A bilevel positive airway pressure non-invasive ventilator

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science & innovation
Department:
Science and Innovation
REPUBLIC OF SOUTH AFRICA

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Acknowledgements

- The National Ventilator Program (NVP), through this funding the basic ventilator technologies and understanding were developed within the CSIR.

- More importantly; The Development Bank of Southern Africa (DBSA), provided funding for the B-LIFE prototype development and initial certification.

DBSA
DEVELOPMENT BANK OF SOUTHERN AFRICA
Building Africa's Prosperity

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Centre for Robotics and Future Production
Who we are

The Smart Factory	Product Development	Customised Robotics	The Learning Factory
Plant/ Process **assessment and benchmarking** to local and international standards Supply chain digital integration Plant **digitalisation and dashboard monitoring** Plant/Process optimisation (***Improved Cost of Production***)	**Product development assessment and benchmarking** Products, parts and tools **localisation** **New products/ parts/tools** development **Product digitalization** (enhanced value addition) Access to specialised **tools, equipment and infrastructure**	Automated **inspection and QC** Automated **materials handling solutions** Customised **robotic equipment development** Machine condition **monitoring** Situational awareness and environmental monitoring Assistive **robotics and augmentation** solutions	**Technical training** in 4IR related technologies Establishment of **Industry specific Learning Factories** **Customisation of training** curriculums to industry specifc requirements Technology development Facilitation of **networking with industry peers**

Centre for Robotics and Future Production
Who we are

- Automated inspection and QC
- Automated materials handling solutions (fixed and mobile)
- Customised robotic equipment development
- Machine monitoring for predictive maintenance
- Human Centred Automation and Assistive robotics
- Augmentation solutions (AR and VR)
- Development of customised training programmes

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Multidisciplinary collaboration: CPAP Ventilator

Full Digital Lifecycle Management:

- Product Development – Industrialisation – Production – Support
- Integrated change control and supply chain management
- Rapid development (Concept to Production < 6 months)

18000 Units manufactured

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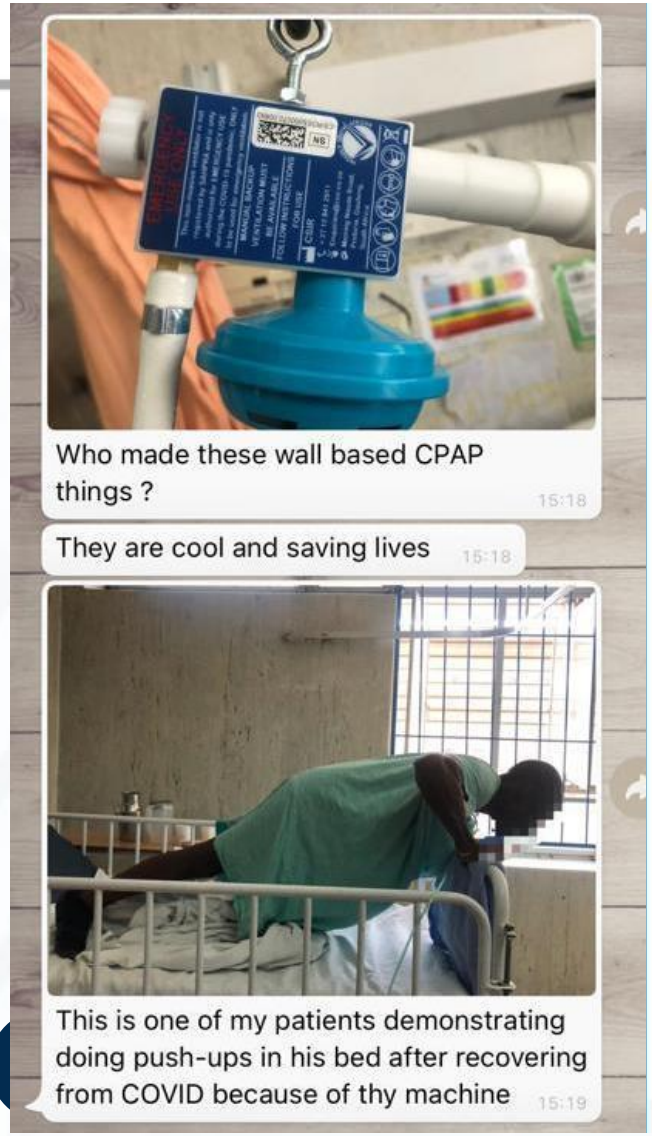
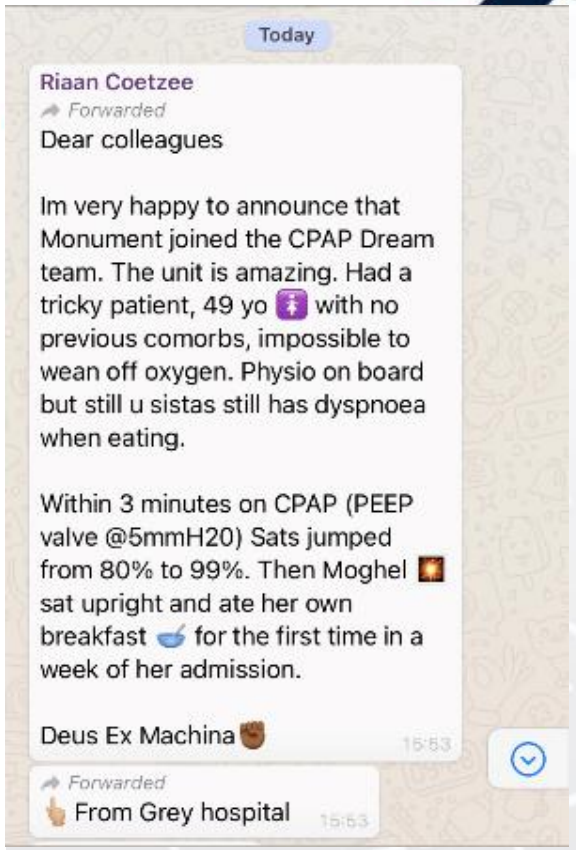
CPAP Impact



Gift of the Givers
6 January at 06:27 ·

The lifesaving CPAP machines have been designed by the South African National Ventilator Group and SKA South Africa, manufactured by CSIR, approved by Sahpra , and funded by the Solidarity Fund. A special thank you 🙏 to all the groups for inventing a South African lifesaving device that is mechanical, not electronic(doesn't need electricity), and can be highly efficient by using a lower oxygen supply at a time when oxygen supply in the country is challenged.

#MakeADifference #ForTheGreaterGood #Healthcare #Health #COVID19 #SecondWave #Level3 #SaveSouthAfrica #StayHome #SaveLives #StaySafeSouthAfrica #SouthAfrica



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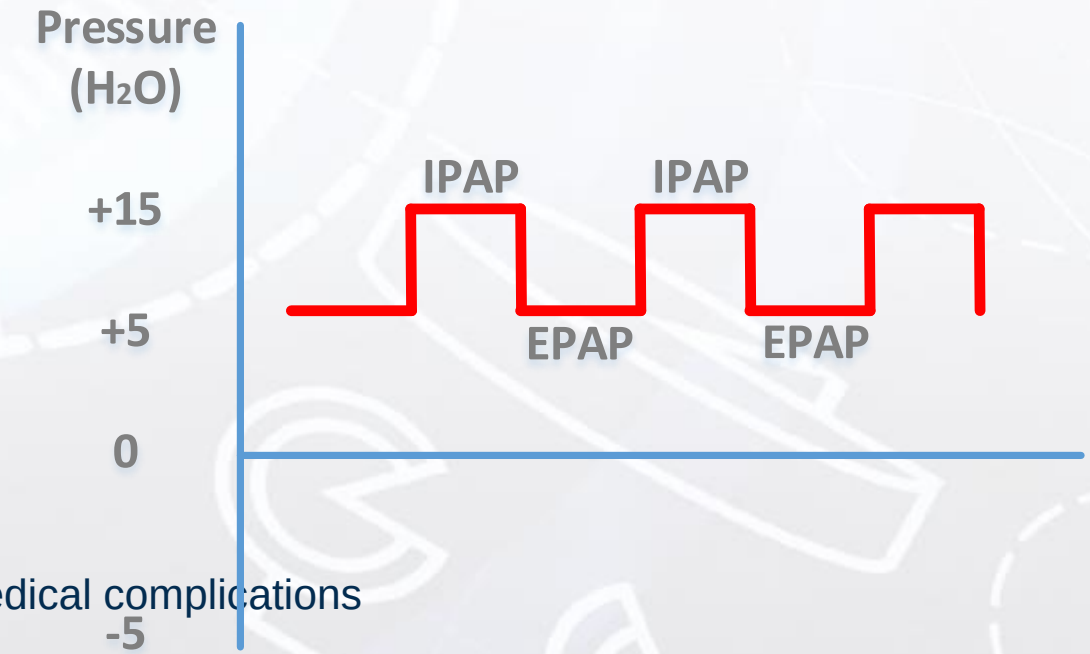
Ventilators – Background (CPAP, BPAP)

- Continuous Positive Airway Pressure (CPAP): Keep pressure on Lungs
- Bilevel Positive Airway Pressure (BPAP): Assist patients both during Inspiration and Expiration phases of breathing



- After that: Intubation with MANY of medical complications

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B-LIFE Strategic Intent

- The collaborative development of the B-LIFE ventilator was triggered by the healthcare sector **vulnerabilities** of the country which were exposed by the global COVID-19 pandemic.
- A longer-term strategic view was committed to, with the objective of creating **impact** at the Governmental, industry and community levels through the **development of capability and capacity in the production of medical devices** that are easily accessible by the broader population in South Africa and Africa.
- The continuation of the B-LIFE **localisation** within industry is a strategic priority for the country and the initial investment must be taken forward as it contributes to the capacity of the country towards strategic independence in the health sector, social empowerment through the proliferation of skills and expertise and economic development through **industrialisation** and the creation of jobs.

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B-LIFE Advantages

- Better use of oxygen resource through pressure and flow control
- Alarming functions; pressure loss, oxygen Loss
- Easier multiple parameter setting on one interface
- Much better patient monitoring
- Allows for remote monitoring (Ideal in ICU settings and for telemedicine)

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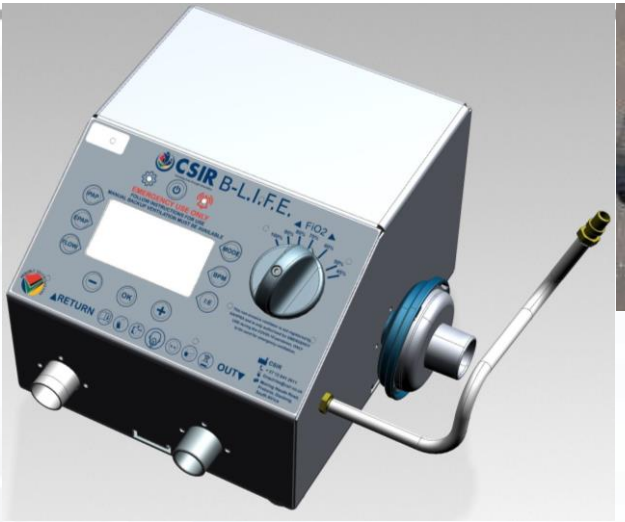
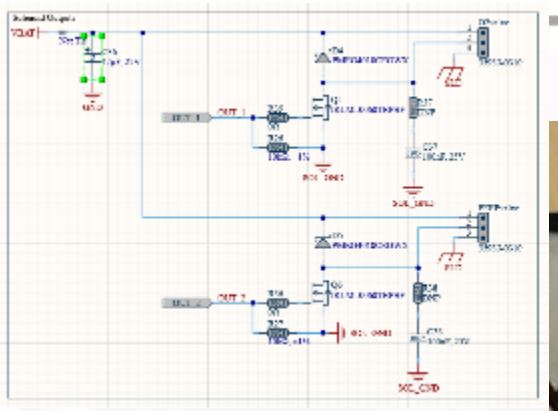
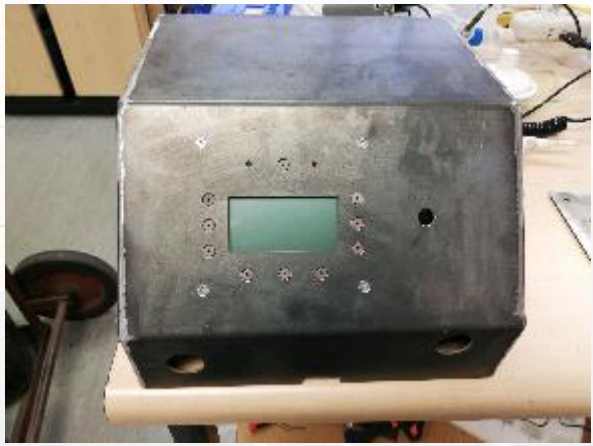
What is B-LIFE Engineering







- Mechanical Design - Mixer core from CPAP
- Custom Electronics Development
- Workshop Manufacture of prototypes
- Novel electromechanical PEEP valve for minimum oxygen utilisation

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What is B-LIFE Challenges

Culture Clash:

CSIR Engineers are not medical personnel, we tend to look at things with an engineering mindset (willingness to adapt, modify) which is NOT the same as how medical people look at things, they tend to have a very different mindset, abide by strict rules etc.

Component availability / shortages

International restriction of ANY medical related and electronic components

SAHPRA approval process

A number of iterations which introduced delays

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What is B-LIFE
Current Status

- Several prototype units developed
- Relevant testing completed (Electrical Safety / EMI / EMC / Usability)
- SAHPRA approval received for B-LIFE under Pandemic (Section 21)
- Expression of Interest for potential commercialisation partner was run twice, and a manufacturer was identified
- Business plan from the viewpoint of CSIR is developed, needs refinement through interaction with commercialisation partner
- Full licensing for general use outside of the pandemic is required for commercialisation

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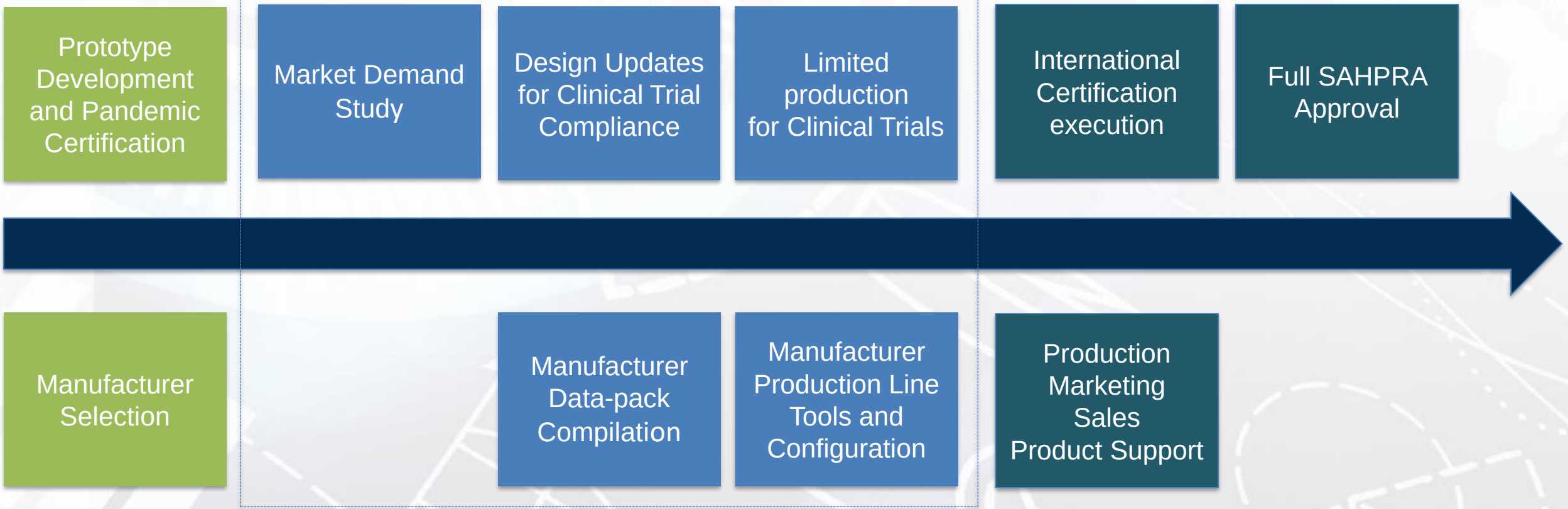
B-LIFE Progression



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B-LIFE Industrialisation (Akacia)

- Launching a new medical device has many unique challenges:
  - Market identification and channel segmentation;
  - The competitive landscape in each channel;
  - Legislative requirements in each channel;
  - Specific needs of:
    - The customer
    - The user
    - The patient
  - Estimates of volume, costing and pricing

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B-LIFE Industrialisation (Akacia)

Market identification and channel segmentation

- Essentially, we look at two market spaces; local and export.
- In the local market we look at the State and then the Private market, which is further segmented into large private groups and emerging groups.
- In the export market, we primarily look at legislative requirements for entry to these markets. Then the barriers to entry to these markets (import restrictions, currency issues, corruption etc.). Thereafter the logistics of entry to these markets.
- Having carried out this research, we then tailor the product offering (and specific unique features) to meet the identified needs in these markets.
- This might be capital cost, or total cost of ownership, or ease of use, or ease of maintenance, or specific safety features.
- We also look at the channels which will show the greatest growth (or potential growth) and best margin.

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B-LIFE Industrialisation (Akacia)

The competitive landscape

- Obviously, the product is entering a marketspace where there is an already established competitive landscape.
- Each channel identified will probably have a dominant competitor and there needs to be an understanding of how this dominance came about to tailor the offering to obtain competitive advantage.
- Price is generally an issue with customers, so, for example, proof of advantageous total cost of ownership may be a way of overcoming this objection.
- There is also the issue of product support – training, maintenance, replacement consumables etc. This is often a factor in less developed markets.
- There is a fundamental requirement therefore to identify unique needs and develop market strategies to address these needs.

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B-LIFE Industrialisation (Akacia)

Legislative requirements in each channel

- There are unique legislative requirements which need to be addressed for each identified channel.
- Many of these legislative requirements are onerous and costly.
- In marketing a life-changing/saving device, clearly the legislative requirements are extensive.
- Certain jurisdictions allow “equivalence” claims to a limited extent. But proving equivalence is often more difficult than proving the efficacy of your own device.

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Specific needs of:

- The customer
  - We define the customer as the person/institution that purchases the product.
  - They will look at price, cost of ownership, efficacy, safety etc.
  - The offering needs to meet these needs.
  - “Imported is best” mindset.
- The user
  - Is the healthcare professional who uses the device in the treatment of the regime.
  - They need to be assured of efficacy, safety, ease of use and reliability.
  - There is often considerable resistance to change, which needs to be overcome.
- The patient (consumer)
  - Obviously has very little say in this case!
  - However comfort, reliability and so on are critical.

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B-LIFE Industrialisation (Akacia)

Volume, Cost and Price

- Clearly any market endeavour needs a commercial justification.
- This is founded on estimates of volumes, costs, and sustainable pricing.
- Manufacturing of medical devices requires specialised facilities and extensive quality management systems.
- Obviously scale is important in reducing cost, as overhead cost is recovered over volume.
- Developmental costs, as described in the previous slides, are also significant and the margin needs to take account of these costs.
- Estimates are at best a guess, so it is critical that the assumptions made in regard to the derivation of these estimates need to be extensively challenged.

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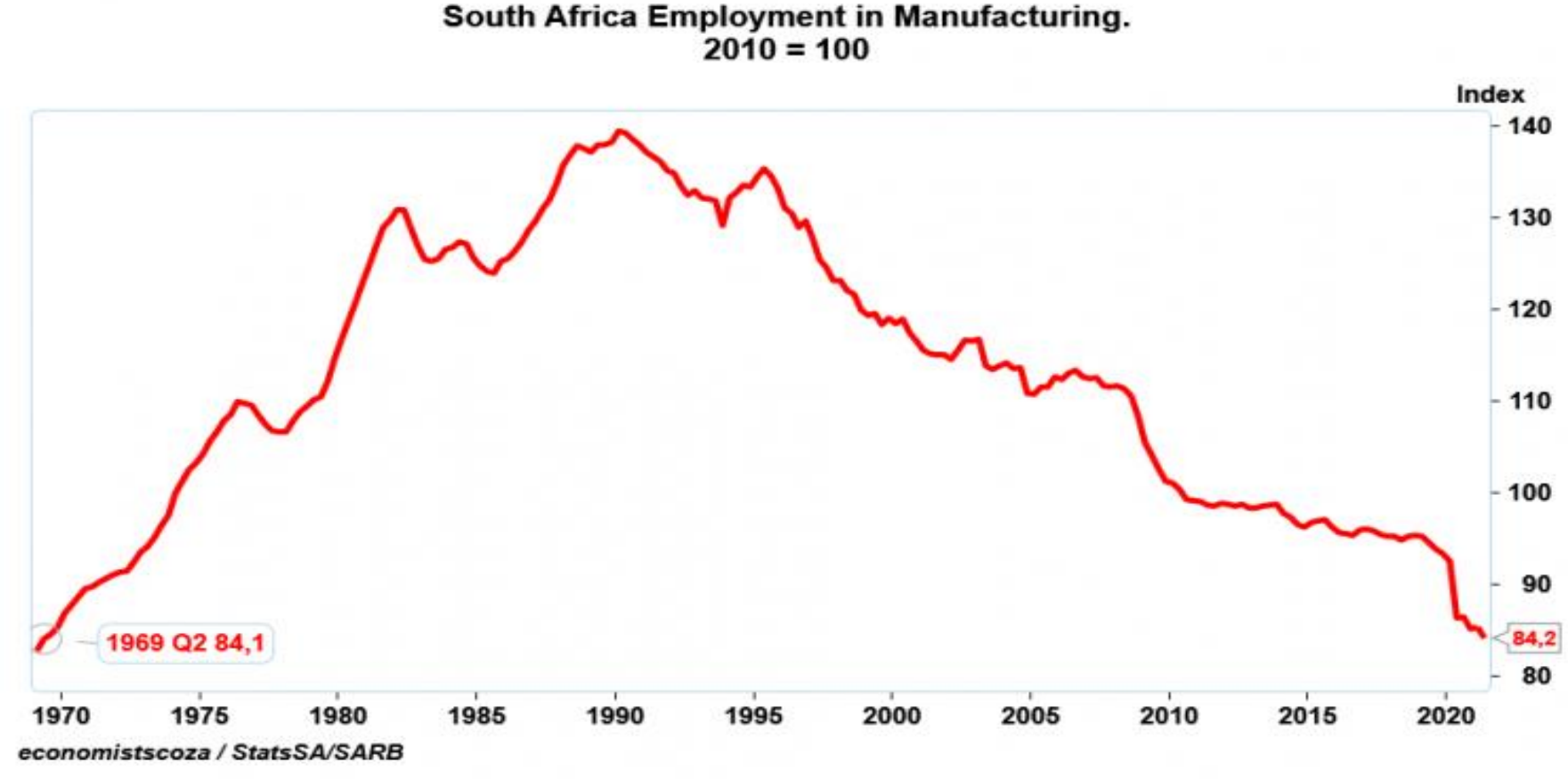
Manufacturing: Why do we need to do something about jobs in this sector?



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Industry: What can we do?

- We can collaborate quickly and well with each other even though we may compete in the marketplace, by utilising limited capability and capacity in the manufacturing space.
- Information management plays a key role in identifying opportunities and in managing activities across the supply chain.
- 3-D printing opens a world of possibilities.
- Even regulatory authorities can move quickly when needed!

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Channel30


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Industry: What can we do?

- The East has shown how collaboration in the supply chain can build great strength and resilience
  - e.g. Motor Assemblies in the late 1960s
- We need to find a way to align all stakeholders to a common goal of sustainable job creation.
- The tragedy is that so much of our manufacturing capability and capacity has been exported to more conducive economies.
- It is just too difficult and unattractive in our legislative framework to create jobs in manufacturing:
  - Labour legislation
  - Lack of adequate technical education, particularly at artisan/technician level
  - Weak currency affected by non-economic factors, largely sentiment

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Industry: What help do we need?

- A more investment-friendly environment
  - Tax-breaks for investment
  - Access to development capital
  - Capital to industrialise innovations
  - Access to trade finance on favourable terms
  - Proper evaluation and monitoring of investments
- An education system aimed at producing artisans and technically qualified people and other manufacturing-aligned skills.
- Some form of preferential procurement.
- A collaborative approach from organised labour.

CONSISTENT AND RELIABLE POWER! 😢

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THANK YOU