

APPENDIX 3H

LOT 8 SPECIFICATION

CONTRAST INJECTORS, CONSUMABLES AND ASSOCIATED OPTIONS

1. Introduction

- 1.1. This Lot is for the supply of static contrast injectors designed to deliver pre-programmed contrast volumes.
- 1.2. The core product lines within this Lot are as follows:

Line Number	
1	Angiography Contrast Injector (Variable Rate)
2	Computed Tomography (CT) Contrast Injector (Single Head)
3	Computed Tomography (CT) Contrast Injector (Dual Head)
4	Magnetic Resonance Imaging (MRI) Contrast Injector

- 1.3. Product line(s) must be supplied with a minimum 7 year expected lifecycle under proper use and maintenance.

2. Line 1 – Angiography Contrast Injector (Variable Rate)

- 2.1. This is the core technical specification for an angiography contrast injector (variable rate) suitable for the delivery of pre-programmed contrast volumes.
- 2.2. The core components of an angiography contrast injector (variable rate):
- 2.2.1. Floor, table or ceiling mounted contrast injector.
 - 2.2.2. Hand control.
 - 2.2.3. Touch screen control console.
 - 2.2.4. Safety requirements.
- 2.3. Floor, table or ceiling mounted contrast injector:
- 2.3.1. The contrast injector must have a variable rate single electromechanical syringe piston drive.
 - 2.3.2. The system must be able to be mounted on either a floor pedestal or the patient table.
 - 2.3.3. The initial syringe filling procedure must be semi-automatic or automatic.
 - 2.3.4. The syringe refilling procedure must be semi-automatic or automatic.
 - 2.3.5. Patient tubing must be single use.
 - 2.3.6. The maximum pressure applied must be user selectable.
 - 2.3.7. The maximum pressure available for fixed rate injection must be at least 8.3 MPa (1200 psi).
 - 2.3.8. The maximum flow rate for fixed rate injections must be at least 40 ml/s.

Document #: LEGAL TEMP 810-06		
Revision: 4		Page 1 of 6

- 2.3.9. The minimum flow rate for fixed rate injections must be no greater than 1 ml/s.
- 2.3.10. The maximum flow rate for variable rate injections must be at least 10 ml/s.
- 2.4. The minimum flow rate for variable rate injections must be no greater than 1 ml/s.
- 2.5. The maximum volume must only be restricted by the syringe capacity.
- 2.6. The minimum volume must be no greater than 1 ml.
- 2.7. Hand control:
 - 2.7.1. The hand control must enable single handed control of flow rate and volume.
 - 2.7.2. The hand control must enable the physician to control flow rate in real time.
 - 2.7.3. Variable rate injections must be user controllable with 0.1 ml/s increments.
- 2.8. Touch screen control console:
 - 2.8.1. The control console must be mounted on either a floor pedestal or the patient table.
 - 2.8.2. The control console display must enable the adjustment of injector settings.
 - 2.8.3. The control console must include pre-programmed injection protocols.
 - 2.8.4. The control console must display the user selectable preselected, volume and flow rates.
 - 2.8.5. The flow rate must be selectable in 1ml/s increments.
 - 2.8.6. The volume must be selectable in 1 ml increments.
 - 2.8.7. The rise time must be user selectable.
 - 2.8.8. It must be possible to program multiple stage injection protocols.
 - 2.8.9. The control console must display the actual volume, pressure and flow rates.
 - 2.8.10. The control console must have an injection delay function.
- 2.9. Safety requirements:
 - 2.9.1. The injector, hand control and control console must have protection against the ingress of fluids.
 - 2.9.2. The syringe must be mounted inside a pressure jacket.
 - 2.9.3. The injector must only be armed when all air purging steps are completed.
 - 2.9.4. It must be impossible to start an injection if there is insufficient contrast loaded in the syringe.
 - 2.9.5. It must not be possible to prepare the contrast syringe or saline without purging air.
 - 2.9.6. It must be possible to visually inspect all tubing and the syringe to ensure air bubbles have been eliminated.
 - 2.9.7. The injector must include an air detection mechanism that automatically stops an injection if air is detected in the tubing.

Document #: LEGAL TEMP 810-06		
Revision: 4		Page 2 of 6

- 2.9.8. An injection must be stopped or slowed if the pressure exceeds a user set or automatic threshold.

3. Line 2 – Computed Tomography (CT) Contrast Injector (Single Head)

- 3.1. This is the core technical specification for a CT Contrast Injector (Single Head) suitable for the delivery of pre-programmed contrast volumes.
- 3.2. The core components of a CT Contrast Injector (Single Head):
 - 3.2.1. Floor, table or ceiling mounted single head contrast injector system.
 - 3.2.2. Touch screen control console.
 - 3.2.3. Safety requirements.
- 3.3. Floor, table or ceiling mounted single head contrast injector system:
 - 3.3.1. The contrast injector must have a single electromechanical syringe piston drive.
 - 3.3.2. The injector head must be mounted on either a floor pedestal or a ceiling suspension system.
 - 3.3.3. The injector head must accommodate single patient use syringes.
 - 3.3.4. It must be possible to administer up to 200 ml of contrast.
 - 3.3.5. The syringe filling procedure must be semi-automatic or automatic.
 - 3.3.6. The maximum pressure applied must be user selectable.
 - 3.3.7. The maximum pressure available must be at least 2 MPa (300 psi).
 - 3.3.8. The maximum flow rate must be at least 10 ml/s.
 - 3.3.9. The minimum flow rate must be no greater than 0.1 ml/s.
 - 3.3.10. The maximum volume must only be restricted by the syringe capacity.
 - 3.3.11. The minimum volume must be no greater than 1 ml.
- 3.4. Touch screen control console:
 - 3.4.1. The control console must be positioned next to the CT control console.
 - 3.4.2. The control console display must enable the adjustment of injector settings.
 - 3.4.3. The control console must include pre-programmed injection protocols.
 - 3.4.4. The control console must display the user selectable preselected, volume and flow rates.
 - 3.4.5. The flow rate must be selectable in 0.1ml/s increments.
 - 3.4.6. The volume must be selectable in 0.1ml increments.
 - 3.4.7. It must be possible to program multiple stage injection protocols.
 - 3.4.8. The control console must display the actual volume, pressure and flow rates.
 - 3.4.9. The control console must have an injection delay function.
 - 3.4.10. It must be possible to integrate the console with the CT console.
 - 3.4.11. The control console must record the contrast delivered to the patient for printout if required by the user.
 - 3.4.12. It must be possible to set the injection protocol based upon the study selected on the CT system.

Document #: LEGAL TEMP 810-06		
Revision: 4		Page 3 of 6

- 3.5. Safety requirements:
 - 3.5.1. The injector head must have protection against the ingress of fluids.
 - 3.5.2. It must be impossible to start an injection if there is insufficient contrast loaded in the syringe.
 - 3.5.3. It must be possible to configure the device so that it cannot start an injection unless the CT scanner is ready.
 - 3.5.4. The syringe filling procedure must include an air purge step.
 - 3.5.5. It must be possible to visually inspect a syringe to ensure air bubbles have been eliminated.
 - 3.5.6. It must be impossible to arm the injector unless the air purge step has been completed.
 - 3.5.7. An injection must be immediately stopped if the preselected maximum pressure, volume or flow rate is exceeded.
 - 3.5.8. The system must include a test injection function to ensure injection site patency.

4. Line 3 – Computed Tomography (CT) Contrast Injector (Dual Head/Multi Use)

- 4.1. This is the core technical specification for a CT Contrast Injector (Dual Head/Multi use) suitable for the delivery of pre-programmed contrast volumes.
- 4.2. The core components of a CT Contrast Injector (Dual Head/Multi Use):
 - 4.2.1. Floor, table or ceiling Mounted dual head/multi use contrast injector system.
 - 4.2.2. Touch screen control console.
 - 4.2.3. Safety requirements.
- 4.3. Floor, table or ceiling mounted dual head/multi use contrast injector system:
 - 4.3.1. The injector head must be mounted on either a floor pedestal, patient table or a ceiling suspension system.
 - 4.3.2. The injector head must accommodate single patient use syringes / lines or suitable alternative.
 - 4.3.3. It must be possible to administer up to 200 ml of contrast.
 - 4.3.4. The filling procedure must be semi-automatic or automatic.
 - 4.3.5. The maximum pressure available must be at least 150 psi.
 - 4.3.6. The maximum flow rate must be at least 10 ml/s.
 - 4.3.7. The minimum volume must be at least 1 ml.
 - 4.3.8. A saline flush facility must be available.
- 4.4. Touch screen control console:
 - 4.4.1. The control console must be positioned next to the CT control console.
 - 4.4.2. The control console display must enable the adjustment of injector settings.
 - 4.4.3. The control console must include pre-programmed injection protocols.

Document #: LEGAL TEMP 810-06		
Revision: 4		Page 4 of 6

- 4.4.4. The control console must display the user selectable preselected, volume and flow rates.
- 4.4.5. The flow rate must be selectable in between 0.1 ml/s and 1.0 ml/s increments.
- 4.4.6. The volume must be selectable in in between 0.1 ml/s and 1.0 ml/s.
- 4.4.7. It must be possible to program multiple stage injection protocols.
- 4.4.8. The control console must display the actual volume, pressure and flow rates.
- 4.4.9. The control console must have an injection delay function.
- 4.4.10. The control console must record the contrast delivered to the patient for printout if required by the user.
- 4.4.11. It must be possible to set the injection protocol based upon the study selected on the CT system.

4.5. Safety requirements:

- 4.5.1. The injector head must have protection against the ingress of fluids.
- 4.5.2. It must be impossible to start an injection if there is insufficient contrast loaded in the injection method.
- 4.5.3. The filling procedure must include an air purge step.
- 4.5.4. It must be possible to visually inspect the injection method to ensure air bubbles have been eliminated.
- 4.5.5. It must be impossible to arm the injector unless the air purge step has been completed.
- 4.5.6. An injection must be immediately stopped or automatically altered if the preselected maximum pressure, volume or flow rate is exceeded.
- 4.5.7. The system must include a test injection function to ensure injection site patency.

5. Line 4 – Magnetic Resonance Imaging (MRI) Contrast Injector

5.1. This is the core technical specification for Magnetic Resonance Imaging (MRI) Contrast Injector suitable to deliver pre-programmed contrast volumes.

5.2. The core components of a Magnetic Resonance Imaging (MRI) Contrast Injector:

- 5.2.1. Pedestal or ceiling mounted contrast injector system.
- 5.2.2. Touch screen control console.
- 5.2.3. Safety requirements.

5.3. Pedestal or ceiling mounted contrast injector system:

- 5.3.1. The injector head must not interfere with the operation of the MR system.
- 5.3.2. The injector head must not affect MR image quality.
- 5.3.3. The injector must be safe to use within a room containing a diagnostic 1.5 T or 3.0 T MR system.
- 5.3.4. The injector head must accommodate single patient use syringes / lines.
- 5.3.5. It must be possible to administer at least 50ml of contrast.
- 5.3.6. The syringe filling procedure must be manual or automated.

Document #: LEGAL TEMP 810-06		
Revision: 4		Page 5 of 6

- 5.3.7. The maximum pressure applied must be user selectable.
- 5.3.8. The maximum pressure available must be at least 275 kPa (40 psi).
- 5.3.9. The maximum flow rate must be at least 10 ml/s.
- 5.3.10. The minimum flow rate must be no greater than 0.1 ml/s.
- 5.3.11. The maximum volume must only be restricted by the syringe capacity.
- 5.3.12. The minimum volume must be no greater than 1 ml.
- 5.3.13. A saline flush facility must be available.

5.4. Touch screen control console:

- 5.4.1. The control console must be positioned next to the MR control console.
- 5.4.2. The control console display must enable the adjustment of injector settings.
- 5.4.3. The control console must include pre-programmed injection protocols.
- 5.4.4. The control console must display the user selectable preselected, volume and flow rates.
- 5.4.5. The flow rate must be selectable in 0.1 ml/s increments.
- 5.4.6. The volume must be selectable in 0.1 ml increments.
- 5.4.7. It must be possible to program multiple stage injection protocols.
- 5.4.8. The control console must display the actual volume, pressure and flow rates.
- 5.4.9. The control console must have an injection delay function.
- 5.4.10. The control console must record the contrast delivered to the patient for printout if required by the user.
- 5.4.11. It must be possible to set the injection protocol based upon the study selected on the MR system.

5.5. Safety requirements:

- 5.5.1. The injector head must have protection against the ingress of fluids.
- 5.5.2. The injector must have a built in warning system/failsafe to prevent an injection being started if there is insufficient contrast loaded in the syringe.
- 5.5.3. If the system is battery powered, it must be impossible to commence an injection if there is insufficient power available to complete the study.
- 5.5.4. It must be possible to visually inspect a syringe to ensure air bubbles have been eliminated.
- 5.5.5. It must be impossible to arm the injector unless the air purge step has been completed.
- 5.5.6. The system must include a test injection function to ensure injection site patency.

Document #: LEGAL TEMP 810-o6		
Revision: 4		Page 6 of 6