

IP and COVID-19: UCL Ventura Continuous Positive Airways Pressure (CPAP) device

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Our team

UCL engineers

- Prof Rebecca Shipley (Director, UCL Institute of Healthcare Engineering)
- Prof Tim Baker (UCL Mechanical Engineering)
- Wider team includes Dr Tom Peach, Mr Tom Rushton, Mr Peter Weston, Mr James Weaver

University College London Hospital clinicians

- Prof Mervyn Singer (UCLH Critical Care)
- Prof David Lomas (UCL Vice Provost Health)
- Dr David Brealey (UCLH Critical Care)

Mercedes AMG HPP (Formula 1)

- Andy Cowell (Managing Director)
- Ben Hodgkinson (Lead Mechanical Engineer)

Other partnerships

- G-TEM (logistics and distribution)
- Oxford Optronix (oxygen analysers)
- LifeRacing (oxygen analysers)
- Avon Protection (breathing circuits)
- Intersurgical (breathing circuits)
- MHRA (UK regulation authority)



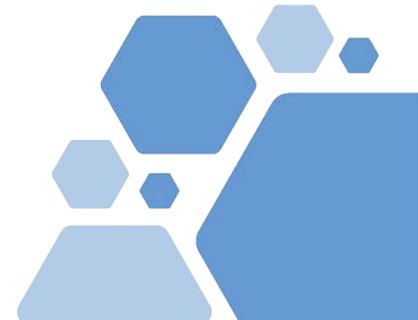
Management of COVID infection

2-13th March: oxygen therapy → ventilation

Data from Italy and China: CPAP devices could help patients and keep them off invasive ventilation

i.e. oxygen therapy →
Continuous Positive Airways Pressure (CPAP) → ventilation

- BUT: (i) there were insufficient devices in the UK
(ii) CPAP wasn't on the NHS care pathway
(iii) CPAP wasn't a priority for HMG's ventilator challenge
(iv) the 'surge' was expected in London 12th April (Easter)

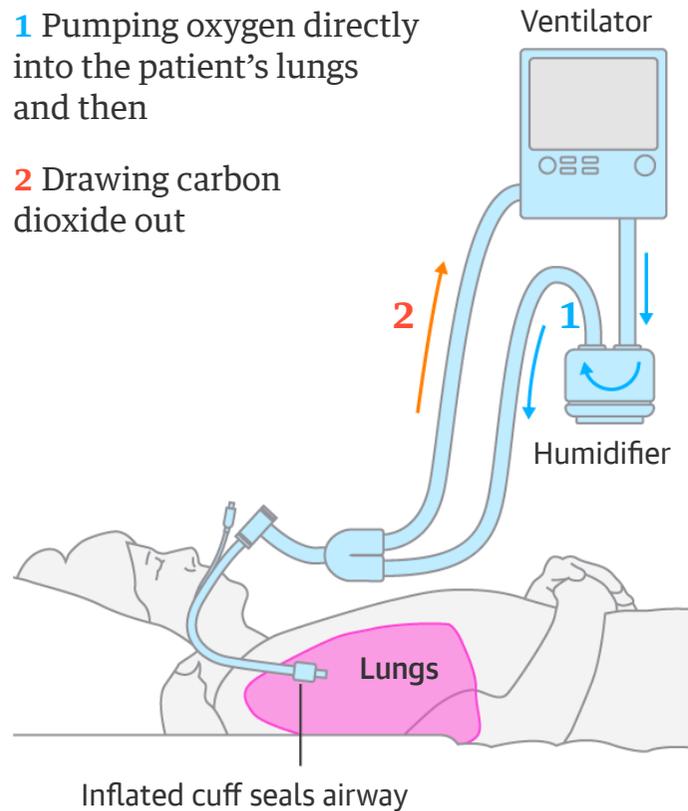


Management of COVID infection

Ventilator

Helps patient breathe by:

- 1 Pumping oxygen directly into the patient's lungs and then
- 2 Drawing carbon dioxide out

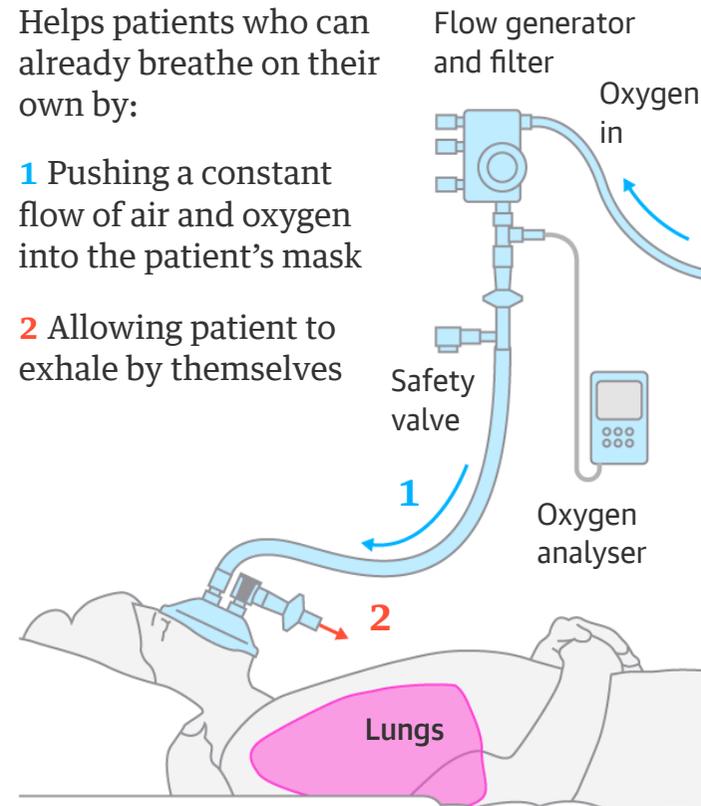


Guardian graphic. Source: UCL, UCLH, Mercedes F1

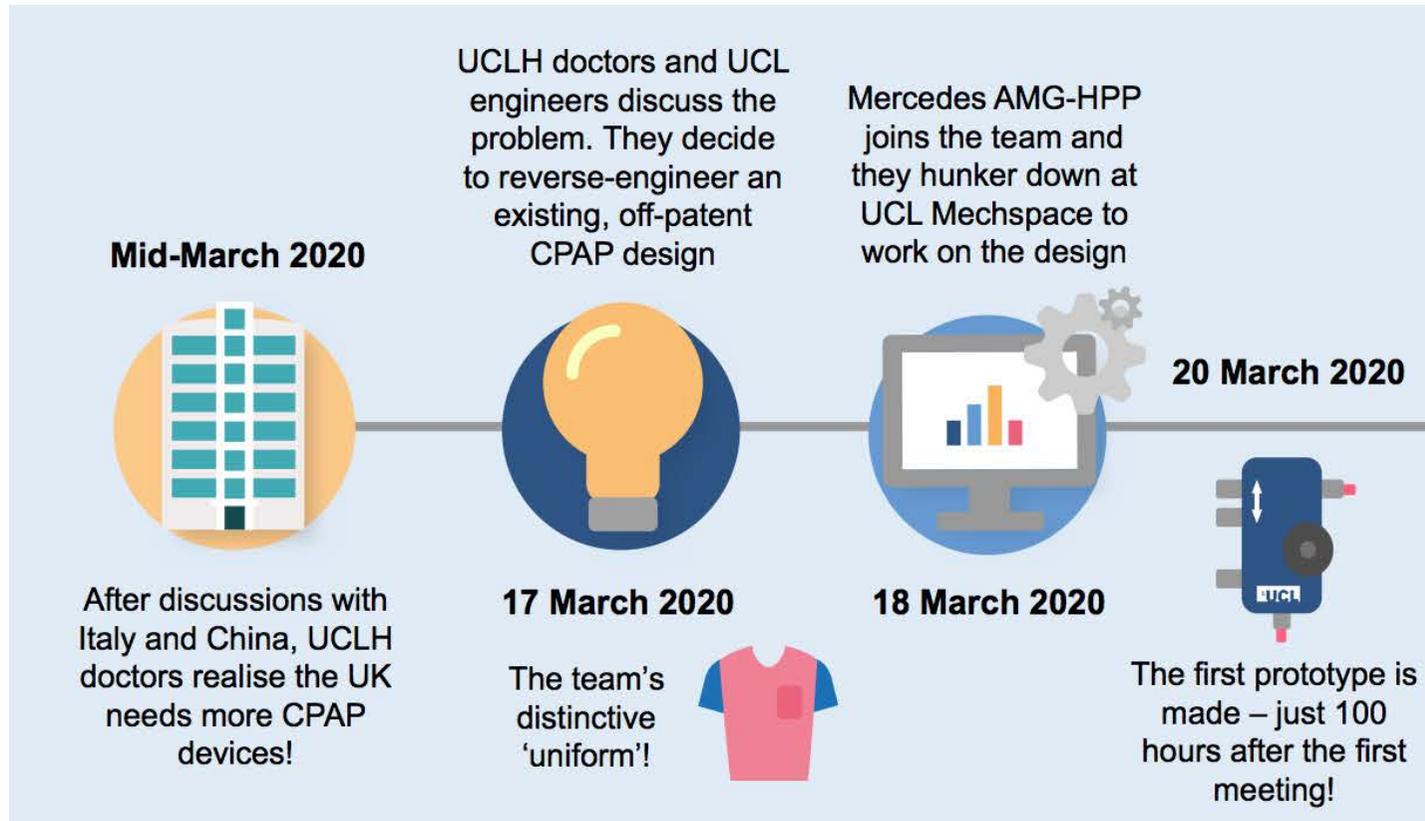
CPAP device

Helps patients who can already breathe on their own by:

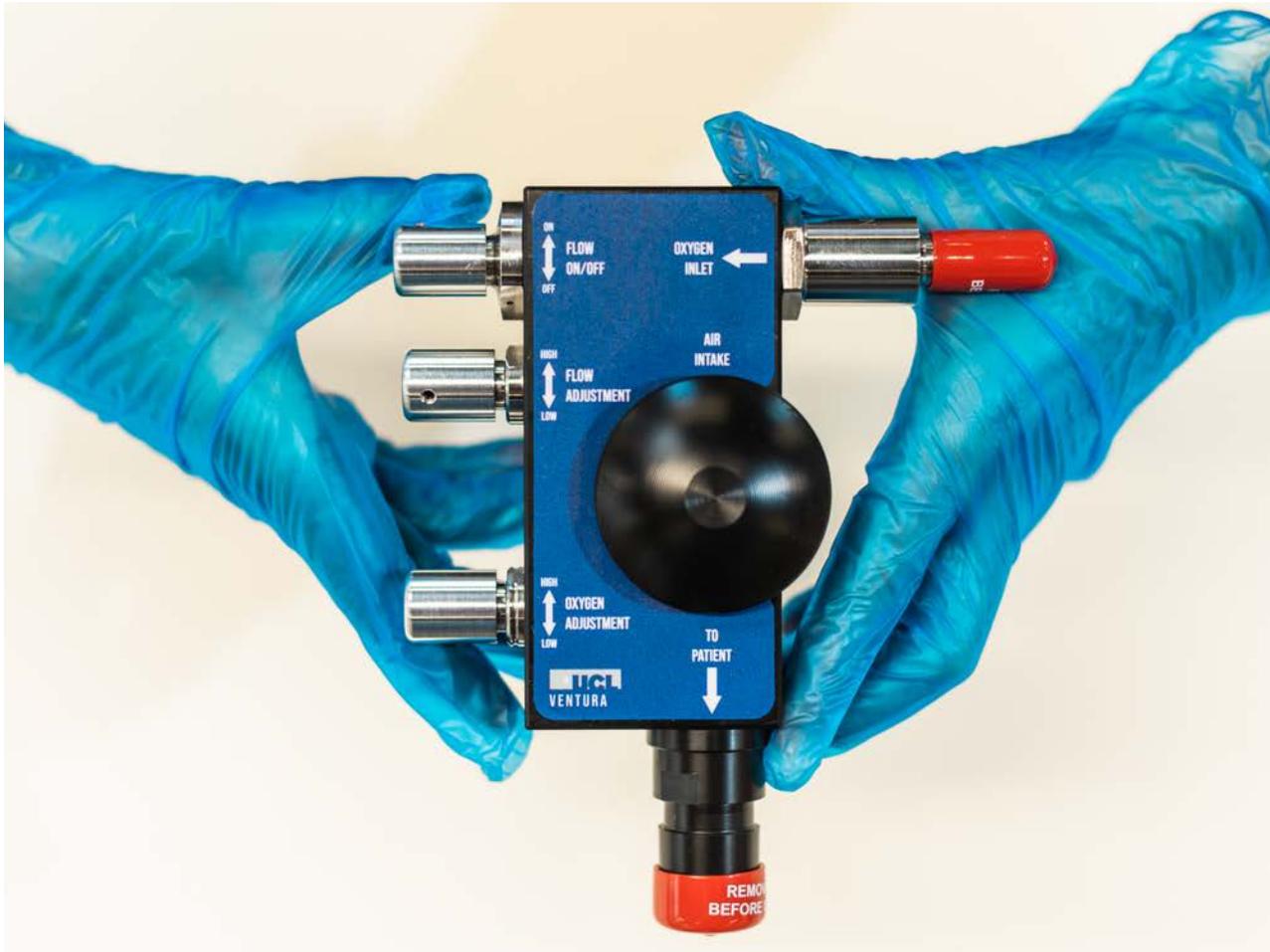
- 1 Pushing a constant flow of air and oxygen into the patient's mask
- 2 Allowing patient to exhale by themselves



Timeline summary



The CPAP Flow Generator Device Mark I and Mark II



- Reverse-engineered an off-patent device, based on the old Philips Respironics Whisperflow CPAP device
- Mark II of our CPAP was developed to reduce oxygen utilisation by up to 70%
- Mark II optimised (a) the air entrainment port, (b) the design of the breathing circuits (valves, filters, mask) for patient comfort and to minimise oxygen utilisation

UCL Ventura – timeline

17th March: team meet at UCL

18th March: contact with Becky Shipley “how can we access the MHRA?”

19th March: contact June Raine Interim Head MHRA (21:46), reply (22:51)

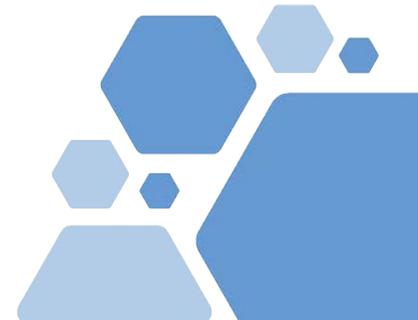
20th March: phone call/e-mail to Andrew Menzies-Gow (Respiratory Clinical Reference Group for Specialist commissioning)

22nd March: prototype delivered to UCL for testing

24th March: NHS issue new guidance including CPAP in care pathway

24th March: NHS honorary contracts issued to Engineering team (UCL + Mercedes HPP) to enable them to continue working/ travelling during lock-down

27th March: MHRA approval for Mark I (10 days after first idea)



UCL Ventura – timeline

29th March: clinical evaluations at UCLH then sister hospitals commence

Concern about supply chains, financing, and promising that HMG would commit – agree to purchase 100

30th March: press release with worldwide coverage

30th March: DHSC commissioned 10,000 devices for £20m by 15th April

31st March: – *manufactured at less than cost and liability? Mercedes wanted to be protected from claims (as did we!). Agreed £5m liability for UCL*

2nd April: MHRA approval for Mark II CPAP device

3rd April: contract largely agreed, Ministerial approval 8th April

15th April: full order of 10,000 CPAPs delivered, and logistics experts G-TEM packaging and next day delivery, with allocation to NHS hospitals through the NHS England and NHS Improvement Oxygen and Ventilator Programme

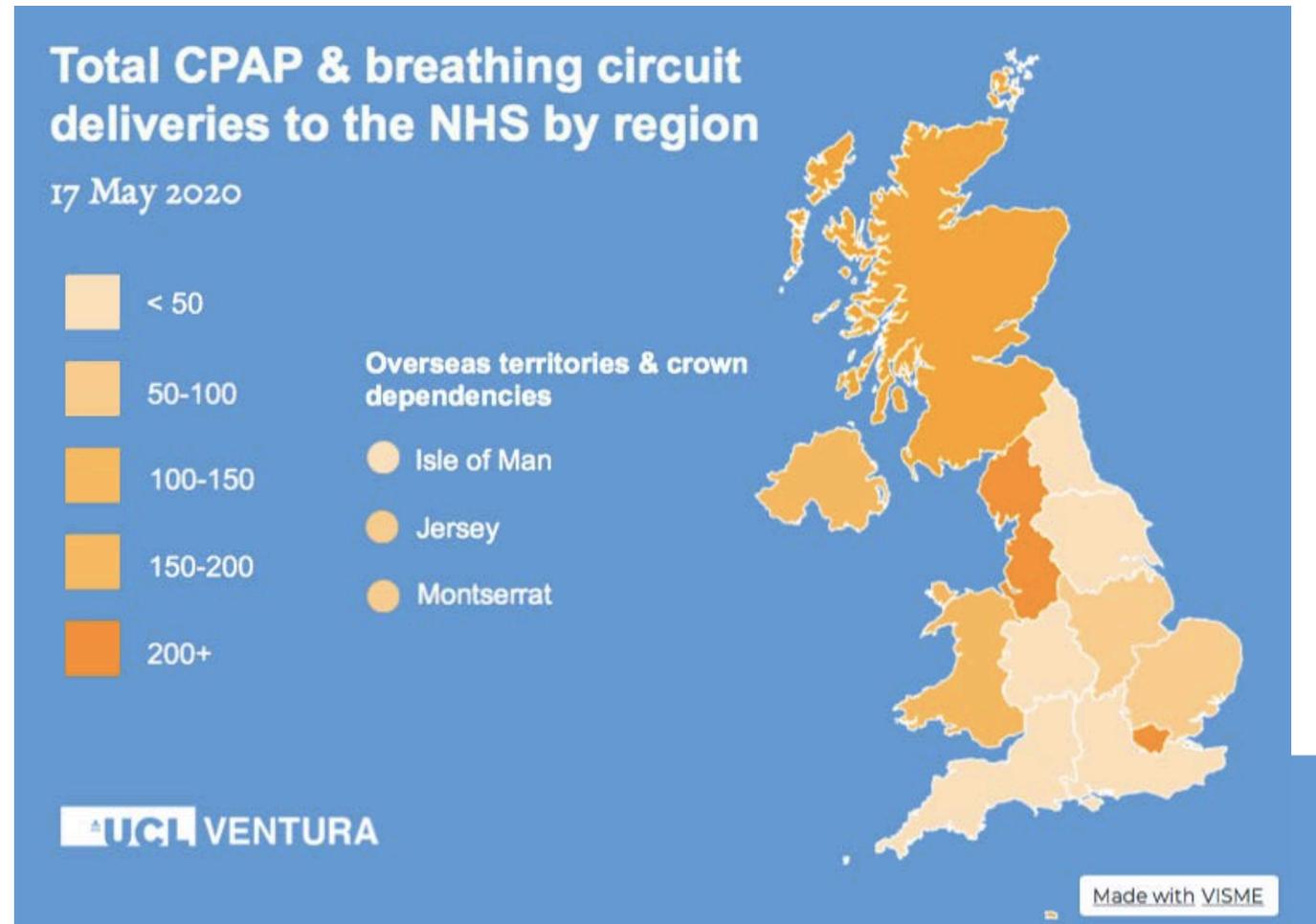


Delivery across UK to NHS hospitals

Approx 1000 CPAPs delivered so far across UK, across 60 NHS hospitals in England, the devolved nations, crown dependencies and overseas territories

Interactive map:

<https://my.visme.co/view/kkx8r133-cpap-uk-distribution>



Release of designs and manufacturing instructions at no cost, for humanitarian use

Partnership with UCL Business

We will authorise requests for free licenses from people representing the following organisations:

- Manufacturers
- Research Institutions
- Healthcare providers
- Non-profit sector

Package of designs and manufacturing instructions contains:

1. Manufacturing drawings
2. System schematics and characteristics
3. Bill of materials and type of manufacturing machines used for CPAP production
4. Development tests information
5. Assembly procedures, including build tooling requirements
6. Test procedure and pass-off protocol



UCL Ventura – the challenges II

(i) No IP despite Mercedes generating a new improved device (a modification to an off-patent device)

(ii) It's hard to give something away!

Approach to licencing:

- limited UCL liability to £10,000
- unable to contract out: death or personal injury from negligence and fraud

Another weekend *pro bono* legal advice started 4th April 2020

5th April fully signed agreement, and release of a dedicated platform for the licensing process on 6th April



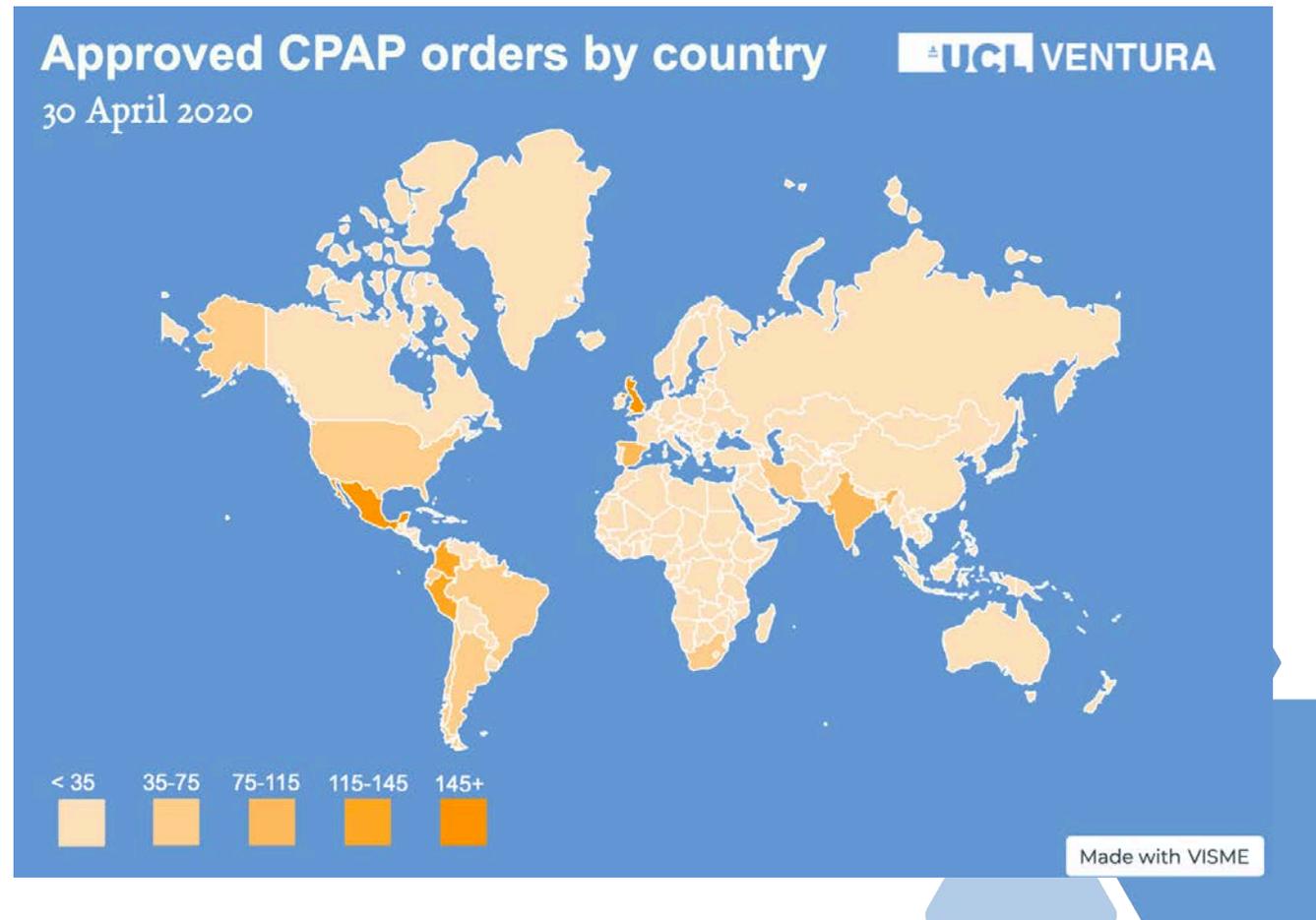
1835 downloads of designs across 105 countries (18 May)

International teams are now making progress with local manufacture

20 teams have successfully manufactured prototypes for testing in Brazil, Bulgaria, Canada, Colombia, Germany, India, Iran, Mexico, Russia, South Africa and the US.

Interactive map:

<https://my.visme.co/view/4d8xdeq9-cpap-approval-orders>



International Support

Support for local manufacturing efforts?

- Working with international groups such as WHO, Just Actions, DFID
- Providing technical and manufacturing support
- Local regulatory approval process (linking to MHRA)
- Ongoing queries around local supply chains, access to materials and financing
- Programme of webinars, online discussion groups

Key considerations:

- Oxygen supply infrastructure and planning (CPAPs need a piped oxygen supply)
- PPE provision
- Resupply of breathing circuits (consumables)
- Training materials



Summary

Team effort to deliver 10,000 CPAP breathing devices in 15 days

Re-design of NHS pathway for care of COVID-19 patients

Great support from MHRA for Mark I and Mark II devices

Download of designs for international use

No patent, contract with DHSC and licence for international use



More information

Website:

- www.ucl.ac.uk/covid19CPAP

Email contacts:

- Queries on accessing devices for international use - CPAPcovid19@ucl.ac.uk
- Additional questions and technical support - ihcovid19response@ucl.ac.uk
- Prof Rebecca Shipley, Director of UCL Institute of Healthcare Engineering - rebecca.shipley@ucl.ac.uk
- Prof Tim Baker, Professor of Mechanical Engineering Design – t.baker@ucl.ac.uk
- Prof Mervyn Singer, Professor of Intensive Care Medicine – m.singer@ucl.ac.uk
- Prof David Lomas, Vice Provost (Health) – d.lomas@ucl.ac.uk



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