Milestone 1: Functioning platform and positioning system

Deliverables: Development of Auto Alignment system capable to position imaging mechano-optics accurately in majority of normal patients within 10 seconds per eye on

Duration: 1- 10

Detailed tasks:

1. Sensors collection and testing – open layout – 2 months.
   1. Control units programing – HW standard of the shelf products\controllers.
   2. Defining final sensors set
   3. Feature detection (face, nose, eyes, iris, etc) algorithms development – 2 months – based on capturing devices – offline testing.
2. Open layout positioning system HW & SW – 7 – months.
   1. HW controller\s development – 3 months
   2. 2D and 3D camera capturing SW integration and analysis – 2 months.
   3. Sensors integration within system - (ultrasound, IR, etc.) – 3 months.
   4. Mechanical system assembly and functionality analysis – 2 months.
   5. Positioning algorithms – 7 months (parallel to all tasks)
   6. Managing application SW – 6 months.
   7. Packaging design, modification, prototype – 3 month.
3. Packaging – 1 month
   1. Final production stage.
   2. Positioning SW – final version SW release.
   3. QA.

Milestone 2: Functioning system incl. safety mechanisms

Deliverables: Development of safety mechanism to cope with various cases of non-conformance and known cases of expected human behaviors and safety events.

Duration: 4 months

Detailed tasks:

1. Safety sensors integration – 1 month
   1. Safety sensors collection and analysis - Main part of this mission done at milestone 1.2
   2. Safety sensors SW implementation – 1 month – HW controller design took place at previous milestone.
2. Safety sensors open layout testing – 1 month.
   1. Algorithm and priority definition and programming.
   2. Different Scenario testing.
3. System integration HW and SW – 3 months.
   1. Main Autonomous SW integration – 3 months.
   2. Main HW integration.
4. General system QC QA – continuous.

Milestone 3: Complete functioning ASOT

Deliverables: System to pass a 3rd party test and safety report

Duration: 2 months

Detailed tasks:

1. Final assembly – 2 months
   1. Preparing system to CE and FCC – regulation itself takes more time, here it is preparation.
   2. Illumination regulation certificating – initialize process
   3. Communication regulation certificating – initialize process
   4. Finalizing production file.
   5. SW & HW integration internal tests
   6. Complete system external test.

Milestone 4: System technical validation

Deliverables: Systems ready for clinical trial

Duration: 5 months

Detailed tasks:

1. CE and FCC certificate
2. Various testing at various environment.
3. Positioning algorithms improvement.
4. Safety rejection fixing.
5. SW improvement – main application.
6. Final release SW & HW version
7. Production testing.

Milestone 5: Clinical validation

Deliverables: Three center clinical trial under IRB approval to validate the device and AI models compared to diagnosis provided by a clinician

Detailed tasks:

1. TBD by Mor and Noam and Anand