STOP the SPREAD

Ventilator Factbase

April 2020

#StopTheSpread

Ventilators are a critical equipment in preventing COVID-related deaths: ~15-25% of patients require hospitalization, many of which rely on ventilators for life support

Patient journey with increase in COVID-19 symptom severity

Patient contracts COVID

Patient is hospitalized and transferred to ICU

Patient is given O2 to prevent deterioration

Options include nasal cannula or CPAP/BiPAP

Patient is put on ventilator as last-resort option

NYC data shows ~12% survival rate for COVID-19 patients vs expected ~20% rate

Invasive ventilators are the primary way doctors are treating severe COVID-19 patients

Mechanical ventilators

Positive-pressure ventilators

These ventilators blow air into the patient's lungs through a tube or mask; they may be invasive or non-invasive

Invasive ventilators

- Involve inserting tube into the patient's airway, which is generally done in two ways:
  - Endotracheal intubation (primary use type for COVID-19 patients): tube is inserted into the patient's airway (trachea) through the mouth or nose
  - Tracheostomy: Tube is inserted through a hole made into the

Key ventilator type currently used in US to treat people with COVID-19

Non-invasive ventilators

- Come with masks and can be used at home by people with respiratory difficulties; there are two key types:

Continuous positive airway pressure (CPAP): Delivers constant air pressure

Bilevel positive airway pressure (BiPAP): Delivers air with different pressures for inhalation and exhalation

Non-invasive ventilators are sometimes being used to treat COVID-19 patients with less severe symptoms

Negative-pressure ventilators

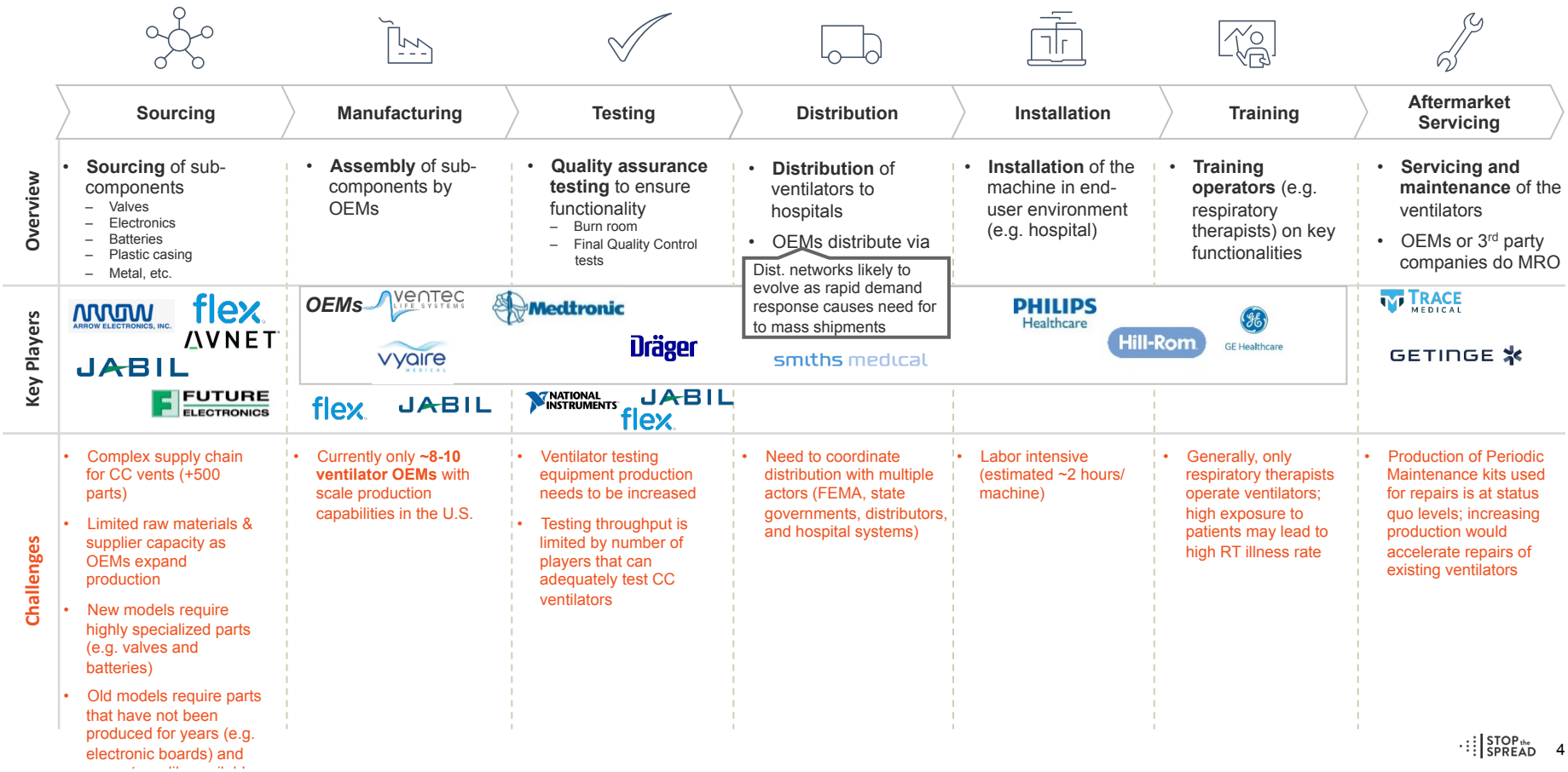
Early ventilators, in limited use now, suck air into lungs by making chest expand and contract

Anesthesia machines

Several modern anesthesia machines are capable of ventilating patients and can be used to increase hospital capacity

Can be adapted to serve as an invasive ventilator

Value chain: The ventilator value chain is complex; monitoring supply chain is needed to ensure ventilator supply targets are met



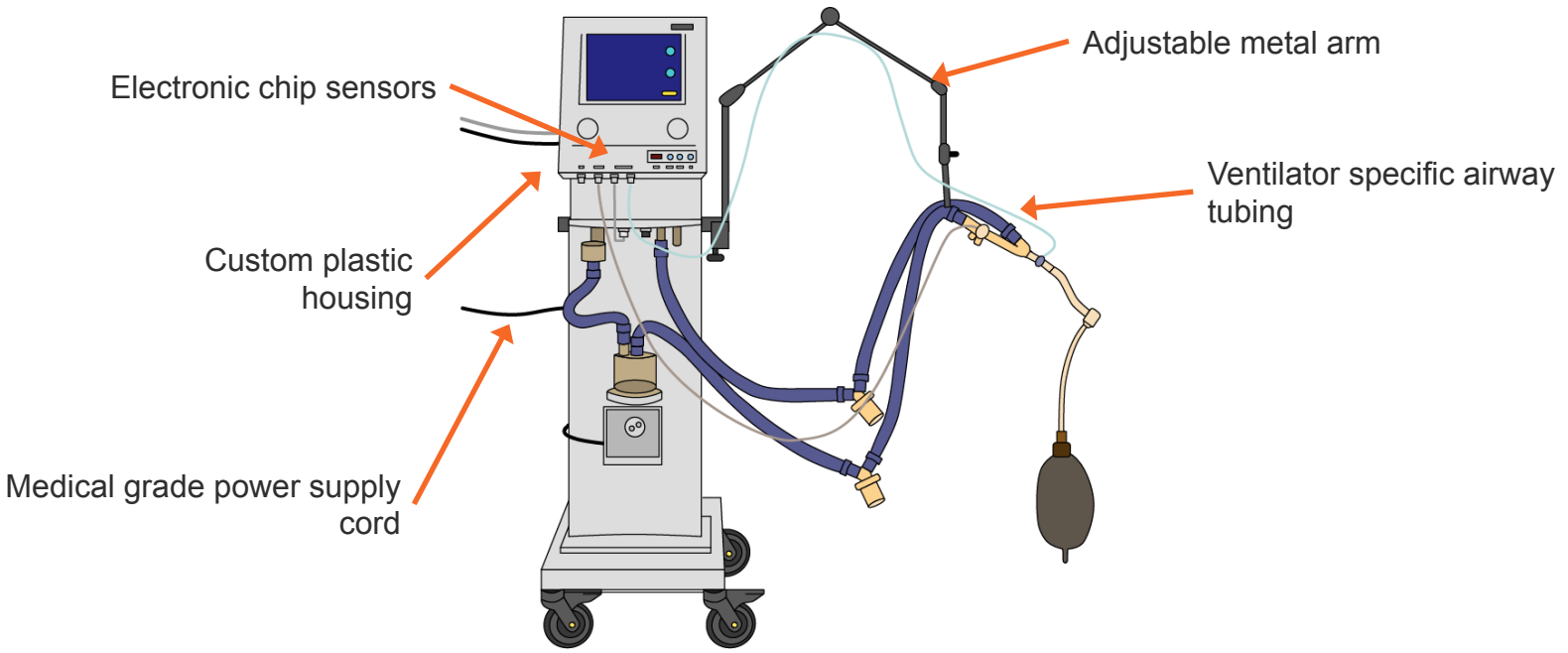
Regulatory: Scenarios and plan of action for private sector actors in the ventilator arena

REGULATORY

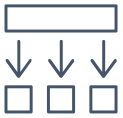
	Challenge	Current FDA process	Action
Scenario 1 	• Existing ventilator manufacturer wants to modify design of already certified ventilator	• OEM to consult with FDA Enforcement Policy; rapid FDA approval expected	• Refer to Enforcement Policy for Ventilators document and email CDRH-COVID19-Ventilators@fda.hhs.gov
Scenario 2 	• Medical device manufacturer (not ventilators) wants to start producing ventilators	• OEM to contact FDA to confirm their facilities and processes are aligned with current standards; can expect expedited approval	
Scenario 3 	• Non-medical device manufacturer wants to start producing ventilators	• OEM to contact FDA to verify standards are ISO compliant; longer review time, but FDA is prioritizing Scenario 3 requests	
Scenario 4 	• Manufacturer develops new design for a ventilator and wants to start production	• OEM to submit an EUA petition; after approval, design can be manufactured and must follow the process described under Scenario 1-3	• Submit EUA petition to CDRH-COVID19-Ventilators@fda.hhs.gov

Sourcing: Roughly ~30-40% of the parts sourced for ventilators are niche, manufactured specifically for ventilators

Examples of niche parts



Sourcing: Ventilators parts can be segmented into four categories; some present a bottleneck risk as OEMs seek to rapidly expand production



Niche parts can be grouped into four segments

Printed circuit boards	Each ventilator contains ~10-15 **PCBs that control electronics**; some of these PCBs **contain niche sensors** that are designed for specific ventilator models
Electronic power supplies	**Common electrical components** (e.g. voltage regulators, power inverters, etc.) that are less complex and widely available
Plastics / metals	**Plastic ventilator box that is custom to each model** and other sub-components made of hard plastic
Mechanicals	**Primarily valves that open and close** so the ventilator can push air and allow the patient to exhale

Parts can be assessed across criteria to determine risk

1 Supplier ability to scale production

- Parts differ in production run timing and frequency
- Parts differ in manufacturer ability and willingness to shift capacity

2 OEM ability to re-engineer part quickly (if shortage occurs)

- OEMs would work with a supplier to re-engineer a new alternative part to address the shortage
- Parts vary in terms of re-engineering complexity and time required to produce
- Parts also vary in terms of supplier capacity to produce

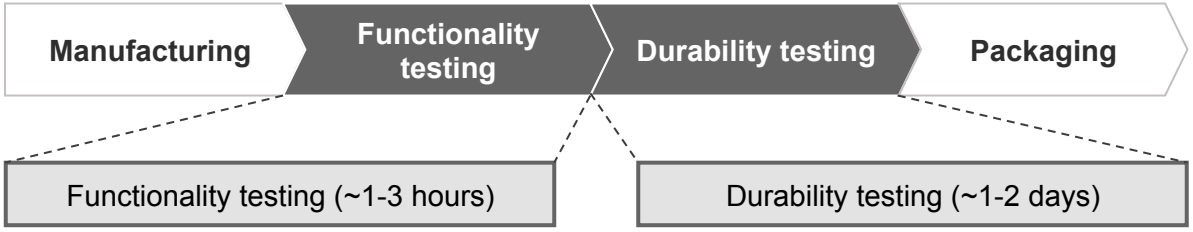
Sourcing: Supply chain evolve rapidly and tend to be OEM-specific; PCB production is challenging to scale or re-engineer designs quickly

	Supplier ability to scale production		OEM ability to re-engineer part quickly	
Printed circuit boards (PCB)	Low	**Chips are produced monthly / quarterly** in short runs on semiconductor fabs that run on strict schedules Unclear how likely manufacturers are to modify schedule due to small runs and high costs	Low	Shortages of niche sensors would drive **OEMs to work with suppliers to re-engineer circuit boards** with available sensors **PCBs are highly complex**; the normal re-engineer lifecycle is 120-180 days; at minimum, process would take 90 days
Electronic power supplies	Medium	Existing **suppliers can scale capacity 2-3x** by running 24/7 operations **Long lead time** for new equipment (~4-6 months)	High	**Power supplies can be redesigned much faster than PCBs**, and substitute parts are widely available
Plastics / metals	High	**Can scale capacity 2-3x** by running 24/7 operations **Shorter lead time** for equipment to increase capacity, relative to electronics and mechanicals	Low	• The **tools used to injection mold plastic parts are complex** and require ~4-6 months to design and test • If a shortage occurred with a custom injection molded part (e.g. ventilator box), it would be faster to increase capacity with the existing supplier than to design a new tool
Mechanicals	Medium	**Existing suppliers can scale capacity 2-3x** by running 24/7 operations **Long lead time** for new equipment (~4-6 months)	Medium	**Mechanical parts in ventilators are somewhat complex** and often control critical functions (e.g. compress the air inside of ventilators) The re-engineer process would be lengthy, but not as lengthy as PCBs

This should not be interpreted as a list of products OEMs are currently requesting

Quality testing: Ventilators undergo extensive testing after production

Ventilators undergo functionality and durability testing before packaging



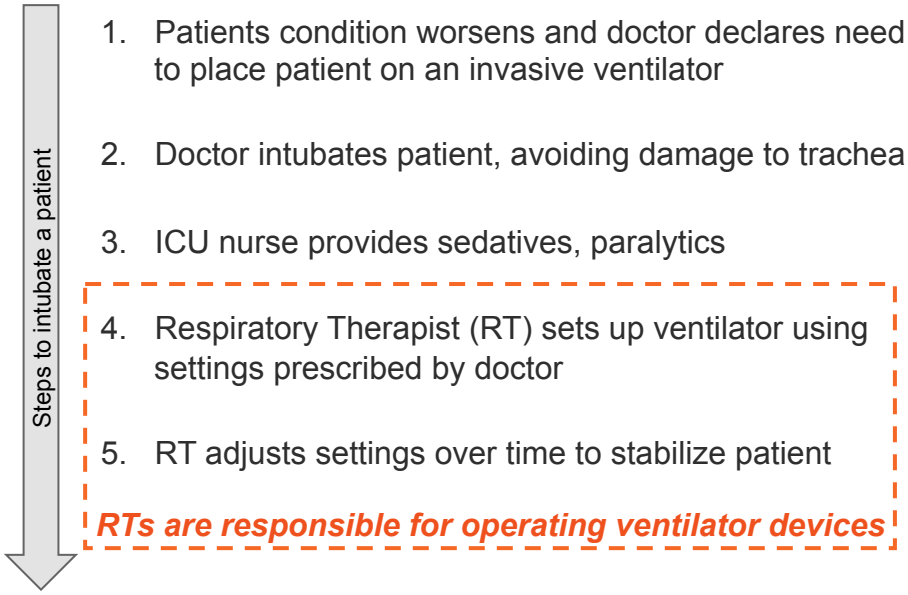
- Ventilators are connected to testing equipment that simulates a patient to test functionality and safety features
- The functionality is tested by ensuring the equipment performs against ~9-10 critical functions
- The safety features are tested by ensuring that the right alarms go off when the patient status changes

- Ventilators are connected to the same testing equipment and placed in an high temp environmental chamber to test the durability of the equipment
- The durability is tested by operating the equipment continuously in a difficult operating environment (i.e. high temp) for 1-2 days
- Environmental chambers are typically the size of garages

OEMs use niche equipment

- **OEMs use niche testing equipment** that was designed to test the unique performance of their ventilator model
- **Designing a new testing system requires time** (designing the system, software, protocols, etc.)
- There are a handful of companies that support existing testing equipment supply and they **appear well positioned to increase capacity** (sub-component parts are not highly complex)

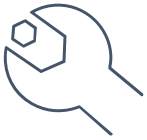
Staffing: In the U.S., Respiratory Therapists are the primary operators of ventilators; using a ventilator requires medical knowledge as well as device-specific information



Overview of Respiratory Therapist Qualifications

- All RTs spend 2 years in specialized training
  - Medical training includes focus on pulmonary and cardiovascular systems
- In the final months of training, RTs begin intensive sessions to become familiar with device handling
- RTs are certified to operate ventilators by state boards; if an RT moves to a new state, they need a new license

Maintenance: Ventilators require periodic maintenance in order to operate safely; there is an opportunity to get existing ventilators online by fixing them



- With periodic maintenance, **ICU ventilators can last >7 years**
- **Maintenance is based on hours of operation**. Hourly milestones trigger different levels of maintenance
- **Parts that require maintenance include:** sensor recalibration, filter and battery replacement, and testing alarm systems, etc.
- OEMs produce model-specific periodic maintenance kits
- For example, for the Pulmonetic LTV Ventilator (in SNS), the following milestones trigger various maintenance requirements:
  - After each use: clean inlet filter and fan filter
  - After 750 hours / every month: perform checkout tests, clean inlet filter and fan filter
  - After 10,000 hours / every 2 years: Calibrate transducers, replace internal battery pack, replace motor board, replace O2 blender filter, etc.
  - 30,000 hours: replace turbine manifold assembly, replace solenoid manifold, replace flow valve, replace rotary knob assembly, replace [illegible]n assembly, replace all silicone tubing, check thermal pads and replace if necessary, etc.

Lists are not exhaustive