The problem we are solving

The surgical power tools sector, especially drilling, involves precise, reliable, and efficient equipment to guarantee patient safety and optimum outcomes. Given the ever-evolving nature of surgical procedures and the increasing need for minimally invasive surgeries, there's ample room for innovation in this sector.

Doctors are actively looking for technological assistance that would lessen the probability of a mistake by guiding surgeries involving standard drilling procedures.

The 2 most common errors that are the easiest to make during a drilling procedure are keeping a precise angle and preventing excessive heat generation.

Studies were made on trained surgeons ability to keep predefined angles:

“**This study shows that the surgeon’s ability to drill accurately (within ±4° error) is limited, particularly at angles ≤60°**. In situations where drill angle is critical, use of computer-assisted navigation or custom-made drill guides may be preferable.”*(source)*

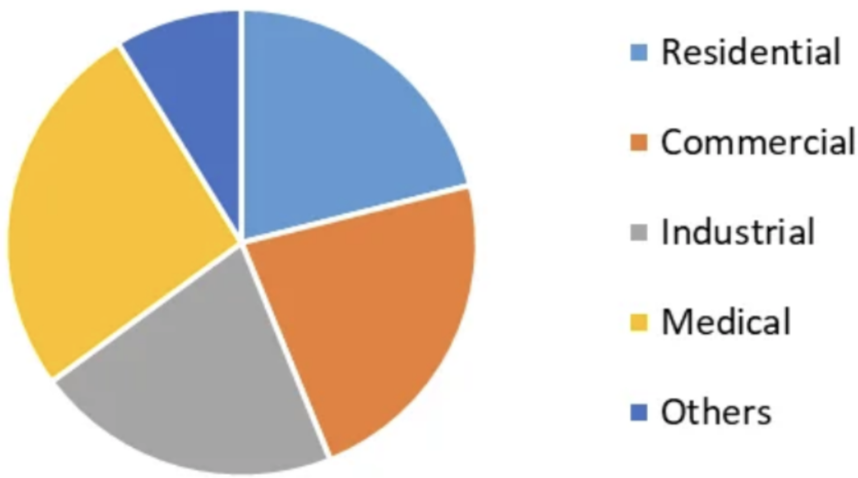
Minimizing the duration and magnitude of the maximum temperature elevation during the machining of bone during drilling and burring is of paramount importance and concern for the surgeon. Also, at these speeds frictional heat within the tools themselves can produce temperatures in excess of 60˚C which can produce burns in the mouth of the patient or to tissue adjacent to the surgical site, as well to others handling the instrument. (source)

“Even in the face of growing evidence as to the negative effects of heat induction during drilling, **simple and effective methods for monitoring and cooling in real-time are not in widespread usage today... advances in prevention of thermal necrosis during bone drilling surgery are expected to reduce the risk of patient injury and costs for the health service.**” (source)

Doctors and hospitals are actively looking for and experimenting with ways to lessen the likelihood of these 2 factors causing damage to the patient.

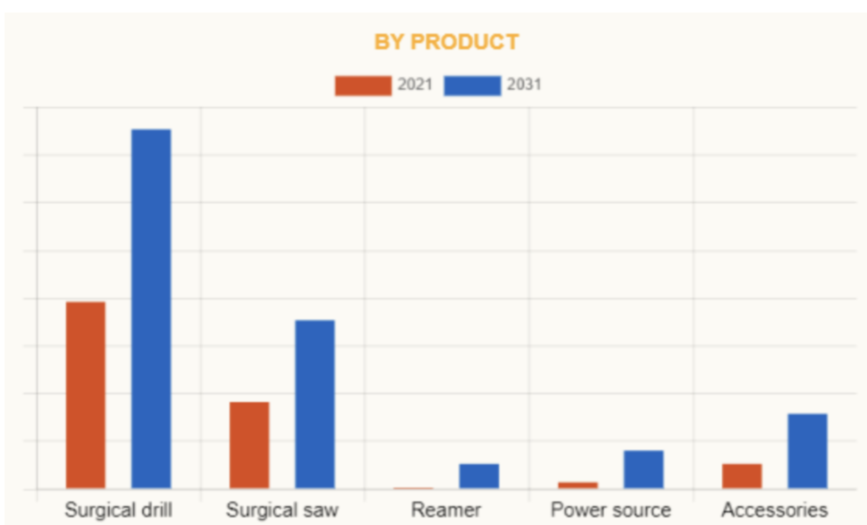
Market

The electric drill market is a huge one. On the following chart, you can see how the industry distribution of the electric drill market looked last year. It is clear that the medical sector is a huge chunk of the industry (it is the biggest one).



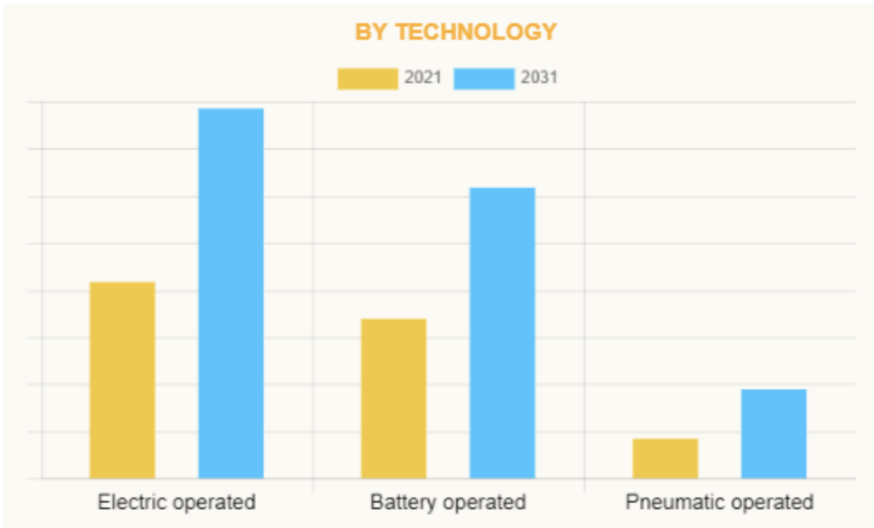
Drill Drivers Market, by Application Type 2022 (%) [(source)]

Surgical power tools (electric and pneumatic drills, saws and accessories) had a total market size of $2,275.2 million back in 2021 and is projected to nearly double by 2031.[(source)]



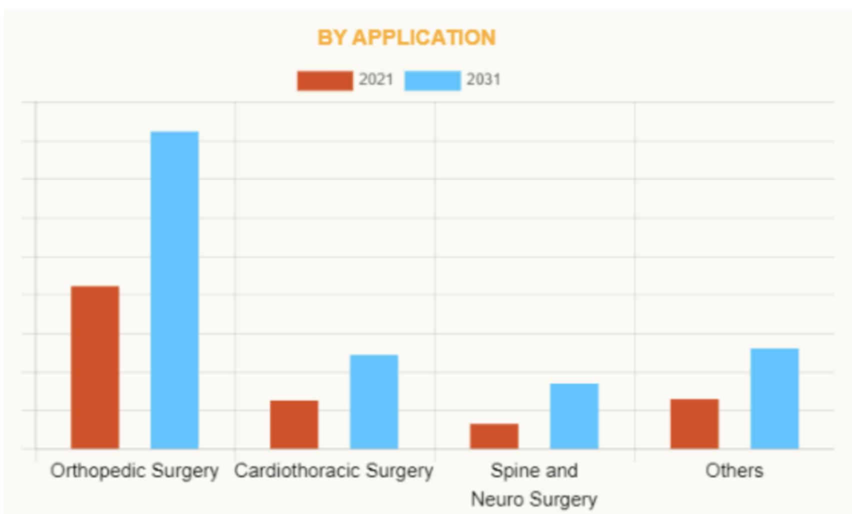
Surgical Power Tools Market - Distribution by product category [(source)]

The above diagram clearly shows that drills are by far the biggest segment in surgical power tools (~60%).



Surgical Power Tools Market - Distribution by technology [(source)]

Due to the convenience factor and the versatility that cordless, battery powered drills bring to the table, in sold numbers they are right beside their wired counterparts (~40% of market).



Surgical Power Tools Market - Distribution by application [(source)]

Based on application, most of the market (~70% of market) falls into orthopedic surgery, spine and neurosurgery and plastic surgery (as you will see, these are exactly our target markets).

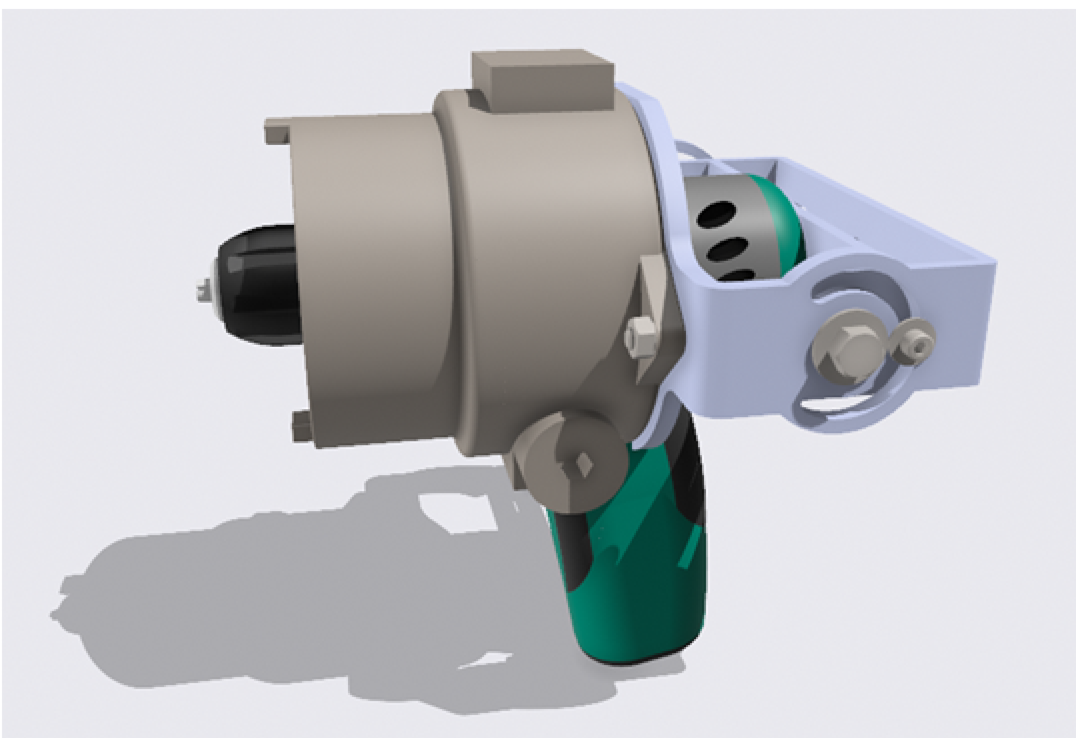
From the above data shown, it can be calculated that the market for surgical battery powered drills was worth approximately **$382 Million ($2,275M * 60% * 40% * 70%)** in 2021 and will worth approximately **$635 Million ($3,783M * 60% * 40% * 70%) by 2031.**

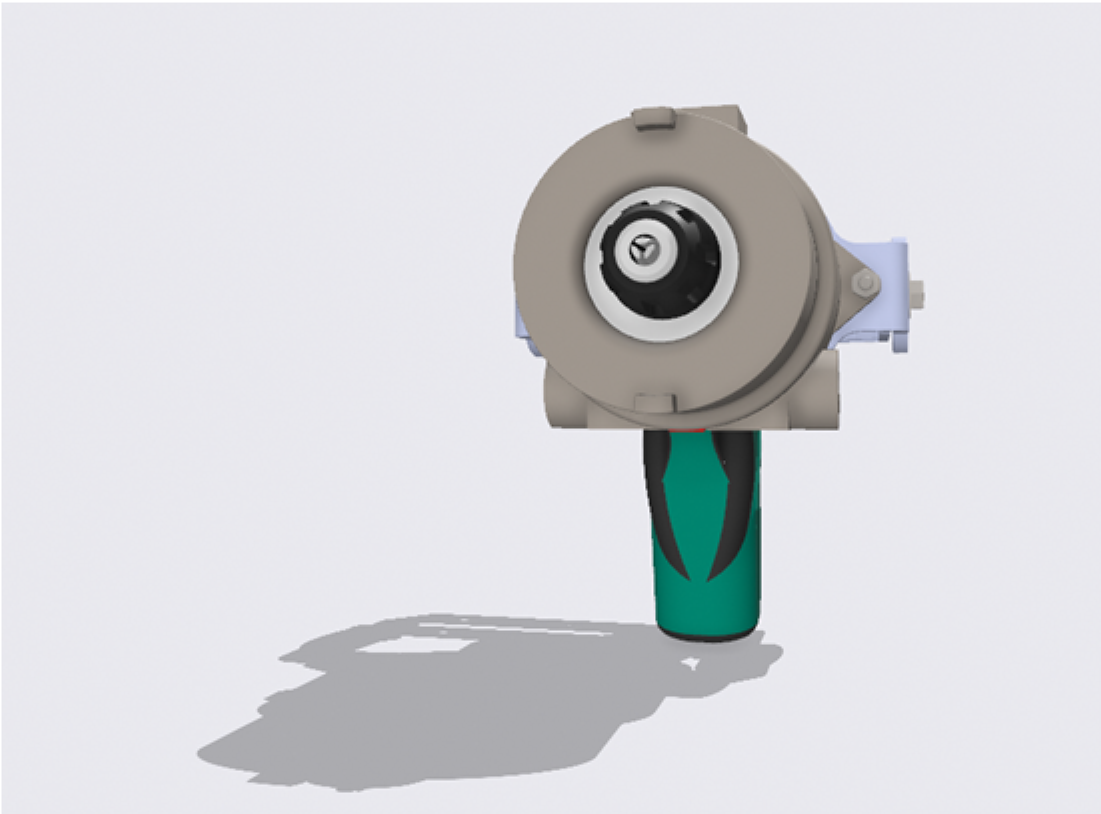
As the problem that we are solving is universal and every single medical practice would greatly benefit from such a tool, our TAM (total addressable market) is the whole mentioned market.

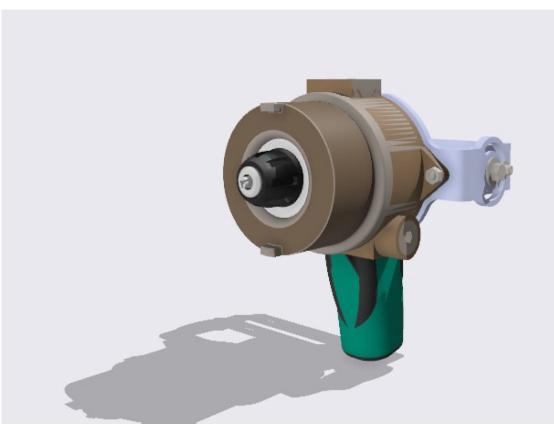
Our product

We propose a solution for surgical drilling that would lessen the probability of heat damage and would prevent drilling in a non accurate angle.

The device could be installed on any drill, including commercial and surgical grade drills. Indeed, commercial drills are used TODAY in surgical operations using for example the ArbutusMedical's HEX drill KIT [(source)], that is a medically licensed product that wraps around the drill and keeps it fully sterile. As we think that the vast majority of clinics would use proper medical grade equipment though, our product also universally fits those drills.







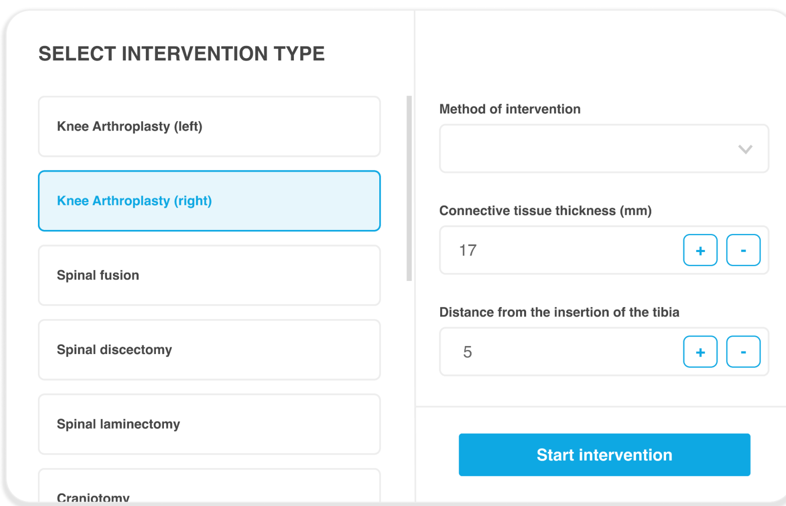
The features and use of our product

1. **Angle Measurement:** Measures the angle of drilling to ensure that it's aligned with the pre-surgical plan.
2. **Depth Sensing:** The device measures how deep the drill has penetrated, preventing accidental penetration too deep and potentially harming crucial structures.

3. **Automatic Pressure:** The drill applies the exact amount of pressure needed using a rail mechanism.
4. **Temperature Monitoring**: Overheating can lead to tissue damage. The system will alert the surgeon if the drill bit or the internals of the drill becomes too hot. In this case, the operation can be stopped, then resumed when the temperatures balance out.
5. **Visual Feedback:** The surgeon sees on an outside screen (tablet) the exact position he/she should hold the device and also sees how deep the drill went.
6. **Data Logging:** For educational and legal purposes, every drilling action is logged and can be reviewed post-operation.

During Surgery

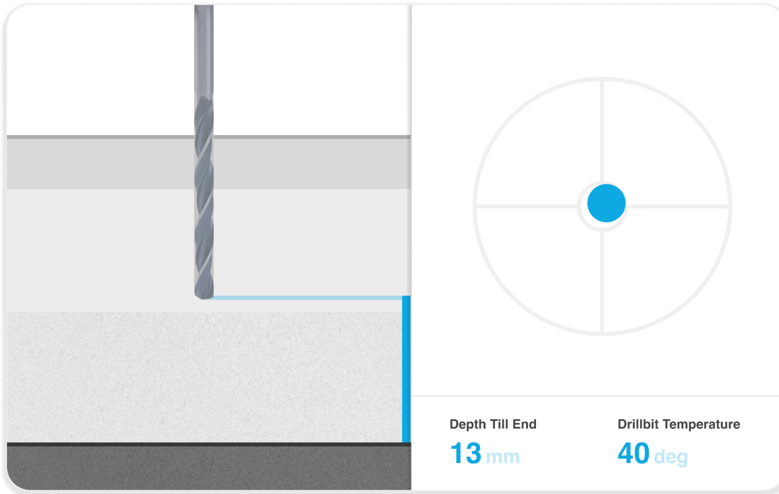
1. Before the operation, the surgeon selects what operation he/she will be doing and provides the exact data of the surgery:



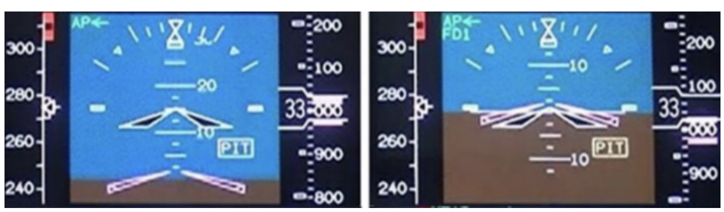
2. before the operation, the system gives the exact position of the insertion.

3. The surgeon places the drill at the insertion point, positions the drill in the exact orientation and presses a button that initializes that point as baseline.

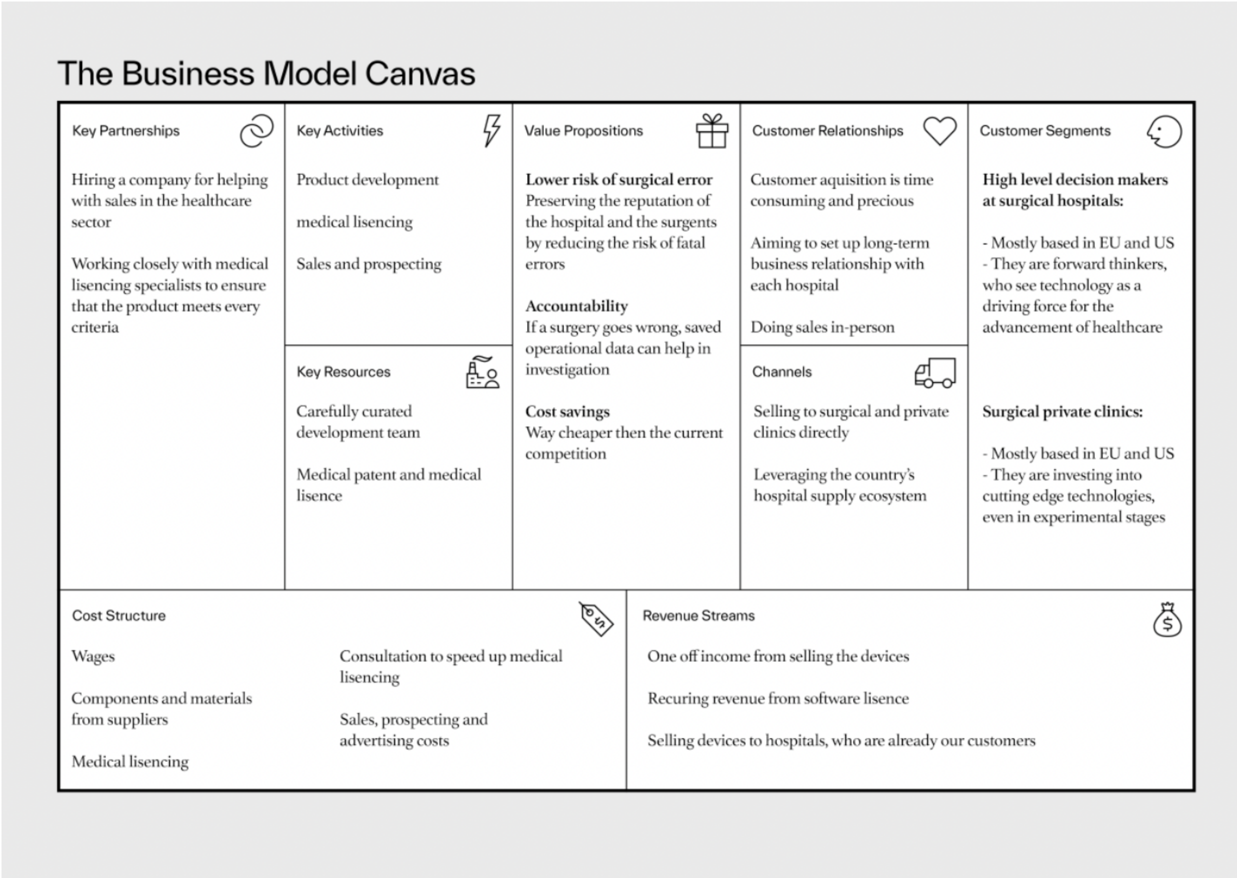
4. On the screen, a crosshair comes up, the center of which is the exact right orientation. If the surgeon rotates the drill, the indicator circle leaves the center and turns red, also there is a beeping sound that pitches up, as it is getting farther.



5. Also, if during the surgery, the trajectory of the drilling is not straight, the screen will show when and by how much the drill should be turned.
6. Keeping a constant RPM during the operation is important, thus it is also handled by the device. To ensure this consistency, a servo presses the button the exact amount, while optically measuring the RPM of the drill bit.
7. When the exact depth is reached, the system notifies and the drill is throttled back.



The simplicity, precision and professionalism of aircraft user interfaces have inspired our systems representation method. Avionics and medical technology similarly demand strict technical systems and standards.



Technical details

Suggested transformations and communication for measuring orientation of the electric screwdriver when using the precision angle detection.

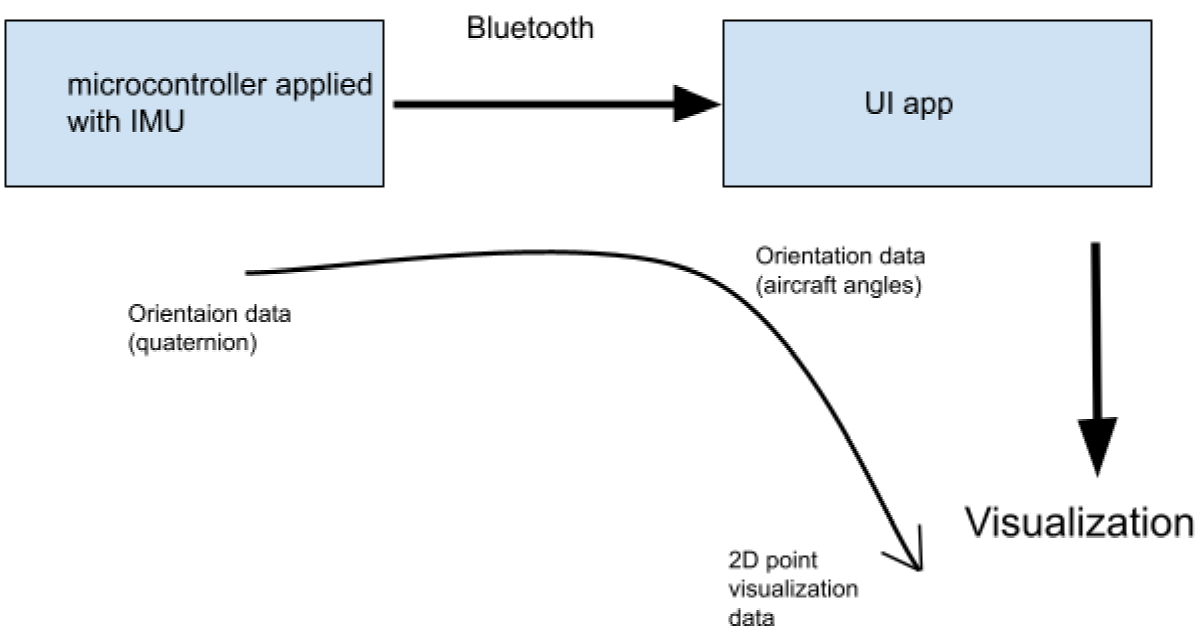
Adafruit BNO08x is capable of sending a so-called rotation vector, referenced to the magnetic north and gravity of the earth. The rotation vector's form is a quaternion that provides an orientation. We would like to measure the orientation of the electric screwdriver compared to another pose that is set before measurement and send this information to another device using Bluetooth.

With this operation, we would like to help the users of the electric screwdriver in such a way that it can help them hold the tool in the correct direction. There is a dedicated button on the screwdriver that can set the base orientation and then measure how similar the current orientation is to the base orientation.

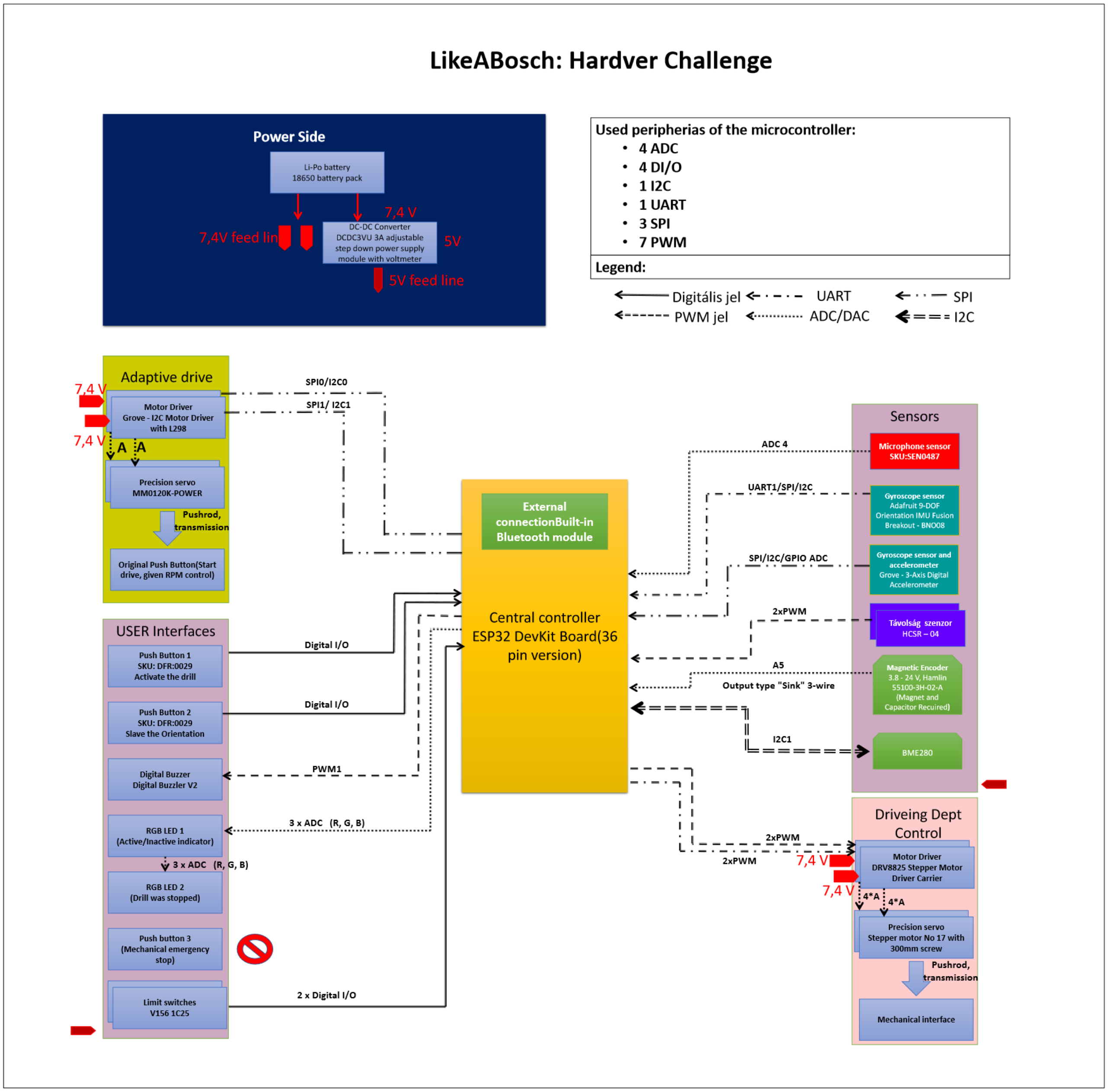
Let's say we have a quaternion q-current = $\{w_c,x_c,y_c,z_c\}$ that represents an orientation or rotation in the reference frame, and we want to express it in another reference frame defined by another quaternion q-base = $\{w_b,x_b,y_b,z_b\}$. The way we calculate the quaternion relative to the base quaternion is:

- The first is calculating the conjugate of q-base. The conjugate of a quaternion q is now denoted as q' and is obtained by negating the vector part of q while keeping the scalar part unchanged. In mathematical notation, if q = (q0, q1, q2, q3), then q' = (q0, -q1, -q2, -q3).
- Perform quaternion multiplication between q-current and q-base' to obtain the transformed quaternion q-transformed. The formula for quaternion multiplication is as follows: q-transformed = q-base * q-current * q-base' where "*" means the dot product of two quaternions.

The q-base quaternion can be collected by pressing a button on the screwdriver; it saves the current rotation vector log of the Adafruit BNO08x imu sensor. After activating this button, the rotation vector log will be the q-current quaternion in the next time steps, so we have everything to calculate the q-transformation for every timestep. After the calculation of the q-transform, we would send it out with the Bluetooth device to the UI. The UI app would receive the orientations and then form visualizations. The quaternion orientation first would be transformed to aircraft principal axes (pitch roll yaw), and then from these angles would be calculated a 2D view where the direction of the drill could be tracked.



System diagram of the gadget tool:


LikeABosch: Hardver Challenge
Power Side
Li-Po battery
18650 battery pack
7,4 V
7,4V feed lin
DC-DC Converter
DCDC3VU 3A adjustable
step down power supply
module with voltmeter
5V
5V feed line
Used peripherias of the microcontroller:
• 4 ADC
• 4 DI/O
• 1 I2C
• 1 UART
• 3 SPI
• 7 PWM
Legend:
Digitális jel
UART
SPI
PWM jel
ADC/DAC
I2C
Adaptive drive
7,4 V
7,4 V
Motor Driver
Grove - I2C Motor Driver
with L298
A
A
Precision servo
MM0120K-POWER
Pushrod,
transmission
Original Push Button(Start
drive, given RPM control)
SPI0/I2C0
SPI1/ I2C1
External
connectionBuilt-in
Bluetooth module
Central controller
ESP32 DevKit Board(36
pin version)
USER Interfaces
Push Button 1
SKU: DFR:0029
Activate the drill
Digital I/O
Push Button 2
SKU: DFR:0029
Slave the Orientation
Digital I/O
Digital Buzzer
Digital Buzzler V2
PWM1
RGB LED 1
(Active/Inactive indicator)
3 x ADC (R, G, B)
3 x ADC (R, G, B)
RGB LED 2
(Drill was stopped)
Push button 3
(Mechanical emergency
stop)
Limit switches
V156 1C25
2 x Digital I/O
Sensors
Microphone sensor
SKU:SEN0487
ADC 4
Gyroscope sensor
Adafruit 9-DOF
Orientation IMU Fusion
Breakout - BNO08
UART1/SPI/I2C
Gyroscope sensor and
accelerometer
Grove - 3-Axis Digital
Accelerometer
SPI/I2C/GPIO ADC
2xPWM
Távolság szenzor
HCSR – 04
A5
Output type "Sink" 3-wire
Magnetic Encoder
3.8 - 24 V, Hamlin
55100-3H-02-A
(Magnet and
Capacitor Recuired)
I2C1
BME280
Driveing Dept
Control
2xPWM
2xPWM
7,4 V
7,4 V
Motor Driver
DRV8825 Stepper Motor
Driver Carrier
4*A
4*A
Precision servo
Stepper motor No 17 with
300mm screw
Pushrod,
transmission
Mechanical interface

BOM

Material costs

Nr.	Component Type	Component name	Cost With Tax (Eur)	Number of items	Total price	Comp Desc
1	Precision servo	MM0120K-POWER	11,71	2	23,42	
2	Motor Driver	Grove - I2C Motor Driver with L298	18,88	2	37,76	
3	BMS safety circuit	2S 20A	2,69	1	2,69	
4	Lipo cell		13,88	1	13,88	
5	Digital Buzzer	Digital Buzzler V2		2	0	
6	LED	WS2812B	15,36	2	30,72	
7	IMU	BNO085	23,57	1	23,57	
8	Magnetic encoder	3.8 - 24 V, Hamlin 55100-3H-02-A	15,39	1	15,39	
9	HAL SENSOR	3.8 - 24 V, Hamlin 55100-3H-02-A	10,23	1	10,23	
10	Limit switch	V-165-1C5OMRON OCB	2,06	2	4,12	
11	Precision servo	Stepper motor No 17 with 300mm screw	19,92	2	39,84	

12	Motor Driver	DRV8825	2,95	2	5,9
13	Button	SKU: DFR:0029		2	0
14	Accelometer	Grove - 3-Axis Digital Accelerometer	10,3	1	10,3
15	Microphone sensor	SKU:SEN0487		1	0
16	Microcontroller	esp32	15,1	1	15,1
17	Distance sensor	HC-SR04-4P	1,76	1	1,76
18	Temperature sensor	BME280-M	3,7	1	3,7

Business Case

Based on the BOM (~€270), the initial investment (~€400,000) and the other parties of the market (basic surgery grade drill range from €500-€1500 and our main competitor costs more than €5000), we would price our product between €1000 - €2000.

To generate recurring revenue, we would:

1) provide the software on a subscription basis (yearly or multi-year long contracts, €5000 / year / hospital, not per device)
2) provide and service the wearing parts.

On average, given the amount of surgical drills a hospital has, we could sell at least 5 devices / hospital.

In a 5 year term, that would generate us between €30,000 (€5,000 + €25,000) and €35,000 (€10000 + €25000) per hospital.

This way, the €400,000 investment would be returned with around 13 hospitals in 5 years.

Competitors

We did not find any direct competitors that offer these kinds of functionalities as a universal drill attachment. Our closest competitor is a product named SMARTdrill 6.0 by OrthoAxis, with the probable (their price is not even listed) cost well above €5000.. Our solution would cost around €1000-€2000 (€400 to manufacture) and the medical practice could use the drills they already own. We position our product as an upgrade to their already trusted devices.
For the price of one of those drills, we can provide the hospital with at least 3 of them which is a huge gap in price.

Our team

We are a team of 5 and everyone is representing their own field.

Armand Vörös - Marketing and Software Engineering
Csaba Dénes - Embedded System Development
Felicián Nagy - Space Engineering
Viktor Hámoros - Electrical Engineering
Zoltán Faludi - Software Engineering

Making it real

As we are talking about a medical device that would be used during surgery, bringing it to market is highly regulated.
As of 26 May 2021, the EU MDR (European Medical Device Regulation) came into force.[source] Each medical device - depending on the amount of invasiveness - is classified into 4 groups (class I, class IIA, class IIB, class III).[source]
As the device aids in decision making and controls multiple functions of the drill, it automatically falls into class III. A medical license on this level would cost around €300,000. This and the development cost of the device would be covered by an investment firm.
Here are a few selected medtech VC-s, that we would reach out to:

415 CAPITAL | ATLANTIC BRIDGE | DEERFIELD Advancing Healthcare®

1. *Drill Drivers Market, 2022*
   https://www.maximizemarketresearch.com/market-report/drill-drivers-market/146884
2. *Surgical Power Tools Market*
   https://www.alliedmarketresearch.com/surgical-power-tools-market
3. *https://tailstrike.com/database/08-january-2016-west-air-sweden-294/*
4. *https://www.banggood.com/MoesHouse-Tuya-Fingerbot-Button-Pusher-bluetooth-finger-robot-App-Remote-Control-Automatic-Switch-Voice-Control-with-Alexa-Google-Home-p-1995029.html?utm_source=googleshopping&utm_medium=cpc_organic&gmcCountry=HU&utm_content=minha&utm_campaign=aceng-pmax-hu-en-pc&currency=HUF&cur_warehouse=CN&createTmp=1&utm_source=googleshopping&utm_medium=cpc_eu&utm_content=dcr&utm_campaign=aceng-pmax-dcrcountry-disca-qufen-9ysale-230829&ad_id=&gclid=CjwKCAjw69moBhBgEiwAUFCx2LPVJpQIovn_dZjzV36DO7ITnutlREHK58P9Jn67oX6WAFR4eAAe-RoCUokQAvD_BwE-*