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SABS Ventilator Test Laboratory**

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CSIR ICC, Pretoria, Gauteng**



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# Background



- CSIR developed a CPAP and BIPAP ventilator system (2019-2021)
- The need arose (from DTIC) to qualify/accredit these devices.
- SABS was identified as the appropriate institution to perform accreditation
- CSIR was identified as the party to provide the test facility.
- MOU established (2021).
  - Lab would focus on the new SABS standard for ventilators.
  - SABS standard would focus on the regulatory needs in South Africa
  - CSIR would focus on the establishment of the physical laboratory



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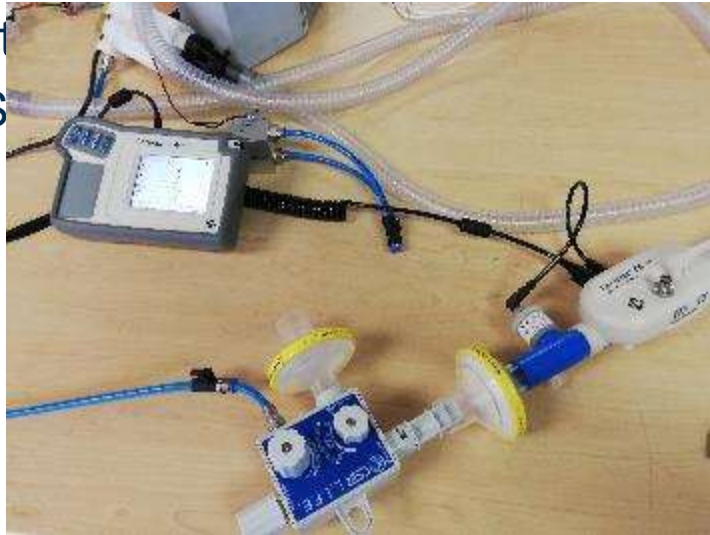


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# Requirements



- Under the current project the lab will test ventilators under the following categories as defined by ISO 80601:
  - Basic Safety
  - Essential performance
  - Functionality
- Certain aspects not covered by ISO 80601:
  - IP rating, EMC, S

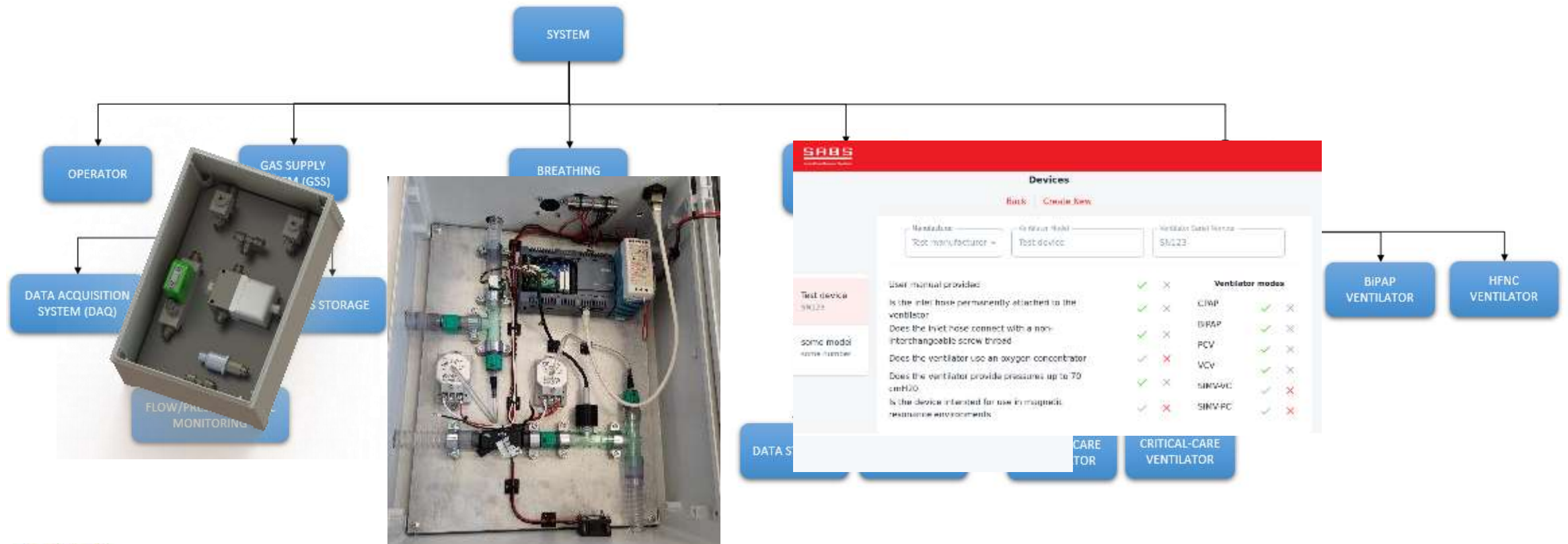


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# System Block Diagram



# Progress



- Project started February of 2022
- Using V-model systems engineering process.
- Requirements and Design phase completed
- Busy with sub system development phase.
- Subsystem Testing, System Integration, System Testing and deployment phases to follow
- Lab space at SABS identified
- Gas Supply space identified



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# Challenges



- Standards
  - Difficult to follow and synchronize
- Cost
  - COTS BSS unaffordable (R600K vs R115K )
  - Addition of Oxygen generator
  - Fully compliant to standard
- Component Availability
  - IC shortage
- Procurement
  - Vetting/blacklisting of suppliers



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# Conclusion



- Test Lab is a use case /blueprint building capabilities to support a capable state and responding to a country need
- Skill building / Upskilling.
- Knowledge generation (CPAP, BIPAP, Testing environments)
- Knowledge transfer to other entities/countries.
- Localisation and Local Support



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**THANK YOU**