



# Rapidly Manufactured CPAP System (RMCPAPS)

Document CPAP001 - Specification

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## Glossary

CPAP: Continuous Positive Airway Pressure a non-invasive ventilation mode which provides a constant steady pressure to keep the lungs expanded

PEEP: The pressure maintained in the breathing system during expiration cmH<sub>2</sub>O:

centimetres of water pressure

HMEF: Heat and Moisture Exchange Filter: device fitted to the patient end of the breathing system, contains hydrophobic medium that absorbs heat and moisture from the patients exhaled breath and uses absorbed moisture to humidify inhaled gases. Can also filter bacteria and viruses, this will be used on all patients. WARNING can affect delivered pressure.

RF: Radio Frequency: Many medical devices are sensitive to RF interference. Care should be taken to ensure that this is kept to a minimum.

EM: Electro Magnetic Emissions: Many medical devices are sensitive to EM interference. Care should be taken to ensure that this is kept to a minimum

FiO<sub>2</sub>: Fraction of inspired oxygen: concentration of oxygen in the gas mixture the patient inhales.

## Introduction

Mechanical ventilation with PEEP through an endotracheal tube remains the mainstay of respiratory treatment in patients with severe respiratory failure from COVID-19. There is however some recent evidence that less invasive means of ventilation may have a role. CPAP can be administered via a face mask, a nasal mask or through a CPAP hood.

This is a specification of the minimally (and some preferred options) clinically acceptable CPAP system to be used in UK hospitals during the current COVID-19 pandemic caused by SARS-CoV-2 virus. It sets out the clinical requirements based on the consensus of what is 'minimally acceptable' performance in the opinion of the anaesthesia and intensive care medicine professionals and medical device regulators given the emergency situation. It is for devices, which are most likely to confer therapeutic benefit on a patient requiring CPAP because of respiratory failure caused by SARS-CoV-2, used in the initial care of patients requiring urgent support. A CPAP system with lower specifications than this is likely to provide no clinical benefit and might lead to increased harm, which would be unacceptable for clinicians.

Intensive care medicine is a whole system of care and CPAP cannot be safely used on any patient without trained staff and other equipment and medicines. Where these impinge on the specification they are mentioned below.

## Specification

**Must:** Defines the minimum viable product clinically acceptable by clinicians

**Should:** Highly desirable features of considerable benefit for therapeutic use. As time is of the essence if omitting one of these features significantly accelerates development and production it should be considered

**Could:** Features or options often found in CPAP systems, but are of significantly lower priority in terms of the current need and should not be considered if they delay production and development or the provision of more important features

## RMCPAP

1. RMCPAP must deliver inspired oxygen concentration in the range 35 – 80% to the patient, selectable by the user. The selection of inspired oxygen should be continuous in the range but could be in steps of 5%.
2. Should consume less than 5 L/m of oxygen, but could consume up to 10 L/m. Must not consume more than 15 L/m of oxygen (this may require the use of a reservoir). However, this requirement may change depending on the availability of oxygen at different stages of the pandemic and in different treatment centres.

## Gas and electricity

3. Incoming Gas Supply.



- a. All gas connectors and hoses must comply with BS EN ISO 5359:2014+A1:2017, ISO 5359:2014/AMD 1:2017 and BS 2050: 1978 Electrical Conductivity.
  - b. Must connect to wall pipeline oxygen supply via BS 5682:2015 compatible probes (Schrader). If hose not permanently fixed to machine, then must connect with NIST (Non- Interchangeable Screw Thread to ISO 18082:2014/AMD 1:2017). Oxygen pipeline pressure is approximately 3.7 – 4.5 bar.
  - c. Oxygen supply from wall outlets outside of ICU and theatres may be limited to approximately 6-10 L/m averaged over the outlets within a ward (HTM\_02-01\_Part\_A).
  - d. Average oxygen consumption must be no more than 15 L/m. This may be allowed to increase as greater certainty is gained over oxygen supply.
  - e. If RMCPAP connects to wall pipeline Medical Air (MA4, NOT SA7) it must be via BS 5682:2015 compatible probes.
  - f. An RMCPAP may include an oxygen concentrator as the source of oxygen. Note these will typically be limited to 10 L/m 96% oxygen.
4. Could have the ability to entrain room air to reduce the oxygen requirement or conversely to entrain oxygen when powered by medical air.
  5. Must maintain a nearly constant airway pressure of between 5–15 cmH<sub>2</sub>O, with the ability to adjust the pressure. This will require the RMCPAP to deliver gas flows which equal or exceed peak inspiratory flow rates in tachypnoeic patients.
  6. Must either alarm or be provided with a suitable air entrainment system if the fresh gas supply fails which prevents significant rebreathing.
  7. Should be able to work with existing specification close-fitting disposable face mask systems (includes hoses), or hoods.
  8. If the RMCPAP entrains room air this must pass through a suitable filter.
  9. Could have the ability to humidify the gas the patient breathes. This may not be required with some breathing systems, such as with low flows of inspiratory gas and where breathing is through the nose.
  10. Must have as low a resistance to expiration as possible and should have a flow rate through the PEEP valve which is largely independent of the PEEP level set.
  11. Expiratory gas must be able to pass through an appropriate filter, which can be fitted using standard connections to reduce contamination of the immediate environment.
  12. Must have a pressure safety release valve to protect the patient from high pressures, having a release pressure of no greater than 25 cmH<sub>2</sub>O. An over-pressure alarm should be provided where possible and should not necessarily be confined to an electrically powered RMCPAP.



13. Must be securely attached to the gas outlet (small gas powered systems), to a suitable pole or rail system or to be provided with a suitable base.

14. Electrical Supply:

- a. If mains powered RMVS must connect to 240V mains via standard UK 3pin plug.
- b. Must be PAT tested to the adapted IEC 60601, IEC 62353 standards.
- c. Must have audible and visual alarm(s) for RMCPAP failure or switch off and if there is over pressure at 25 cmH<sub>2</sub>O.

15. Infection control:

- a. All parts coming into contact with the patient's breath must be either disposable or designed to be reusable.
- b. All working components of the device must be contained within an impermeable casing.
- c. All external surfaces must be cleanable in the likely event that they get respiratory secretions or blood splatter on them. Cleaning would be by healthcare workers manually wiping using an approved surface wipe with disinfectant or cloths and approved surface cleaning liquid.
- d. There must be a separately sourced HMEF-bacterial-viral filter between the machine and patient or filters fitted to the gas outlet of the machine and the exhaust from the PEEP valve. These may impact on resistance within the system, which may need to be accounted for. The pressure being delivered to the patient is the specified pressure. Viral filters may have much higher resistance that may be clinically relevant.

16. Biological Safety.

The authoritative standard covering this area is ISO 18562-1:2017 "Biocompatibility evaluation of breathing gas pathways in healthcare applications. Evaluation and testing within a risk management process".

- a. Materials of Construction (raw materials).
  - i. The chosen material must be reasonably pure and simple in nature (minimise the use of additives where possible).



- ii. For components requiring flexibility avoid the use of materials requiring plasticisers. Good candidates are those materials that belong to the polyolefin family, examples include polyethylene and polypropylene.
- iii. For structural components materials such as polycarbonate or Acrylonitrile butadiene styrene (ABS) should be used without additives, although reinforcement with glass fibre would be acceptable.
- iv. Polyvinyl chloride (PVC) must be avoided in the patient gas pathway.
- v. PVC should be avoided elsewhere.

#### 17. Manufacturing process (risk from contaminants)

- a. Mould release agents used within extrusion or injection moulding techniques may be required in setting up the machine, they should not be needed once a process is in full scale production.
- b. Approximately, the first 20 or so items in an injection moulding production run should be discarded to minimise risk from contamination with mould release agents.
- c. Extrusion and moulding techniques are comparatively simple and well controlled; therefore, RMCPAPs will not be required to be manufactured within cleanroom specifications.
- d. Manufacture in a reasonably clean room and protection of components and products from contamination should suffice.
- e. If A-D is followed, chemical or particulate testing of the air coming out of the breathing circuit should not be necessary.

#### 18. Hazard Mitigation

- a. Particulate matter: solid particles suspended in a gas- Particulate matter emissions are not of significant concern if the manufacturing process is adequately controlled as per the above criteria.
- b. Volatile organic compound (VOC): organic compound whose boiling point is in the range of 50°C to 260°C- Risk of exposure to VOCs can be minimised through the appropriate choice of materials as set out in section 1.
- c. Leachable substances (in condensate): chemical removed from the medical RMCPAP by the action of water, other liquids or other gases related to the use of



the RMCPAP- ensure a suitable filter is used between the RMCPAP device and the breathing system.

#### 19. Software Safety

Software, if used in RMCPAP will almost certainly have the capability to cause serious injury or death if risk control measures are not adequately implemented. See appendix C for details of minimal necessary risk control measures.

#### 20. Miscellaneous

1. Must be reliable. RMCPAP must be capable of continuous operation (100% duty cycle) for 14 days.
2. Should be capable of operation continuously for more than 14 days.
3. The expected durability must be specified.
4. Could be floor standing.
5. Could be small and light enough to mount on patient bed with orientation independent functioning.
6. Should not be excessively noisy.
7. Should be as robust as possible. For example, it may be dropped from bed height to floor.
8. It must be intuitive to use for qualified medical personnel, but these may not be specialists in RMCPAP use.
  - a. Must not require more than 30 minutes training for a doctor with some experience of RMCPAP use.
  - b. Must include Instructions for Use.

21. Instructions for use should be built into the labelling of the RMCPAP, e.g. with 'connect this to wall' etc.

- a. Must include clear labelling of all critical functions and controls using standard terms, pictograms and colours that will be readily recognised by UK healthcare staff.
- b. Must have transparent design, supply chain, manufacture, quality assurance and testing processes that are of sufficient quality to enable MHRA officials to deem appropriate for usage in exceptional circumstances.



- c. Must not be excessively cumbersome so that it would impede hospital operations or prevent easy movement within hospital premises.
- d. Must be made from materials and parts readily available in the UK supply chain (anticipating increasing global restrictions on freight movement).
- e. Standards – there are many standards that exist in this area. Below is a list of the most relevant ones. They are not formal regulatory requirements, but many standards are designated against regulatory requirements. Consider them as helpful advisory standards for now. MHRA will lead an exercise to define which can be ‘safely’ relaxed for this emergency situation. A full list of designated standards for medical devices is available at: [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/950183/ds-0034-21-medical-devices-notice.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/950183/ds-0034-21-medical-devices-notice.pdf).
  - i. BS ISO 80601-2-84. Medical electrical equipment. Part 2-84. Particular requirements for basic safety and essential performance of emergency and transport ventilators (very similar to IEC 60601).
  - ii. ISO 80601-2-12:2020 Medical electrical equipment — Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators
  - iii. ISO 19223:2019, 3.11.15 Lung ventilators and related equipment. Vocabulary and semantics. CPAP

## 22. Testing





- a. It is accepted that full demonstration of compliance to ISO 80601-2-12:2020 is unrealistic in the time frame required for development. Nevertheless, compliance with the essential safety standards must be demonstrated for patient safety. 2.
- b. It is not anticipated that RMCPAPs will be UKCA or CE marked and approval by the MHRA will be through the “Exceptional use of non-UKCA or non-CEmarked medical RMCPAPs” route (<https://www.gov.uk/guidance/exceptional-use-of-non-UKCA-marked-medical-devices>) through a streamlined derogation process. (We will continue to accept CE marked devices on the Great Britain market until 30 June 2023).

23. When the current emergency has passed these RMCPAPs will NOT be usable for routine care unless they have been CE marked or UKCA marked through the Medical Device Regulations. The RMCPAP must display a prominent indelible label to this effect. We will continue to accept CE marked devices on the Great Britain market until 30 June 2023.

24. Usability testing at both prototype and final production stages will be required. This should be done as a short Formative Usability Test as described in ISO62366 in a realistic environment if possible. The user will be wearing complex protective clothing which includes: Eye goggles (in addition to spectacles if worn), Face shield, Plastic apron, Surgical gown, Two layers of gloves, usually nitrile non-handed small, medium, large variants, Gloves are donned in layers and sticky taped onto sleeves of gown in between layers.

25. The user must be able to instantly see the settings selected and be able to easily operate all controls while dressed in protective gear. They may be required to remain so clothed and operating the RMCPAP for a number of hours without breaks.

#### 26. Unknown Issues

- a. How much oxygen is currently consumed by RMCPAP systems. Preference is given to designs consuming the least oxygen, but a mixture of designs is needed, and some designs cannot fundamentally limit the minimum oxygen flow.
- b. Absolute minimum oxygen requirement is the human consumption of about 250 ml/min in a healthy person but up to 500 ml/min in severe sepsis. However, achieving this is only possible if certain breathing system designs are used and ‘driving’ gas is air.
- c. Specifically, would have to use circle breathing system with active CO<sub>2</sub> absorption. Is sufficient soda lime available?
- d. If consumption in the range 1-6 L/min is acceptable then a wider range of designs is possible, but some very basic designs are not.
- e. If consumption in the range 10 L/min is acceptable then any possible design can be considered.



- f. Is there any need to consider running from only low-pressure oxygen e.g. from a concentrator? This makes design more complex.
- g. How plentiful is the supply of syringe drivers and drugs for sedation?
- h. If monitoring can be done by another machine it could be left out of the RMPAP, but essential parameters must be available to the clinician.
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Appendix A:

**Clinical guidelines for infection control of RMCPAP.**

This appendix is intended to guide developers on the likely clinical guidance users will be working to. It is not actual guidance for users of such equipment.

1. RMCPAP equipment is kept in close proximity to patients and while the RMCPAP itself does not come into direct or invasive contact with the patient, it will be physically connected to equipment which does. Therefore, it is important all proposed RMCPAPs can be thoroughly decontaminated by health care professionals in the health care setting.
2. The process for how this is carried out and guidance on design factors to be considered are detailed below.
3. Where possible the process for cleaning RMCPAPs should be intuitive, however documentation for the correct method of decontamination should be detailed in the instructions for use.
4. Preferably all components into direct contact with the patient's breath will be disposable, where this is not possible the process for sterilising reusable components should be detailed in the instructions for use.
5. All information in the instructions for use should be presented as described in ISO 17664:2017 Processing of health care products.
6. The external surfaces surface of the RMCPAP will need to be regularly decontaminated, once every 24 hours minimum for multi day single patient use, and between each individual patient use. This decontamination will be carried out by a nurse or other health care professional, using either a single use disinfectant wipe or a liquid disinfectant applied with a disposable cloth.
7. All external surfaces of the RMCPAP will be cleaned, including screens, buttons and, control switches. For this reason, it is important all RMCPAPs are designed in a way to prevent the ingress of fluid through the casing. All screens should also be made of a material that that will not cloud or smear after disinfection.
8. To prevent contamination of the patient gas pathway, and internal components, the RMCPAP should be designed to use separately sourced HMEF-bacterial-viral filter between the machine and patient. These filters will be place at the exhalation and inspiration ports of the RMCPAP I.E. ports for breath in and out. The filters are bulky, measuring approximately 10CM each on average and designs should be made with adequate spacing for both filters on dual port RMCPAPs.
9. To prevent dust and other contaminates from entering the internal components of the RMCPAP, all inlets and outlets to room air should also have a filter in place. Instructions on the method of changing these filters, as well as the frequency that change is required, should be detailed in the RMCPAP's instructions for use.



10. If the option of using a hot water humidifier is also included in the design, methods of preventing fluid ingress through inhalation and exhalation ports should be considered.

## Appendix B

### **Testing protocol for final validation of safety and performance of RMCPAP.**

This testing protocol will be used by the independent testing facility advising MHRA on the suitability of RMCPAP.

The protocol may have to be varied at the discretion of the tester. It is here for advisory purposes to explain the likely testing that RMCPAP will undergo.

#### **General**

1. Enclosures of RMCPAPs shall provide at least an IP22 degree of protection to the harmful ingress of water.
2. All external surfaces must be cleanable in the likely event that they get respiratory secretions or blood splatter on them.
3. Cleaning would be by healthcare workers manually wiping using an approved surface wipe with disinfectant or cloths and approved surface cleaning liquid.
4. Mains powered RMCPAPs must be 240V and EST tested to the adapted IEC 60601, IEC 62353 standards and have an alarm that sounds when power fails.
5. RMCPAPs relying on mains power for operation must have 20 minutes back up battery power available in case of mains electricity failure.
6. All parts of the breathing system which can, or could, come into contact with the patient's expired gas must be either single patient use only and labelled with an ISO 7000-1051 mark or the words "Do not re-use" or must be able to be decontaminated between patients.
7. All components of the gas pathways in the breathing system must use materials which have been evaluated for biocompatibility according to ISO 18562-1:2017 and shall not contain phthalates or other substances, which are classified as endocrine disrupting, carcinogenic, mutagenic or toxic to reproduction, in a concentration that is above 0,1 % weight by weight of any article.
8. A RMCPAP and its parts, including applicable accessories, shall have adequate mechanical strength when subjected to mechanical stress caused by normal use, pushing, impact, dropping and rough handling.
9. If a connector is provided for the gas exhaust port, it shall be a 30 mm connector conforming with ISO 5356-1:2015. Labelling A clearly visible permanent label must be attached with the words "Follow Instructions for Use" accompanied by the following ISO 7010 compatible permanent labels: M002, M004, M009, M013 and M016. A clearly visible permanent label with the words "Restricted RMCPAP for use during COVID-19 pandemic, only to be used for emergency ventilation – any adverse incidents must be reported to MHRA."



10. The size and font of the text on the labels should be appropriate to the size of the RMCPAP. Must include clear labelling of all critical functions and controls using standard terms, pictograms and colours that will be readily recognised by UK healthcare staff.
11. Breathing system inlets and outlets must be clearly marked with direction arrows.
12. A clearly visible permanent label with the words “Manual Back Up Ventilation Must Be Available” in a minimum of 50 point text.
13. Must include clear marks or labels to indicate the default settings of 90-100% oxygen, 400mls tidal volume and / or inspiratory plateau pressure 35 cmH<sub>2</sub>O, 15 cmH<sub>2</sub>O PEEP, rate 20 breaths min<sup>-1</sup>. Pressurised gas input operated RMCPAPs- Oxygen and / or Air.
14. If the RMCPAP is intended to be connected to a 4bar medical gas pipeline system using BS 5682:2015 compatible probes, then oxygen consumption used to drive the RMCPAP shall not exceed 15 L/m averaged over 1 minute.
15. Any transient input flow rate shall not exceed 200 L/m averaged over 3 s. If high-flows (50 – 200 L/m) are used to drive the RMCPAP it should be marked as a “High-Flow RMCPAP”. It should only be connected to a pipeline installation designed using a diversity factor that allows for the indicated high flow at a specified number of terminal outlets, in order to avoid exceeding the pipeline design flow, thereby minimising the risk that the RMCPAP interferes with the operation of adjacent equipment.
16. The inlets for pressurised gases into the RMCPAP must be marked with the gas name or chemical symbol and the rated gas pressure.
17. For a RMCPAP with two or more high-pressure input ports (oxygen and medical air), a means shall be provided to limit reverse gas flowrate (leakage) and cross leakage from gas intake ports into the supply system of the same gas to a flowrate less than 100 ml/min in normal condition or single fault condition.
18. Each high-pressure input port shall be provided with a filter having a pore size less than or equal to 100 µm.

### **RMCPAP test conditions**

19. Connected to gas supplies as specified for normal use • Industrial grade oxygen and air may be substituted for the equivalent medical gas, as appropriate, unless otherwise stated.
20. When using substitute gases, care should be taken to ensure that the test gases are oil free and appropriately dry. If air can be used instead of oxygen without affecting performance this should be done to conserve medical oxygen supplies.
21. Gas flowrate, volume and leakage are expressed as STPD apart from the breathing system which are expressed as BTPS.



## Test Set Up

- Attach the RMCPAP via the intended breathing system to an adult test lung (to protect the sensors from spikes of high pressure) with an electronic RMCPAP tester in series. This should have:
  - A pressure sensor at the connection of the breathing system and the test lung with a 10-90% rise time of  $\leq 10$  ms.
  - A flow sensor between the breathing system and the test lung with a 10-90% rise time of  $\leq 10$  ms.
  - An oxygen sensor (0-100 %  $\pm 1\%$ ) in the inspiratory limb of the breathing system. • (Optional) Place a temperature sensor between the breathing system and the test lung (0-50 oC  $\pm 0.5$  oC
  - Data acquisition from sensors to be  $\geq 200$  samples s<sup>-1</sup>

## Test Schedule

- Connect RMCPAP to medical gases and 240V as required
- Attach a 2m length of 22mm corrugated breathing hose (hoses if required) to the outlets of the RMCPAP using filters if required in clinical use
- Gas should pass from the RMCPAP through the electronic tester to the test lung and PEEP applied either at the test lung or in the flow generator

## Acceptable Performance

- CPAP will be generated at a pressure  $\pm 10\%$  of the set value for set PEEP valves and internal valves in CPAP generators.  $\pm 20\%$  is acceptable for single use PEEP valves
- Under steady-state conditions, the indicated airway pressure shall be accurate to within  $\pm(2 + (4 \% \text{ of the actual reading}))$  cmH<sub>2</sub>O
- Oxygen concentrations will be  $\pm 5 \%$  of the set value
- Continuous gas flow nor flow on demand will be greater than 50 L/m
- Disconnect alarm will sound within 3 seconds of disconnection

## Function Tests (Continuous Flow)

- Set the RMCPAP to maximum flow and minimum oxygen and record flow, pressure and oxygen concentration
- Set the RMCPAP to maximum flow and maximum oxygen and record flow, pressure and oxygen concentration



- Set the RMCPAP to minimum flow and minimum oxygen and record flow, pressure and oxygen concentration
- Set the RMCPAP to minimum flow and maximum oxygen and record flow, pressure and oxygen concentration
- Repeat for at least 5 intermediate steps and record flow, pressure and oxygen concentration

### **Function Tests (Dynamic Flow, Optional)**

- Attach the RMCPAP with its intended breathing system to a breathing simulator through a cuffed endotracheal tube (no leak)
- Set the simulator to 20 breaths per minute of 500 mls
- Set the RMCPAP to maximum flow and minimum oxygen and record flow, pressure and oxygen concentration
- Set the RMCPAP to maximum flow and maximum oxygen and record flow, pressure and oxygen concentration
- Set the RMCPAP to minimum flow and minimum oxygen and record flow, pressure and oxygen concentration
- Set the RMCPAP to minimum flow and maximum oxygen and record flow, pressure and oxygen concentration
- Repeat for at least 5 intermediate steps and record flow, pressure and oxygen concentration
- Repeat through a CPAP mask, repeat through a nasal CPAP mask, repeat through a CPAP hood as required

### **Function Tests (Hood CO<sub>2</sub> removal, Optional)**

- Attach the RMCPAP with its intended breathing system to a breathing simulator fitted with a CPAP hood
- Set the simulator to 20 breaths per minute of 500 mls and an end-tidal CO<sub>2</sub> of 5 kPa
- Set the RMCPAP to maximum flow and minimum oxygen and record flow, pressure and oxygen concentration and inspired CO<sub>2</sub>
- Set the RMCPAP to maximum flow and maximum oxygen and record flow, pressure and oxygen concentration and inspired CO<sub>2</sub>
- Set the RMCPAP to minimum flow and minimum oxygen and record flow, pressure and oxygen concentration and inspired CO<sub>2</sub>
- Set the RMCPAP to minimum flow and maximum oxygen and record flow, pressure and oxygen concentration and inspired CO<sub>2</sub>





- Repeat for at least 5 intermediate steps and record flow, pressure and oxygen concentration and inspired CO<sub>2</sub>

### **Pressure Relief Tests**

- Set the RMCPAP to maximum flow and minimum oxygen, or whichever condition generates the maximum flow
- Set maximum pressure level and alarm (if fitted) to 35 cmH<sub>2</sub>O.
- Occlude the outlet of the breathing system and confirm that the pressure release valve works
- Record maximum pressure reached.
- Set the pressure relief valve to its maximum blow off pressure and confirm that when the outlet is occluded the pressure does not rise above 60 cmH<sub>2</sub>O



## Appendix C Software development requirements for a RMCPAP System.

The authoritative standards for the development of software for medical RMCPAPs are BS EN 62304:2006+A1:2015 Medical RMCPAP software — Software life-cycle processes and BS EN ISO 14971:2012 Medical RMCPAPs – Application of risk management to medical RMCPAPs.

Where possible software for a RMCPAP System should be developed in a facility which has experience of developing software using these standards.

A RMCPAP System incorporating software is likely to be a higher-risk RMCPAP and will almost certainly, before the implementation of software risk control measures (RCMs), have the capability to cause serious injury or death. It is essential any software being developed to an accelerated life cycle applies the following principles:

1. The software is developed under strict process control using a quality management system, ideally BS EN ISO 13485 or BS EN ISO 9001.
2. A process is followed to determine the risks arising from the operation of the software and to mitigate those risks. This is most easily done by the application of BS EN ISO 14971.
3. A software development process is followed to achieve a low probability of failure of the software in use. This is most easily done by the appropriate application of BS EN 62304 based on the risk management process in 2 above.
4. Less emphasis need be placed on the requirements of BS EN ISO 62304 software post-production monitoring and maintenance processes. The minimum steps adhered to are:
  - a. The software development must be planned.
  - b. The system requirements specifications must be translated into software requirements specifications.
  - c. There must be enough software architecture and software design to enable the risks arising from the use of the software to be determined.
5. The risks arising from the operation of the software must be determined and the risk control measures (RCMs) for these risks must be translated into software requirements. Special attention must be paid to any software of unknown provenance or commercial off the shelf software incorporated into the RMCPAP.
6. The implementation and effectiveness of the RCMs must be verified and validated.
7. The verification and validation of the software must be planned and reported on.
8. The outputs of the software must be reviewed against the software requirements prior to the release of the software for clinical use. MHRA will review that the software has been developed under satisfactory control and is safe and effective before use. At least the following artefacts should be produced to aid this review:



- a. Software Development plan.
- b. System and software requirements specifications.
- c. Appropriate software architecture and software design documents.
- d. A risk management plan and report.
- e. Software verification and validation plans and reports.
- f. A software release note.