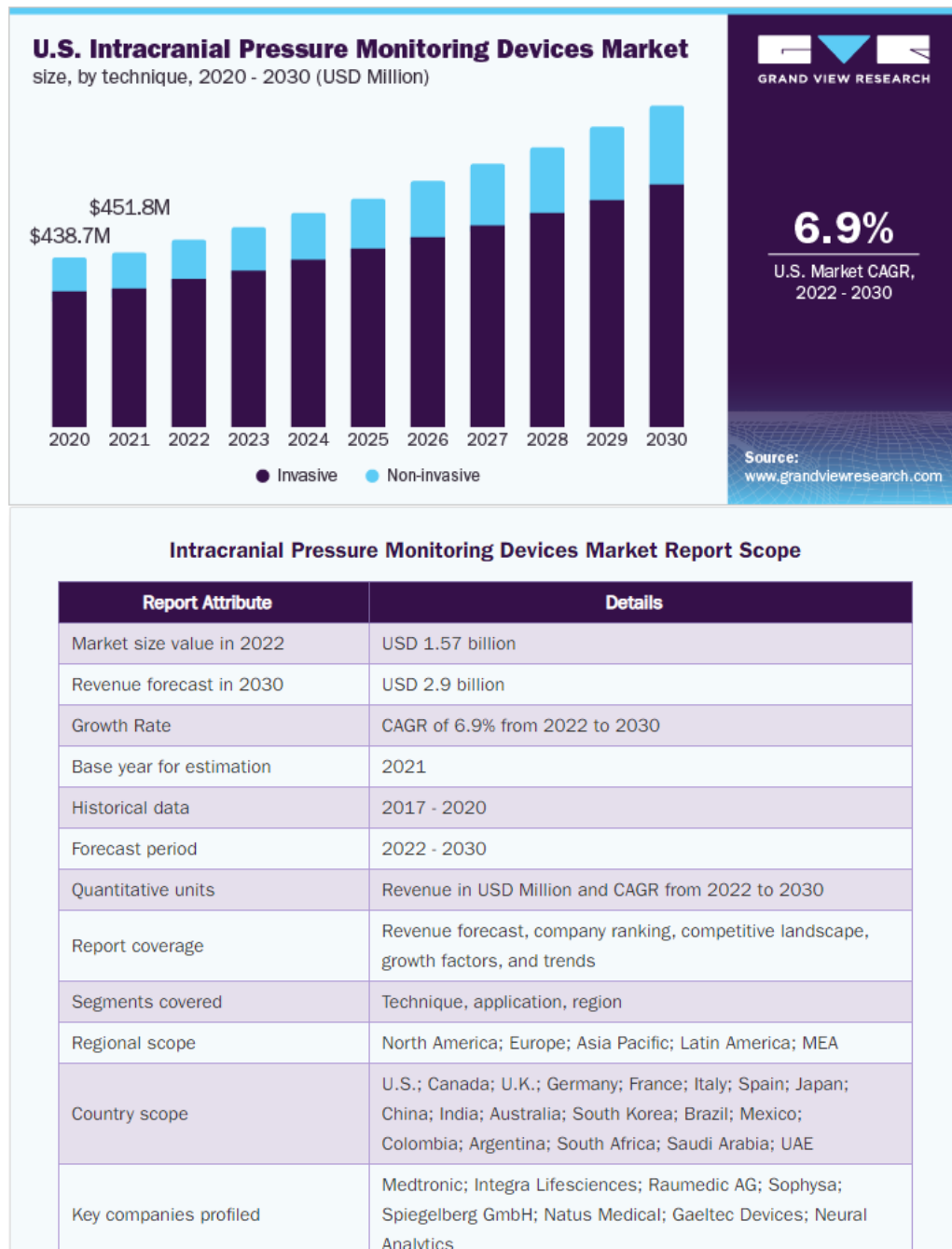


Figure 4: Market analysis of ICP devices

2.2 Problem : Visualizing internal damage in a outstation trauma management

Source: Neurosurgeon from Colombo National Hospital (7/Nov/2022)

When a medical/paramedical team goes for a site of an accident it is mandatory to evacuate the patient from the site without causing a secondary injury for example the way or the direction the patient who might be stuck could cause a secondary injury such as a spinal cord damage or a burst of an artery. Thus some sort of a portable scanner that could be used in accident sites would be greatly beneficial.[II]

2.2.1 Need statement2

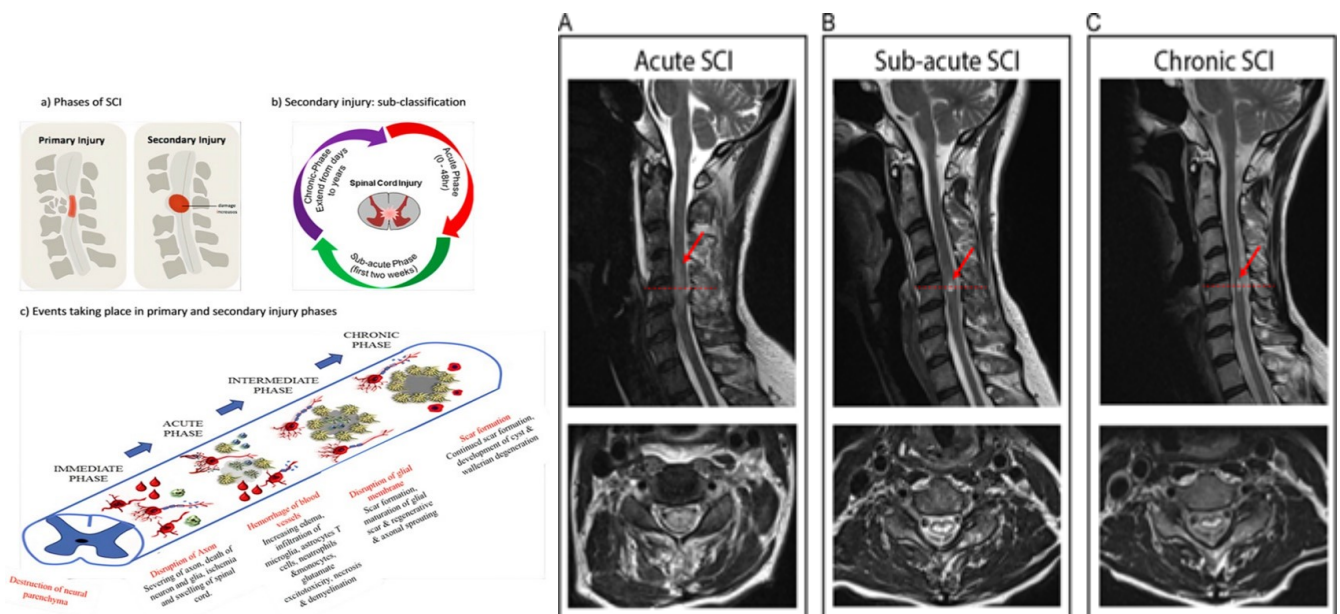
- **Problem :** visualizing how the internal damage is in a out station
- **Population :** Out stationed trauma patients
- **Outcome :** Evacuation of the patient from the accident site without secondary injuries

”The way to address problem of visualizing the internal damage of out stationed trauma patient that facilitate the evacuation the patient from the accident site without secondary injuries”

2.2.2 Disease state foudamentals

Spinal Cord injuries may occur during extraction of a victim from an accident site.

Axons of the neurons that lies within the spinal cord performs a crucial role in maintaining the peripheral nervous system and the motor functions associated. If an axon is damaged the region that was controlled by that neuron would become immobilized. Rupturing of blood vessels in the spine could cause vascular ischemia that would lead tissue destruction or extravastion of immune cells causing edema. Thus even in a minor injury that does not fully damage the axon, swelling would occur and severe pain would be resulted due to the pressure applied on the nerves and even spinal tissue death.



2.2.3 Existing Solutions

Mechanical collars and supporters in transportation but not much solutions in extraction.



2.2.4 Stakeholder Analysis

Patients : Evacuation of trauma patients will be done properly without causing any more distress. It will be efficient and comfortable for the patient.

Doctors : Because the patient receives proper pre-hospital care, the condition of the patients transported to the hospital will be less severe.

Hospital management: Pre-hospital care will be more efficient, reducing post-traumatic stress and complications.

2.2.5 Market Analysis

Since there are no such devices in the current market, it will be new and harder to analyze.

2.3 Problem : Analysing the sounds in stethoscope

Source : few medical students local and abroad (9/Nov/2022)

The stethoscope is an instrument that almost every doctor uses daily. Through practice and techniques, they are able to uniquely identify and determine various cases of abnormalities. If we could take the stethoscope sound, analyze it, and give a proper prediction to common breathing abnormalities, we would be able to drastically change the normal procedures in medical checkups. Having such an instrument at home could save many doctor visits, and even for doctors, it could give a second opinion.

2.3.1 Need statement3

- **Problem :** Differentiating Stethoscope sounds
- **Population :** almost all patients
- **Outcome :** At home detection of simple respiratory abnormalities

”The way to address differentiation of different stethoscope sound of most patients that facilitate patients to detect simple respiratory abnormalities ”

2.3.2 Disease state foudamentals

When it comes to stethoscope sound analysis, the following are some of the abnormalities that doctors usually come across.

- **Wheezing :**High-pitched sounds produced by narrowed airways.
- **Rhonchi :**low-pitched sound similar to snoring. This occurs when air is blocked or air flow becomes rough through the large airways.
- small clicking sound in the lungs called Rales

- Wheeze-like sound(called stidor) due to a blockage of airflow
- Absent or decreased sounds can indicates pneumonia,reduced airflow in lungs ,heart failures etc.

2.3.3 Existing Solutions

There are only a few alternatives other than the manual stethoscope, which doctors use every day. There is a handheld ultrasound scanner developed to capture the sounds. Masood Ahmad, M.D., a professor at The University of Texas Medical Branch, developed this device to listen to heart sounds but not analyze them. We couldn't find any stethoscope sound analyzers on the market right now.

2.3.4 Stakeholder Analysis

- **Patients :** Even for minor coughs, patients must physically visit a hospital to have their health checked. With a device that can give a prediction with some accuracy, we can facilitate these patients, saving their trips and time at hospitals.
- **Doctors :** Automation of manual decision-making that relies more on the experience the doctors have can help them validate their decisions and provide confidence when it comes to identifying the health issues of the patients.
- **Hospital management :** Less crowd in hospitals will be easy to handle and more efficient than today.

2.3.5 Market Analysis

Since there are no similar devices on the market and most doctors are used to the traditional method, it will be hard to predict the market for such an instrument.

3 Need Selection

We screened our three problems, assigned marks according to our analysis, and selected the best one.

	A	B	C	D	E	F	G	H	I	J
1	Need	Estimated	Patient	Providers	Feasibility					
2		Market	Impact	Impact	Index	Co-owners	Preference	Total	Rank	
3		Out of 5	Out of 3	Out of 5	Out of 5	1 - lowest		Out of 24		
4						I	II			
5										
6										
	Non Invasive Intracranial pressure measurement / Neurovascular monitoring in the head	4	3	4	3	3	2	19	1	
	Visualizing internal damage in a outstation trauma management	4	3	3	3	2	3	18	2	
	Analysing the sounds in stethoscope	3	2	1	5	1	1	13	3	

4 Conclusion

In conclusion, we identified problem 01 **Non Invasive Intracranial pressure measurement / Neurovascular monitoring in the head** ,as the most needed and viable need. We will be planning to implement a method to noninvasively measure ICP continuously.

References

- [I] Rajashekar d, liang jw. intracerebral hemorrhage. [updated 2022 feb 10]. in: Statpearls [internet]. treasure island (fl): Statpearls publishing; 2022 jan-. <https://www.ncbi.nlm.nih.gov/books/NBK553103/>.
- [II] Anjum a, yazid md, fauzi daud m, idris j, ng amh, selvi naicker a, ismail ohr, athi kumar rk, lokanathan y. spinal cord injury: Pathophysiology, multimolecular interactions, and underlying recovery mechanisms.pages int j mol sci. 2020 oct 13;21(20):7533. doi: 10.3390/ijms21207533. pmid: 33066029; pmcid: Pmc7589539.1.
- [III] Intracranial pressure monitoring devices market size, share trends analysis report by product (invasive, non-invasive), by application (traumatic brain injury, intracerebral hemorrhage, meningitis), by region, and segment forecasts, 2022 - 2030 <https://www.grandviewresearch.com/industry-analysis/intracranial-pressure-icp-monitoring-devices-market/methodology>.