



WombOx: Minimally-Invasive Monitoring of Fetal Blood Oxygen

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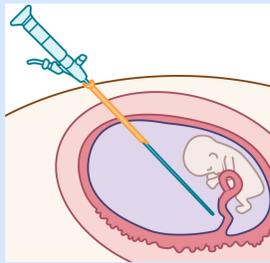
Risk of hypoxia during fetal surgery

25,000 babies/year born with operable congenital defects^{1,2}

- Over \$2.6 billion/year spent on treatment of defects *post-partum*

During fetal surgery, instruments pass into the womb through a trocar

- Intervention can correct congenital defects *in-utero*, such as spina bifida, improving clinical outcomes and reducing costs *post-partum*



Endoscope accesses womb through trocar (blue) to visualize fetal defects.

Surgical procedure carries risk of inducing fetal hypoxia

- Sustained low blood oxygen can cause organ damage or death

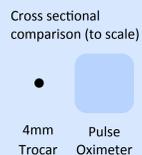
SpO₂ monitoring improves surgical outcomes

Pulse oximetry is a global standard of care

- Alerts of drops in blood oxygen level (SpO₂) and changes in heart rate (BPM)
- Reduces anesthesia related mortality by 20x



Adult finger clip pulse oximeter.



No oxygen monitors exist for use during fetal surgery

- Current pulse oximeters are **50x** the size needed to pass through a standard 4mm trocar

MONITOR → ALERT → INTERVENE

Project objective: to design a safe and effective device for minimally-invasive monitoring of SpO₂ during fetal surgery

WombOx is the solution

Pulse oximeter designed for fetal surgery

- Low profile** device able to pass through standard trocar and attach to fetus

Provides continuous monitoring of fetal SpO₂ and BPM

- Outputs vital signals during surgery in **real-time**

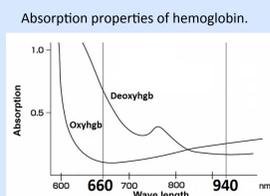
Alerts surgeons of fetal hypoxic events

- Prompts surgeons to administer drugs to restore SpO₂

Principle of pulse oximetry technology

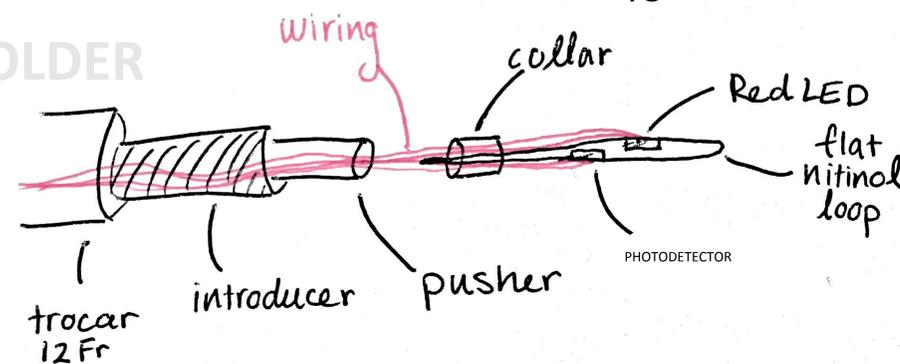
Oxygenated and deoxygenated blood have unique absorption of red and infrared light

- Difference in transmitted light indirectly measures SpO₂
- Peaks/time calculates BPM

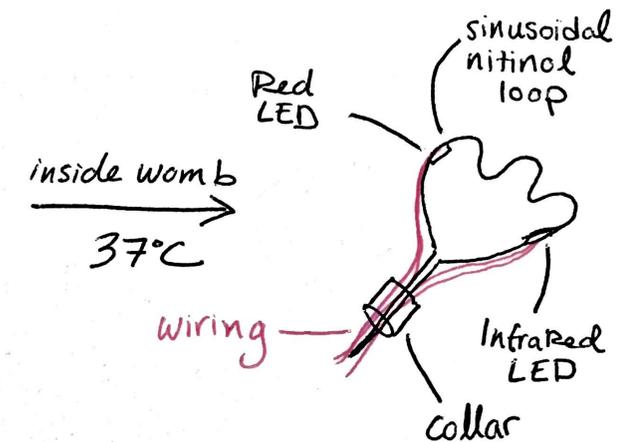


Inside WombOx The Continuous Fetal Blood Oxygen Monitor

PLACEHOLDER IMAGES

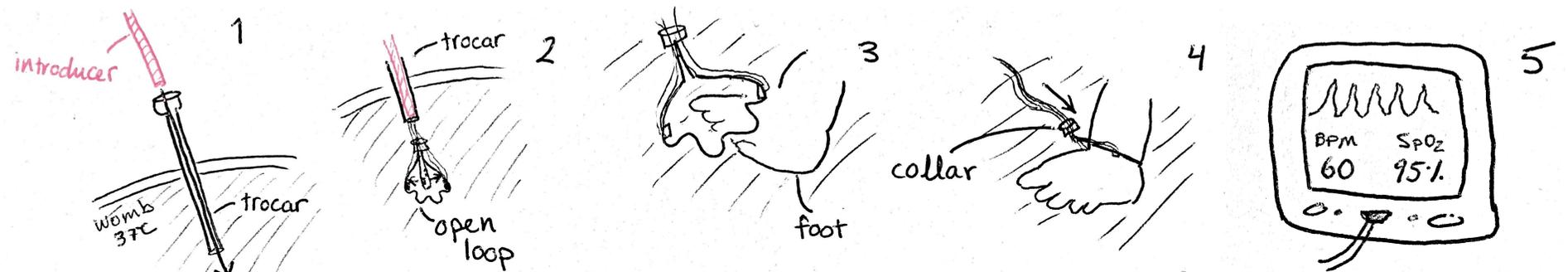


Expanded view of WombOx packaged flat in "closed" position



WombOx in "open" position upon contact with womb

How To Use WombOx During Fetal Surgery



Place loaded introducer in trocar entry and push until it through the length of the shaft.

Upon contact with womb, temperature nitinol loop will open. Remove introducer.

Guide WombOx to fetal extremity and loop device around it.

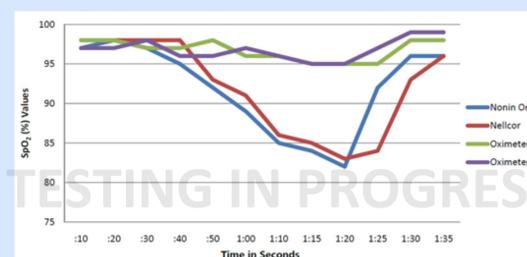
Using the pusher, push the collar towards the skin until WombOx has made firm contact with fetal skin.

Plug DB9 connector into surgical monitor. When procedure is complete, loosen collar, unloop, and remove WombOx through the trocar.

WombOx works: testing results show device meets design criteria

- Accuracy:** accurately measures SpO₂ and BPM
 - Calibrated with Fluke SPOT Light using standard Nellcor R-curves
 - Durable attachment ensures continuous monitoring throughout surgery

WombOx accurately tracks hypoxic events.



- Compatibility:** used alongside endoscopic instruments
 - Can pass through surgical trocars ≥4mm
 - Once attached, connects to monitor through DB9 connector and 0.01mm wires

- Integration:** easily integrates into surgical workflow
 - Usability study: TBD% found the device easy to use
 - Average total insertion, fixing, and removal time on bench-top model is TBD (n=15)

Task	Time To Complete (min)	Ease of Use Rating (1-5)
Deploy	TBD	TBD
Attach	TBD	TBD
Retrieve	TBD	TBD

- Safety:** imposes no additional risk to fetus or mother
 - Does not require a larger trocar or significantly increase procedure time
 - Does not overheat
 - Multiple safety features including water-proofing and nitinol sinusoid to prevent over-tightening
- Cost:** reasonable cost for disposable device
 - Price including labor, burden, materials is <\$300

New standard of care in fetal surgery

- Adapts traditional pulse oximetry technology for use during fetal surgery
- Alerts surgeons of hypoxic events and allows for immediate action through continuous monitoring of SpO₂
- Excellent usability testing results suggest low barriers to adoption

Project impact: ~80% decrease of complications due to anesthesia could push WombOx to become the **new standard of care**

The future of WombOx

- Further development
- Optimization of introducer, pusher, and collar system
 - Full integration with operating room monitoring systems
 - Miniaturization and design for manufacturing
- Regulatory pathway
- Clinical testing to obtain FDA approval-Class II Medical device

References:1. <http://ems.pennstate.edu/images/Product/medium/154.jpg> http://www.setrust.hscni.net/images/Smoke_free_wombs.jpg http://stormanesthesia.com/images/diseases/pulse-oximeter/album/Pulse-oximeter-waveforms_w.jpg http://www.axiasurgical.com/Axia_Surgical_Patient_Monitors.html

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Feedback and questions welcome! Contact us at: Team WombOx teamwombox@gmail.com

