Alcor A-1497
Case Report

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Alcor A-1497 Case Report Contents:

1. Overview

Information is derived from multiple sources and is all converted to Mountain Standard Time. (Arizona Time)

Ronald Selkovitch, Alcor patient A-1497, was pronounced deceased on 28-Aug-2015, at a hospital in Escondido, California. A team from Suspended Animation (SA) was dispatched to conduct standby assistance for this patient. He received stabilization, washout, and was transported to Alcor Life Extension Foundation (Alcor) by ground transport. Surgery, cephalic isolation, cooling, and vitrification were performed by Alcor's team.

On 07-Sep-2015, a CT scan was performed on patient A-1497's head to assess the post-vitrification status and condition of this patient. The results will be linked to this report on the Alcor website.

His mother and his wife had both earlier been cryopreserved by Alcor, in March 2008 and May 2015 respectively.

2. Personnel

Suspended Animation Team:

Tabitha Carvalho, RN, SA Director of Client Services; SA Standby Team Leader
Sayer Johanson, NREMT; Standby Team Member
Robert Wesley, MD, Ph.D.; Cardiothoracic Surgeon
Amanda Rollins, CCP; Perfusionist

Alcor Team:

Thomas Wolvos, MD; Surgeon
Aaron Drake, NREMT-P, NAEMSE; Surgical Assistant
Hugh Hixon, Cryoprotection Perfusionist; Preps, Cool-Down, and Clean Up
Steve Graber, Assistant Cryoprotection Perfusionist; Preps, Cool-Down, and Clean Up
Jacob Graber, Perfusion System Trainee
Joel Baer, Perfusion System Trainee; Recorder
Jerry Searcy; Clean Up
Marji Klima; Support

Deployment Committee:

Steve Harris, MD, Critical Care Research
Aaron Drake, Medical Response Director, Alcor Life Extension Foundation
Catherine Baldwin, COO, Suspended Animation

3. Medical History

Ronald Selkovitch, Alcor member A-1497 was an 81-year-old man, approximately 6'0" in height and 193 lbs (87.7 kg) in weight.

His health history, as reported, included abdominal surgery to construct an ileostomy on 06-Aug-2015. The patient's son advised that he had undergone a unilateral radical nephrectomy, although this was not in the patient's chart, and it is uncertain which kidney was removed.

His final hospital admission commenced on 30-Jul-2015, with a diagnosis of an epidural abscess. The etiology was not noted. A Do Not Resuscitate order (DNR) was eventually put into place with a directive for comfort measures only. This directive can have many variables, but, in general, indicates that the patient or substitute decision maker has opted out of CPR in the event of cardiac arrest, and other life-saving methods such as intubation.

Patient A-1497 suffered a witnessed cardiac arrest at approximately 0500 hrs on 28-Aug-2015. He was pronounced legally deceased at 0502 hrs. His arrest was witnessed by hospital staff personnel, and he was subsequently stabilized and transported to Alcor by the SA team.

4. Pre-Deployment

Alcor received an emergency text from their TeleMed Emergency Call Center on Wednesday, 26-Aug-2015, at 1221 hrs. This call was conducted by SA, at the request of Alcor's CEO, Dr. Max More, as Alcor's Medical Response Director was on another Alcor case at the time. This text was a callback request from the attending physician, who was in charge of caring for the Alcor patient. The physician reported that the patient had a poor prognosis related to septic shock. Following the call, the Deployment Committee voted to direct SA to commence standby procedures. This directive was based on the patient's reported prognosis, vital signs and diagnosis of sepsis as assessed by the attending physician.

Two SA team members departed SA headquarters at 1323 hrs with their mobile operating vehicle to the patient's hospital in Escondido, California. A surgeon and a perfusionist were also notified and dispatched. While en route to the hospital, the SA team leader contacted multiple funeral facilities near the hospital for assistance with filing the death certificate, acquiring a transit permit for the patient and preparing for the possibility of transporting the patient by air to Arizona. Emphasis was placed on the urgency of the situation and the importance of haste in this matter. They were successful in contracting with one facility who agreed to handle the matter with the necessary urgency.

SA arrived at the hospital at 1530 hrs. The initial meeting was conducted by Tabitha Carvalho, RN, Director of Client Services and Donor Recovery (SA), Sayer Johanson, NREMT (SA), along with the social worker and the charge nurse of the Intermediate Care Unit (IMC) of the hospital. Expected procedures were discussed regarding what would happen as the patient declined and experienced cardiac arrest. This information was also shared with the floor staff who were present. Arrangements were made by the SA team and the floor charge nurse to set up the equipment close to the patient's room. Plans for the most expeditious route from the patient's room to the SA vehicle were then arranged with security staff personnel.

5. Patient Presentation

Initially, the patient was alert with occasional periods of confusion. He was able to follow commands and express discomfort. His blood pressure (BP) was 105/54, heart rate (HR) was 100-115 beats per minute (BPM) with his rhythm being atrial fibrillation. His respiratory rate (RR) was 20 breaths/ minute. He was receiving oxygen via high flow nasal cannula at 20 liters/ min as he had refused any other method of oxygen delivery. His SpO_2 was 99%, and his FiO_2 was 60%. He had generalized pitting edema. His ileostomy was intact, and he had a Foley catheter. His primary nurse felt that he was stable and not in danger of decompensating any further at that time. Vital signs, laboratory results, and medication lists were reported to the Deployment Committee members but were not available for this report.

Based on the patient's stable vital signs and presentation, the standby team departed to a hotel six minutes travel from the hospital. The floor staff members were instructed to contact SA team members if the patient's status changed. The SA team left for the hotel at 2330 hrs.

SA standby team members returned to the patient's bedside at 0830 hrs on 27-Aug-2015. The patient's vital signs remained stable, and this information was relayed to the Deployment Committee members. SA members remained in a waiting area near the patient's room.

6. Standby

On 27-Aug-2015, at 0956 hrs the SA team leader requested documentation from the funeral facility to expedite the removal of the patient after pronouncement and filing of the death certificate.

At approximately 1100 hrs, the SA team met with the patient's son to discuss what would take place related to standby and address any concerns he might have. He advised them that he had spoken to the patient earlier and confirmed his wishes regarding his DNR and end-of-life care. At that point, he changed the patient's medical directives from "all care except intubation" to

"comfort measures only". More specifically, the new directives indicated that all care be withheld except for pain medication. This directive was initiated at 1215 hrs on 27-Aug-2015. At this time, the patient's vital signs were as follows: HR 85 BPM, RR 19, BP 102/68, SpO_2 99% and FiO_2 50%. There was little change in the patient's vital signs throughout the day. The SA team remained on standby overnight in shifts outside the patient's room.

At 2015 hrs there was a noticeable decline in the patient's vital signs. BP was 96/52, RR 6-10, SpO_2 92% with a decreasing level of consciousness (LOC) and increased lethargy. This was conveyed in real time to the Deployment Committee members.

At 0442 hrs on 28-Aug-2015, the patient began experiencing increasing periods of apnea and his SpO_2 declined to 60%. The charge nurse, primary nurse and circulating nurse were called to the patient's bedside as SA team members waited outside the room.

The patient experienced cardiac arrest and was pronounced legally deceased at 0502 hrs on 28-Aug-2015.

7. Stabilization

The following procedures were captured with a digital video camera from 0502 hrs to 0556 hrs. Some of the points covered in the "Case Issues and Actions" are based on concerns viewed on the video.

The SA team began medication administration with Propofol 200 mg, and Heparin 100,000 IU via an existing peripherally inserted central catheter line (PICC). Due to the patient's weight, assistance was required to transfer the patient to the ice bath from the hospital bed. Hospital staff members assisted. Once inside the portable ice bath (PIB), chest compressions were initiated with the AutoPulse® CPS device. The patient's head was covered with ice and ice water was re-circulated over him using the SA cooling mask and tubing circuit.

All necessary transport documentation had been previously completed; the patient was then transferred to the waiting SA vehicle at the back entrance of the hospital.

In the first 13 minutes post-pronouncement, SA administered Aspirin 300 mg with THAM, Vasopressin 200 IU, THAM 100 mL and Vital-Oxy 150 mL in saline via the existing PICC line inside the elevator of the hospital. The patient reached the SA vehicle at approximately 0515 hrs.

In the following 32 minutes, airway management was established via intubation and the patient was placed on a ventilator. Intraosseous (IO) access was obtained in the left tibia. Through this access point, Sodium Citrate 10 g, Gentamicin 80 mg, L-Kynurenine Sulfate 1.5 g, S-

Methylthiourea 400 mg, Niacinamide 500 mg, Streptokinase 250 000 units, and Epinephrine 1 mg were administered. High volume medications were administered via the IO access point. A manual reading of nasopharyngeal temperature at 0530 hrs was 26.0 ºC. Maalox was omitted due to the initiation of surgery.

8. Field Washout

The thoracic surgeon scrubbed in and prepped for surgery while the above-mentioned medications were being administered. Cardiopulmonary support (CPS) was stopped at 0528 hrs. At 0529 hrs the first incision was made in the chest. At 0534 hrs the sternum was divided with a battery-powered oscillating saw. The pericardium was opened, and cardiac structures were found to be essentially normal in appearance.

A stab wound was made in the distal ascending aorta and a 24 Fr. arterial cannula was inserted and secured with an aortic purse-string suture using 2-0 silk, and sutured to the chest wall. An opening was made in the right atrial appendage, and a large two-stage venous catheter was inserted and advanced into the inferior vena cava (IVC). This cannula was secured with a 2-0 silk atrial purse string suture. The cannulas were connected to the Cardiopulmonary Bypass System (CPB), and perfusion was initiated.

Exsanguination and perfusion with MHP2 organ preservation solution of 317 milliosmoles per kg (mOs/kg) (SA formulation) started at 0548 hrs. A manual reading of nasopharyngeal temperature was 25.4 ºC. Although the perfusate had been kept on ice most of the night, it was set up and the circuit primed when the patient began presenting with agonal symptoms. Ambient temperatures were unusually high, causing the perfusate to warm up. There was minimal pre-cooling of the circuit before the patient went on bypass. A manual arterial side reading was 21.4 ºC. Good flow was observed.

Perfusion was interrupted at 0551 hrs to change a loose venous connection, and the patient was placed back on bypass at approximately 0553 hrs. At approximately 0603 hrs perfusion was interrupted to connect the second bag of MHP2. (Bags are 15 liters) The nasopharyngeal temperature at this time was 24.4 ºC and the arterial circuit temperature was 13.3 ºC.

After clear venous effluent was observed, the patient circuit was closed, and recirculation started at 0629 hrs. The nasopharyngeal temperature was 18.8 ºC. Arterial circuit temperature was 10.8 ºC. Peak flow rate observed was 2.7 L/min and the lowest flow rate was 2.0 L/min. Initial perfusion pressure was averaged at 186 mmHg and the pressure during closed circuit was averaged at 196 mmHg. The SA team continued to give the remainder of the Mannitol and Hespan during the closed circuit.

The SA vehicle experienced a brief power interruption at 0638 hrs. Perfusion and surgical lighting were maintained with battery backup power; however the bypass heat exchanger pump power failed. Power was restored at 0646 hrs. There was a second power interruption of the SA vehicle at 0705 hrs. Power was again restored at 0709 hrs.

At approximately 0707 hrs, a sterile probe designed for circuit use was placed inside the chest cavity near the heart as an experiment to try to explain the persistently high arterial side circuit temperature readings as well as the disparity between arterial temperature readings and nasopharyngeal temperature readings. The nasopharyngeal temperature was 12.4 ºC. Arterial circuit temperature was reading 13.0 ºC and chest probe temperature was 6.1 ºC. Although the probe used was not designed for this purpose, the disparity between the temperatures suggested that the arterial circuit temperature readings were possibly inaccurate, perhaps by as much as 6 ºC.

At 0716 hrs the experimental probe was moved from the heart area to a position just above the diaphragm for a rough assessment of abdominal temperature. Temperature readings here were 11.3 ºC. Additional ice and 91% alcohol solution were added to the perfusion heat exchanger/ cooling bath to facilitate further cooling.

The perfusion pump was shut off at 0724 hrs. All 30 L of MHP2 organ preservation solution were used. The nasopharyngeal temperature was 10.5 ºC. The surgeon disconnected the circuit from the patient, removed the cannula, and the vessels were ligated. The sternum was re-approximated with four 6- Steel wires, followed by closing with 3-0 Prolene sutures and staples for the skin.

9. Transport

While patient A-1497 was undergoing surgery and perfusion, the funeral director filed the patient's death certificate and applied for a transit permit. Alcor's Medical Response Director indicated that the patient did not have additional funds for private air transport. The decision was made to drive the patient to Alcor as this would be faster than waiting 3-4 hours for the transit permit to be issued with additional delays in shipping and receiving the patient on a commercial air flight.

Additional ice was placed over and around the patient and preparations made for the six-hour drive to Alcor.

10. Cryoprotective Surgery and Perfusion

Ronald Selkovitch arrived at Alcor at 1525 hrs on 28-Aug-2015. The patient was transferred from the PIB to the Alcor gurney which had a wrap-around body bag prepared with a bed of ice and a cushion to elevate the patient's shoulders. The issue with the van's ambient temperature contributed to there being a large amount of water from melted ice remaining in the vehicle which was a challenge to control.

At 1545 hrs the transfer into Alcor was complete. The nasopharyngeal temperature was 1.7 ºC. The thermocouple sewn into the chest was reading 13.4 ºC. At the beginning of the perfusion, it was noted that the patient's brain was noticeably shrunk (>0.5 cm).

The right sided burr hole was initiated at 1557 hrs, and it took two minutes to complete. Concurrently, at 1559 hrs, the left burr hole was initiated. It took one minute to complete. The burr holes were then further enlarged and prepared using a rongeur instrument. At 1604 hrs a thermocouple was placed into the left burr hole and was sutured by the surgeon to secure it. Nasopharyngeal readings taken at 1607 hrs indicated a temperature of 2.4 ºC with a chest thermocouple reading of 13.1 ºC.

At 1609 hrs the patient's neck was cleansed with alcohol, and then at 1610 hrs the surgeon made the first incision on the left side of the anterior neck to identify the carotid artery while the surgical assistant worked on identifying the carotid artery on the right side. By 1631 hrs both the left and right carotid arteries were identified and isolated.

At 1634 hrs the patient's cephalon was separated from his trunk using an osteotome and a mallet. By 1636 hrs the cephalon was fully isolated. The nasopharyngeal temperature was 4.0 ºC and the chest thermocouple was reading at 11.8 ºC. The cephalon was moved into the neuro ring and secured at 1639 hrs.

At 1645 hrs the right carotid artery was cannulated with an 18 Fr. catheter, followed by a 14 Fr. catheter in the left carotid artery. By 1700 hrs, both carotids were open and connected. The left and right vertebral arteries were identified, isolated and clamped.

At 1702 hrs the pressure was increased to 100 mmHg. At 1712 hrs the ramp was turned on. The mixing reservoir volume was 900 mL. At 1714 hrs the fluid flowing from the right sided jugular vein was noted at 9.57 Brix.

At 1720 hrs the refractometer line was fed into the left jugular vein. By 1730 hrs the mixing reservoir volume was at 900 mL. By 1740 hrs the out valve for the circulatory reservoir was clamped.

The out valve for the circulatory reservoir was unclamped at 1747 hrs. The mixing reservoir volume had risen from 900 mL at the last measurement to 1370 mL.

At 1800 hrs circulatory reservoir volume was measured at roughly 1200 mL. It was noted that the reason that it had decreased was because the out tube was unclamped and there was some fluid noted in the tray. The out tube was then re-clamped. At 1801 hrs the out valve unclamped volume was roughly 1340 mL. By 1815 hrs the mixing reservoir volume was measured at roughly 1300 mL. Measurements taken at 1830 hrs had a mixing reservoir volume of approximately 1360 mL.

At 1836 hrs it was observed that the right cornea of the patient had become concave from dehydration. The left cornea was noted to be still convex in shape. The brain, especially on the right side was noted to be retracted.

At 1842 hrs the box was opened to insert a second nasopharyngeal probe to confirm the accuracy of the primary nasopharyngeal probe. By 1845 hrs circulatory reservoir volume was at 1375 mL.

At 1900 hrs circulatory reservoir volume was 1260 mL, the M22 reading was 8900 mL, and the effluent level was roughly 2200 mL. The tubing for the addition of M22 had unexpectedly been pulled above the liquid on the M22 reservoir which affected the readings of the M22 addition.

At 1914 hrs the ramp was paused. 30.6 Brix on the left jugular vein and 31.4 Brix on the right jugular vein had been reached.

At 1915 hrs the left cornea was observed to have become concave from dehydration, and by 1916 hrs circulatory reservoir volume was at 1260 mL, the M22 volume was roughly at 8600 mL, and the effluent volume was roughly 2500 mL. The box temperature was set to -3 ºC at 1923 hrs.

At 1930 hrs the ramp was restarted. Circulatory reservoir volume was 1190 mL, M22 volume was at 8450 mL, and the effluent volume was at 2600 mL. The system pressure was observed to be 18 psi at 1932 hrs. At this point, the second filter was opened. A test for lateralization of perfusate flow to the brain was initiated at 1939 hrs by clamping the right cannula and placing all flow through the left cannula. After two minutes to allow the pump speed to settle, the right cannula was unclamped. After allowing the pump speed to settle back to its prior level using both cannulas, by 1934 hrs, the procedure was repeated by clamping the left cannula. Interpretation of the results of this test was compromised by the use of a 14 Fr. cannula for the left carotid artery.

At 2006 hrs the dump was off. The circulatory reservoir volume reading was at roughly 1000 mL. By 2015 hrs the circulatory reservoir volume was at roughly 960 mL, the M22 was at roughly 6000 mL, and the effluent level was roughly at 4600 mL.

At 2020 hrs the right venous Brix had reached 50.3. Circulatory reservoir volume was roughly 870 mL, the M22 was at 6000 mL, and the effluent level was at 4600 mL. The ramp was turned back on at 2043 hrs.

The 2045 hrs readings were as follows: Circulatory reservoir volume 1120 mL, M22 volume at 5700 mL and effluent level at approximately 4900 mL. The ramp was turned back off at 2053 hrs.

At 2115 hrs an issue was noted with the left refractometer. It no longer seemed to be producing correct readings. It was reading about 3 Brix below what was expected. The reading was 47.18 Brix. A manual reading was done, and it was found to be 50.2 Brix. From this point forward, Alcor staff members used manual readings in place of this device. Protocols required another 30 minutes at 50.3 Brix. As an experiment, the refractometer feeds were switched so that the left side was feeding into the right side and the right side was feeding into the left side. This seemed to have resolved the problem with the left venous refractometer readings and subsequently the reading of the left side was 53.25 Brix and of the right side was 53.5 Brix.

At 2120 hrs mortuary personnel arrived to pick up the patient's trunk, excluding the cephalon.

The procedure was stopped at 2121 hrs based on the new refractive index readings of 53.38 and 53.58. From these results, it was extrapolated that a Brix of over 50.3 for greater than 30 minutes was achieved. The volume readings for the concentrate bottle were 4600 mL, the effluent was 5400 mL and about 500 mL was disposed of into the dump.

A total of 15 liters of B1 was used and 6.6 liters of M22 x 1.25

Cooldown was initiated at 2135 hrs, plunging to -110C and descending thereafter at -1C/hour to LN2. The cooldown was uneventful.

11. Timelines *(Mountain Standard Time/ Arizona Time)*

Notification:

26-Aug-2015

1221 hrs TeleMed notified Alcor of a call from the patient's attending physician.

1255 hrs Alcor's Deployment Committee informed and authorized SA to deploy to the patient's location.

1323 hrs The SA team departed with the vehicle to the hospital.

1530 hrs The SA team arrived at the hospital and met with hospital representatives.

2330 hrs The SA team retired to the hotel, a six-minute drive from the hospital.

27-Aug-2015

0830 hrs The SA team returned to the patient's bedside.

0956 hrs The SA team leader requested documents from the funeral facility.

1100 hrs The SA team met with the patient's son to discuss his standby and DNR status.

1215 hrs The patient's status was changed to DNR with comfort measures only.

2015 hrs The patient's vital signs began to decline visibly.

28-Aug-2015

0442 hrs There was further decompensation in the patient's status with increased apneic periods and decreasing SpO_2.

0500 hrs The charge nurse, float nurse and primary nurse were at the patient's bedside.

Stabilization and Transport: *(from notes and integrated video data)*

August 28, 2015

0502 hrs 0:00:00 (video timer)
The patient experienced cardiac arrest and was pronounced legally deceased.

0503 hrs 0:01:37
An SA team member poured water from a 5-gallon container into the ice bath, while the team leader was preparing to push medications.
Heparin 100,000 units and Propofol 200 mg were administered via the existing PICC line.

0505 hrs 0:03:07
The team, including the hospital staff, performed a five-person transfer of the patient from the hospital bed to the ice bath.

0506 hrs 0:03:58
The AutoPulse® was attached to the patient.

0506 hrs 0:04:13
The AutoPulse® straps were undone to remove the gown and the bed sheet from under the patient. The patient was log rolled to remove the bed sheet.

0507 hrs 0:04:58
The team and two nurses were still working to remove the bed sheet. The team leader then poured the first bag of ice on the patient.

0508 hrs 0:06:00
The AutoPulse® was started, establishing cardiopulmonary support/ circulation (CPS) via mechanical CPR.
The cooling mask for the Surface Cooling Convection Device (SCCD) was applied, and ice water began circulating over the patient.
Two more bags of ice were added to the ice bath

0510 hrs 0:07:53
The team leader made the decision to move the patient. The team gathered the kits and began pushing the ice bath with the patient into the hospital ward hallway.

0512 hrs 0:09:45
Aspirin 300 mg, Vasopressin 200 IU, and THAM 100 mL were administered via the PICC line.
The team was now in the elevator with the patient.

0513 hrs 0:11:37
The AutoPulse® stopped working

0514 hrs 0:11:57

Vital-Oxy 150 mL in normal saline was administered via the PICC line.
The patient was brought inside the SA vehicle.

0518 hrs 0:15:51
The patient was intubated with a Combitube double-lumen airway.
The surgeon began prepping the patient for surgery.

0519 hrs 0:17:00
The AutoPulse® failure was noticed.

0:17:38
The AutoPulse® was restarted with a new battery.

0520 hrs 0:18:05
A team member attached a bag-valve mask to the Combitube and made a partial attempt to ventilate the patient twice. He then disconnected the bag.

0525 hrs 0:22:58
The nasopharyngeal (NP) probe was inserted.
More ice was applied to the patient's head.

0527 hrs 0:24:49
The patient was placed on a Simplified Automatic Ventilator (SAVe).
Vasopressin was given and the patient prepared for surgery.
The perfusionist turned on the ventilator.

0528 hrs 0:26:14
Circulation was discontinued as the AutoPulse® was stopped for surgery.
The surgeon cleansed the surgical site.
The team leader initiated IO access in the left tibial plateau.

0529 hrs 0:27:26
Streptokinase 250,000 units were administered via the IO access.
The surgeon began to open the patient's chest.
S-Methylthiourea 400 mg was administered via the IO access.

0530 hrs 0:28:12
The first dose of Epinephrine 1 mg was administered via the IO.
Gentamicin 80 mg was given via the IO.
Niacinamide was given IO with the use of a filter on the syringe.
A manual reading of nasopharyngeal temperature was 26.0 ºC.

0531 hrs 0:29:08
Sodium Citrate 10 g was administered via the IO.

0532 hrs 0:30:14

The surgeon attempted to separate the sternum with the bone saw. He experienced some difficulties with the bone guard on the saw.

0533 hrs 0:30:53
Epinephrine 1 mg was administered via IO

0:31:13
L-Kynurenine 1.5 g was administered via IO. It was quite hard to push.
There was no circulation at the time due to surgery.

0534 hrs 0:32:48
The surgeon used a chest retractor to separate the ribcage.

0537 hrs 0:35:04
Epinephrine 1 mg was administered via the IO.

0:35:47
The THAM administration was complete.

0538 hrs 0:36:50
More ice was added to the head of the ice bath.
L-Kynurenine 60 cc was pushed via the IO.
Nasopharyngeal temperature = 25.4 ºC. Arterial circuit temperature = 21.4 ºC.

0540 hrs 0:38:01
Epinephrine 1 mg was administered IO.

0541 hrs 0:38:58
The surgeon attempted to suction the chest cavity using a Yankeur and a portable suction device.

0542 hrs 0:40:10
Nasopharyngeal temperature = 24.9 ºC. Arterial circuit temperature = 13.8 ºC.

Ketorolac 0.25 mL was administered.

0544 hrs 0:42:20
Epinephrine 1 mg was administered IO.

0548 hrs 0:46:13
Epinephrine 1 mg was administered IO.
The surgeon was suturing cannulas into the chest, and bypass/ washout was established with venous and arterial cannulae inserted.

Video 2 (clock reset)

0550 hrs 0:00:54

The chest was suctioned of blood.

0551 hrs 0:01:48
Bypass was stopped to change a loose venous connection.

0552 hrs 0:03:30
The surgeon ordered that the ventilator be turned off.

0553 hrs 0:04:10
The patient was placed back on bypass.
Nasopharyngeal temperature = 24.3 ºC. Arterial circuit temperature = 13.3 ºC.
Epinephrine 1 mg was administered.

0554 hrs 0:05:22
The camera stopped.

End of Video

0603 hrs Second 15 L bag of MHP2 initiated.
Additional ice and isopropyl alcohol added to heat exchanger bath.

0607 hrs Nasopharyngeal temperature = 22.9 ºC. Arterial circuit temperature = 11.8 ºC.

0621 hrs SA updated Alcor on the status of the patient.

0629 hrs The washout was completed.
MHP2 recirculation started.
Vital-Oxy administered by perfusionist.
Nasopharyngeal temperature = 18.8 ºC. Arterial circuit temperature = 10.8 ºC.
Continued the administration of high volume medications, Mannitol, and Hetastarch.

0633 hrs Nasopharyngeal temperature = 18.0 ºC. Arterial circuit temperature = 11.3 ºC.

0638 hrs The power was interrupted.

0640 hrs Nasopharyngeal temperature = 16.9 ºC. Arterial circuit temperature = 12.3 ºC.
Heat exchanger bath drained to add more ice and alcohol.

0644 hrs SA discussed the option of driving vs. flying to get patient to Alcor. The decision was made to drive.

0646 hrs The power was restored.

0652 hrs Nasopharyngeal temperature = 14.8 ºC. Arterial circuit temperature = 9.7 ºC.

0705 hrs The power was interrupted.

0707 hrs Nasopharyngeal temperature = 12.4 ºC. Arterial circuit temperature = 13.4 ºC. A chest probe was added experimentally, reading a temperature of 5.6 ºC.

0709 hrs The power was restored.

0710 hrs Nasopharyngeal temperature = 11.7 ºC. Arterial circuit temperature = 11.5 ºC. Alcohol and ice were added to the ice bath and the heat exchanger/ cooling bath.

0716 hrs Chest probe moved from near the heart to just above the diaphragm. Temperature = 11.3 ºC.

0717 hrs Nasopharyngeal temperature = 10.6 ºC. Arterial circuit temperature = 11.5 ºC. Chest temperature = 12.0 ºC.

0719 hrs Nasopharyngeal temperature = 10.8 ºC. Arterial circuit temperature = 12.0 ºC. Chest temperature = 7.3 ºC.

0722 hrs Nasopharyngeal temperature = 10.6 ºC. Arterial circuit temperature = 12.3 ºC. Chest temperature= 7.7 ºC.

0724 hrs Recirculation ended. Nasopharyngeal temperature = 10.5 ºC. Arterial circuit temperature = 12.4 ºC. Chest temperature = 7.7 ºC.

Timeline at Alcor *(From notes and audio recording by A. Drake, S. Graber, J. Baer, H. Hixon; no video provided. Volumes listed are approximate)*

1525 hrs Patient A-1497 arrived at Alcor.

1545 hrs Transfer from vehicle to inside building complete. Nasopharyngeal temperature = 1.7 ºC. The thermocouple was sewn into the chest = 13.4 ºC.

1557 hrs Right burr hole initiated.

1559 hrs Right burr hole completed; left burr hole initiated.

1600 hrs Left burr hole completed.

1601 hrs Burr holes cleaned with rongeur instrument.

1604 hrs Thermocouple placed in the left burr hole.

1607 hrs Nasopharyngeal temperature = 2.4 °C; chest thermocouple = 13.1 °C.

1609 hrs	Patient's neck prepped with alcohol.
1610 hrs	Left side of patient's neck accessed to identify carotid arteries.
1631 hrs	Left and right carotid arteries identified and isolated.
1634 hrs	Cephalic separation underway.
1636 hrs	Cephalon fully isolated. Nasopharyngeal temperature = 4.0 °C. Chest thermocouple temperature = 11.8 °C.
1639 hrs	Patient's cephalon moved to the neuro ring and secured.
1645 hrs	Cannulated right carotid artery. Patient placed on the pump.
1700 hrs	Both carotid arteries open and connected. Left and right vertebral arteries clamped.
1702 hrs	Pressure of perfusate in the line was increased to 100 mmHg.
1703 hrs	M22 initiated via a pump.
1712 hrs	Ramp initiated. Circulatory reservoir volume 900 mL, M22 (cryoprotectant) volume = 2000 mL with a concentration of 1.00 (100%), effluent volume = 0 mL.
1714 hrs	Right venous jugular outflow = 9.57 Brix.
1720 hrs	Refractometer placed in left jugular vein.
1730 hrs	Circulatory reservoir volume = 0.9 liters, M22 volume = 1660 mL, effluent volume = 0.3 L.
1740 hrs	Out valve for circulatory reservoir clamped.
1747 hrs	Out valve for circulatory reservoir unclamped. The volume rose from 0.9 L at the last measurement to 1.37 L. Circulatory reservoir volume = 1.37 L, M22 volume = 1380 mL, effluent volume 0.6 L.
1800 hrs	Circulatory reservoir volume = 1.2 L. *Note: It decreased because the out tube was unclamped and there was some in the tray. It was re-clamped. M22 volume = 1060 mL, effluent volume = 0.9 L.

1801 hrs	Out valve for circulatory reservoir unclamped. Circulatory reservoir volume = 1.34 L.
1815 hrs	Circulatory reservoir volume = 1.3 L; M22 volume = 745 mL; effluent volume = 1.2 L.
1830 hrs	Circulatory reservoir volume = 1.36 L, M22 volume was 430 mL, effluent volume = 1.55 L.
1836 hrs	On observation, the right cornea appeared dehydrated, the left cornea did not. The brain appeared retracted; more on the right side than the left.
1842 hrs	Inserted a second nasopharyngeal probe to confirm temperature readings were accurate.
1845 hrs	Circulatory reservoir volume = 1.375 L, M22 volume = 115 mL, effluent volume = 1.85 L.
1900 hrs	Circulatory reservoir volume = 1.26 L, M22 volume = 8900 mL, effluent volume = 2.2 L.
1910 hrs	Ramp was paused as a Brix of 3.6 was reached on the left venous system and 31.4 Brix on the right venous system.
1915 hrs	On visualization, the left cornea appeared dehydrated.
1916 hrs	Circulatory reservoir volume = 1.26 L, M22 volume = 8600 mL, effluent volume = 2.5 L.
1923 hrs	The box temperature was set to -3 °C.
1930 hrs	The ramp was restarted. Circulatory reservoir volume = 1.19 L, M22 volume = 8450 mL, effluent volume = 2.6 L.
1932 hrs	System pressure = 18 psi; the second filter was opened.
1945 hrs	Circulatory reservoir volume = 1.4 L, M22 volume = 6750 mL, effluent volume = 4.2 L.

1951 hrs The ramp was turned off. When the dump was open, the volume was still increasing in the reservoir.

2002 hrs Circulatory reservoir volume = 1.17 L, M22 volume = 6000 mL, effluent volume = 4.6 L.

2015 hrs Circulatory reservoir volume = 0.96 L, the M22 volume = 6000 mL, effluent volume = 4.6 L.

2020 hrs The right venous system reached 50.3 Brix. Circulatory reservoir volume = 0.87 L, M22 volume = 6000 mL, effluent volume = 4.6 L.

2043 hrs The ramp was turned back on.

2045 hrs Circulatory reservoir volume = 1.12 L, M22 volume = 5700 mL, effluent volume = 4.9 L.

2053 hrs The ramp was turned back off.

2120 hrs Mortuary staff arrived to retrieve the patient's trunk.

2121 hrs End of cryoprotection process based on a refractive index reading of 53.38, 53.58 Brix.

2135 hrs Began cooldown.

2253 hrs Completed basic clean-up.

September 1, 2015

0919 hrs Cooldown ended.

September 5, 2015

1121 hrs Cephalon placed in neurocan.

September 7, 2015

1620 hrs CT scan obtained of the patient's cephalon.

September 16, 2015

1200 hrs Debriefing of case actions with Alcor and SA teams.

Summary:
(hh:mm)

00:14	Pronouncement to the beginning of surgery (median sternotomy)
00:12	Surgery to the beginning of washout
01:27	Washout and cooling
01:53	The end of washout to departure from Escondido
06:38	Travel time from Escondido to Scottsdale
01:47	Arrival to being placed on the pump (surgery)
04:36	Perfusion
00:14	The end of cryoprotection to the beginning of cooldown
11:44	Pronouncement to the beginning of perfusion
16:34	Pronouncement to the beginning of cooldown

13. Case Issues & Actions

Stabilization:

Issue: Perfusate removed from cooler too soon. **(SA)**

Corrective Action: Maintain perfusate on ice until patient enters vehicle.

Issue: Maalox not given due to start of surgery. **(SA)**

Corrective Action: No corrective action.

Issue: Saw blade was on the wrong side based on the surgeon's preference. **(SA)**

Corrective Action: Clarify with surgeon preference for blade position.

Issue: Faulty suction machine battery. **(SA)**

Corrective Action: Replaced with a new battery on September 11, 2015.

Issue: No venous circuit temperature probe placed. Arterial circuit probe may have been placed incorrectly. **(SA)**

Corrective Action: Request that perfusion contractor provides immediate in-service to perfusionist and surgeons on probe use and temperature monitoring.

Issue: Unusually high ambient temperature which required maximum cooling from vehicle and auxiliary air conditioning units creating exceptionally high loads on vehicle power systems. This caused the safety breakers to trip twice.
(SA)

Corrective Action: SA will install a higher idle switch on the vehicle to increase engine RPM needed to compensate for load and prevent future power outage. Additional battery powered backup heat exchanger pump was added 11-Sep-2015.

Issue: AutoPulse® shut off after five minutes of operation which went unnoticed for six minutes, with four team members present, while medications were administered without circulation. CPS was restored after 6 minutes of warm circulatory arrest. **(SA)**

Corrective Action: Immediate re-education of staff regarding the importance of circulation and manual chest compressions in the absence of the AutoPulse®.
SA team members were retrained and retested on CPS, medication administration and ice protocols, November 2015.

Issue: Medications administered without circulation, before the AutoPulse® was initiated, 6 minutes after cardiac arrest. The previous issue was not recognizing that the AutoPulse® had failed and giving medications regardless. This issue involves the time from pronouncement to CPS initiation when medications were pushed without any effort to circulate them. **(SA)**

Corrective Action: Emphasize the importance of circulation when medications and ventilation are being administered. Without circulation, neither is providing any benefit.
Immediate re-education of team members regarding the importance of circulation and manual chest compressions in the absence of the AutoPulse® is suggested.
SA team members were retrained and retested on CPS, medication administration and ice protocols, November 2015.

Issue: Very little ice was placed on the patient during CPS. The temperature of the brain would be controlled by the temperature of the blood during CPS, which is controlled by the temperature of all heat-exchange areas of the body. At least 100 lbs of crushed ice should be kept in coolers during standby, and used on the patient. **(SA)**

Corrective Action: SA team retrained and retested November 2015.

Issue: The patient was not intubated for 15:51 minutes, after his face was saturated with ice water, negating the airway protection offered by the intubation process. Intubation was not verified with ventilation/ auscultation or $EtCO_2$ output. **(SA)**

Corrective Action: SA team retrained and retested November 2015.

Issue: Despite intubation at the 15:51 minute mark post-arrest, the patient was not ventilated for another 9 minutes post intubation. **(SA)**

Corrective Action: SA team retrained and retested November 2015.

Issue: The SA team demonstrated either a poor understanding of, or poor compliance with creating a sterile field for surgery. There were multiple breaches of technique demonstrated throughout the video. **(SA)**

Corrective Action: The SA team would benefit from re-education on sterile fields in austere environments.

Issue: SA team members pushed boluses of epinephrine every 3 minutes without CPS, indicating a knowledge deficit regarding the purpose of epinephrine, which is to support blood pressure during CPS. **(SA)**

Corrective Action: SA team retrained and retested November 2015.

Issue: The surgical time spent in warm ischemia to put the patient on bypass was 20 minutes. If the surgery is going to take longer than 5 minutes to establish bypass, rules need to be set for minimum CPS cooling times and maximum temperatures at which stopping CPS for surgery is permissible. There is a need to rely on CPS to cool the patient to a temperature at which 20 minutes of circulatory arrest is safer than normothermic circulatory arrest. **(Alcor & SA)**

Corrective Action: No corrective action indicated.

Issue: Alcohol was added to the ice water bath of the perfusate heat exchanger to speed cooling. The expected result of adding alcohol to an ice water bath would be to lower the temperature below 0° C. This might carry the risk of freezing the perfusate in the heat exchanger if perfusion must be stopped. **(SA)**

Corrective Action: No corrective action indicated.

Issue: Between declaration of legal death and beginning of blood washout, the patient spent a total of 14 minutes on CPS, and 32 minutes in warm circulatory arrest (ischemia). This is likely why the patient's brain didn't completely vitrify according to the written CT scan report. Sodium citrate was given 30 minutes post-arrest. It needs to be given immediately after CPS is started to facilitate blood washout and CPA perfusion according to 21CM Medicine research. **(SA)**

Corrective Action: SA's protocol lists sodium citrate as the second medication to be administered. The team was re-educated on this protocol, including labeling, placement and administration order of medications, November 2015.

Transportation:

Issue: As ambient Arizona temperatures exceeded 40 ºC, the interior vehicle temperature exceeded 26 ºC, melting ice that was on the patient as fast as it could be applied. **(SA)**

Corrective Action: Replace ice bath liner with higher insulation material and possible top closure.

Alcor Surgical Perfusion:

Issue: Differential pumping of arterial and venous return lines. **(ALCOR)**

Corrective Action: Clamp arterial line into the pump. This works most quickly when the main pump is left on the computer control and goes to maximum speed.

Issue: The chiller was throwing temperature spikes. Could the solenoid valve be sticking? **(ALCOR)**

Corrective Action: No corrective action indicated.

Issue: There was a problem with the refractometer windows becoming obscured. **(ALCOR)**

Corrective Action: Flushing the windows helped. Swapping the feeds demonstrated that the problem was in the refractometer.

Issue: Left-right flow check showed more resistance on the left side which may or may not be related to the cannula. **(ALCOR)**

Corrective Action: No further corrective action.

Issue: The team was selectively occluding the left and right cannulae during neuro perfusions to quantify differential flow. The issue was that depending on circuit capacitance and the degree of flow lateralization,

suddenly clamping one of the cannulae while the system is pumping at a rate generating 100 mmHg through both cannulae could spike the pressure to hundreds of millimeters in the remaining open cannula. **(ALCOR)**

Corrective Action: When quantifying the flow rate through a single cannula, one wants to see what the flow is as the target perfusion pressure is increased, not see what it is after spiking the pressure. If doing this, either greatly reduce the set point pressure, or briefly stop perfusion before starting.

Issue: The SA nasopharyngeal probe gave a high reading in the data collection system. There was some improvement with Alcor's TC but pharyngeal temperature lagged behind venous temperatures. **(ALCOR)**

Corrective Action: No corrective action.

Issue: The cool-down plot for the plunge indicated the possibility of minor ice formation in the pharyngeal area. **(ALCOR)**

Corrective Action: No corrective action.

Issue: The CT scan performed on September 7, 2015, showed significant cerebral shrinkage but incomplete perfusion of the center of the brain. **(ALCOR)**

Corrective Action: Continual process improvement with all Alcor and SA cases.

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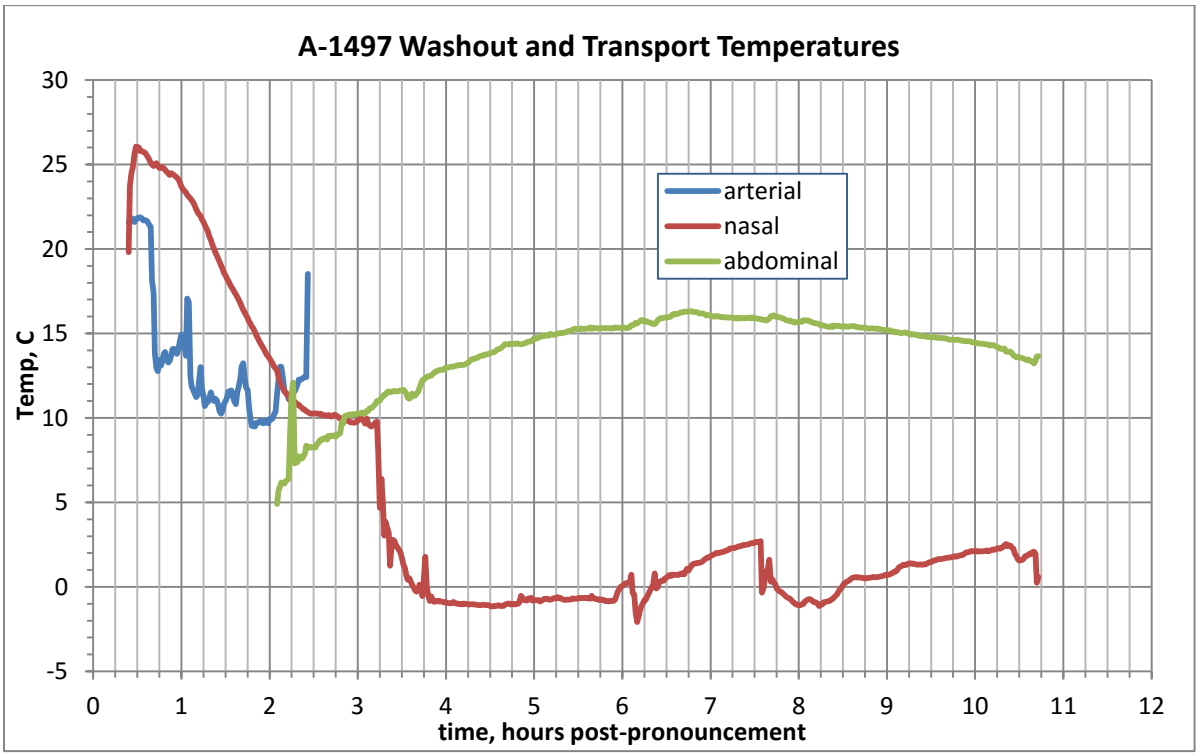
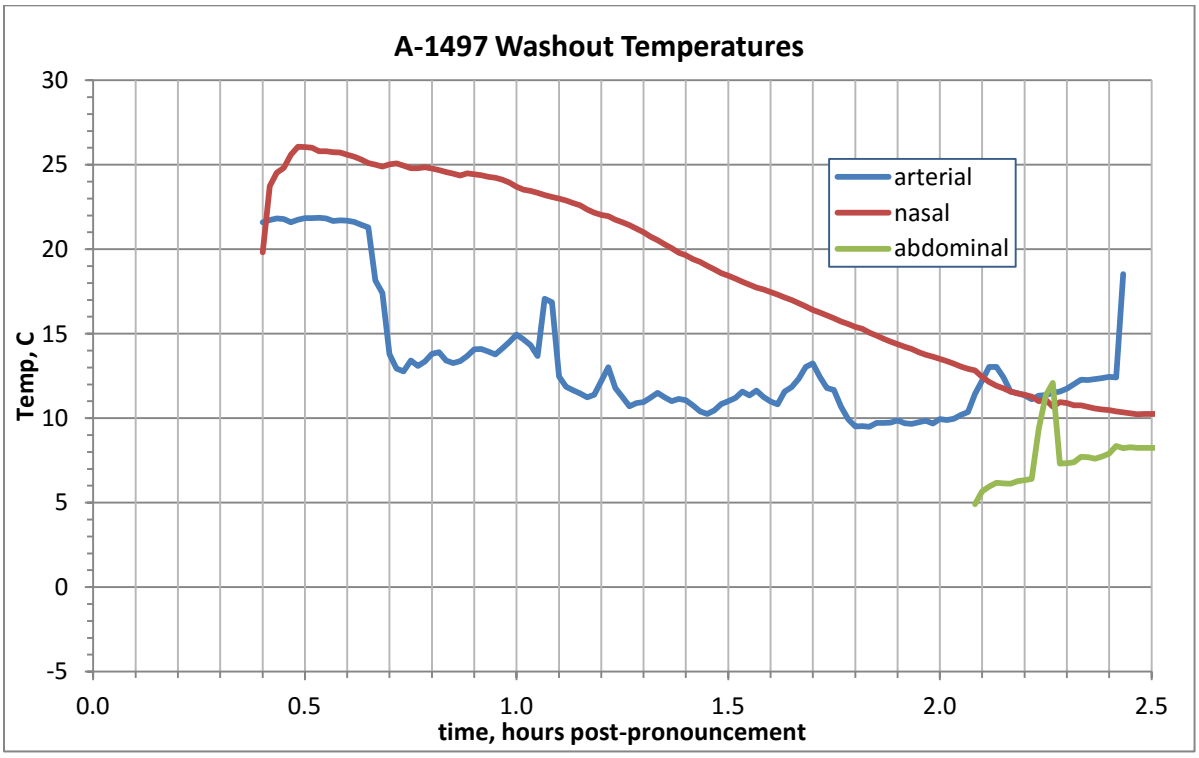
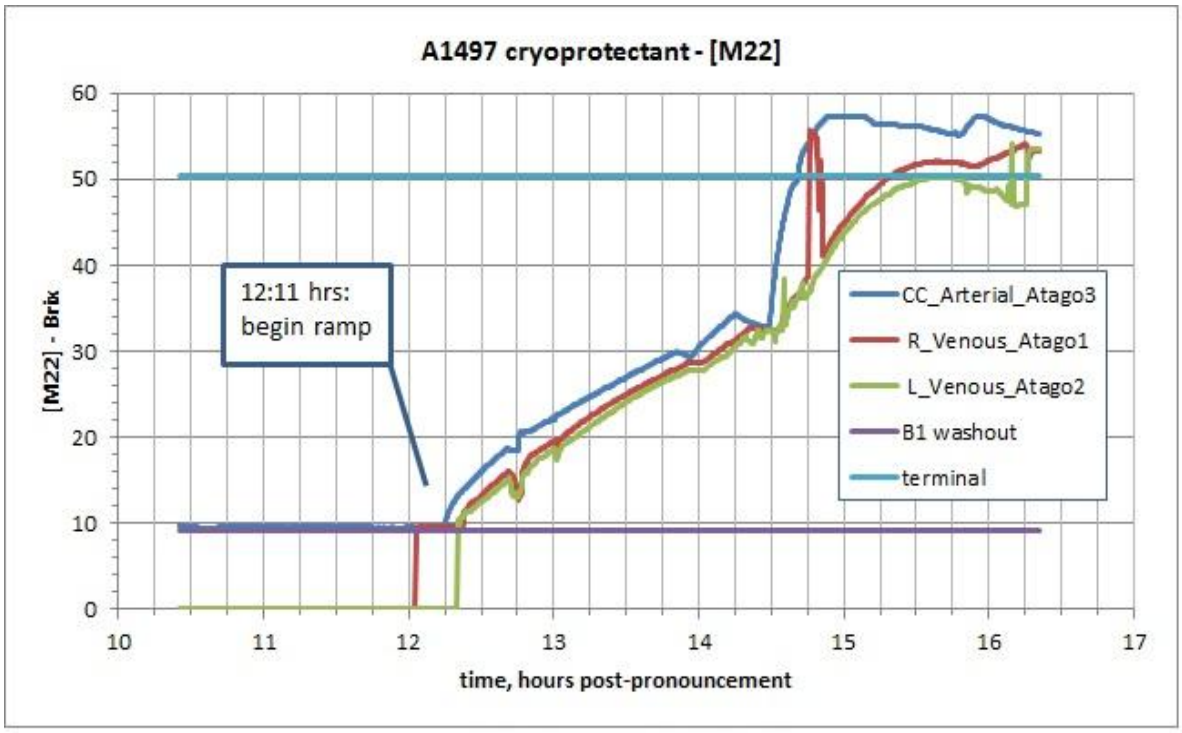
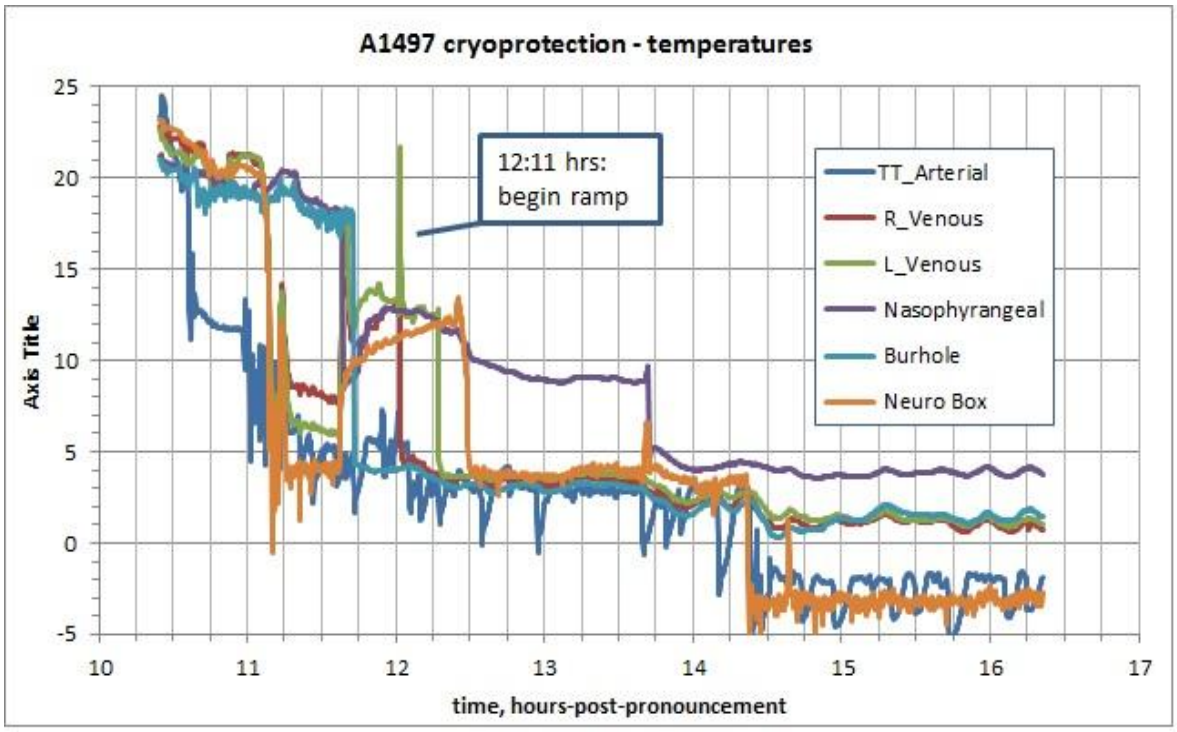
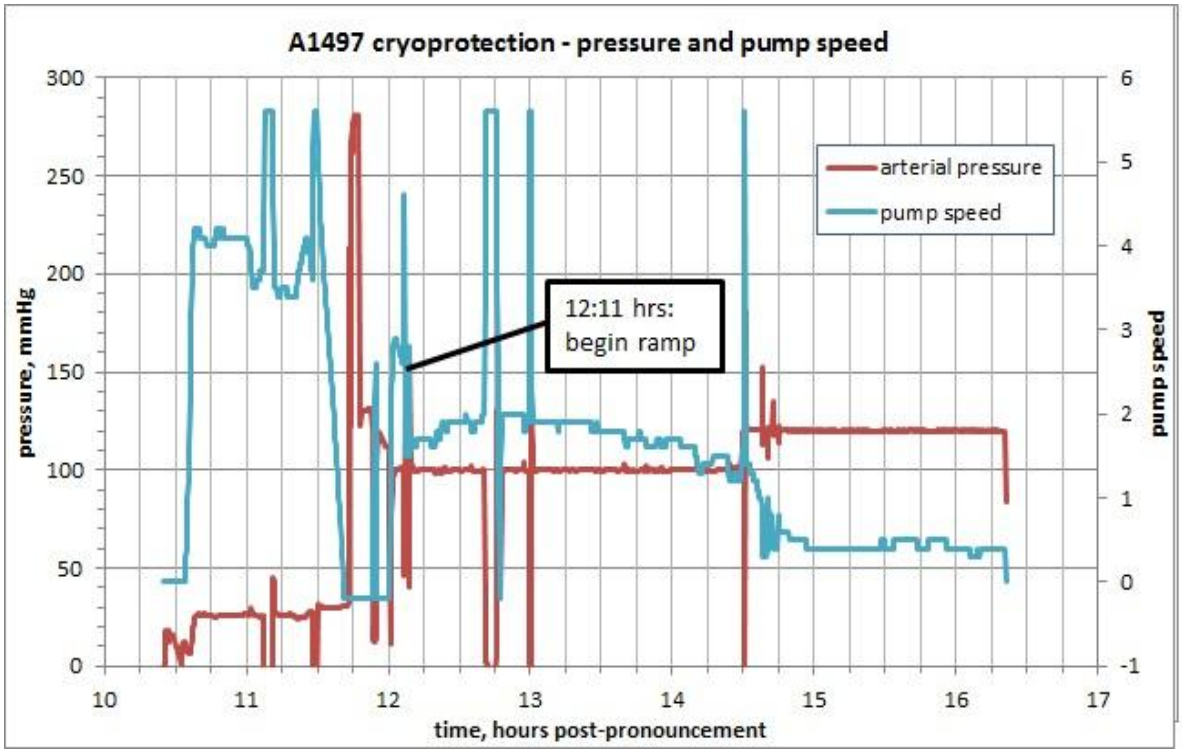
14. Graphs

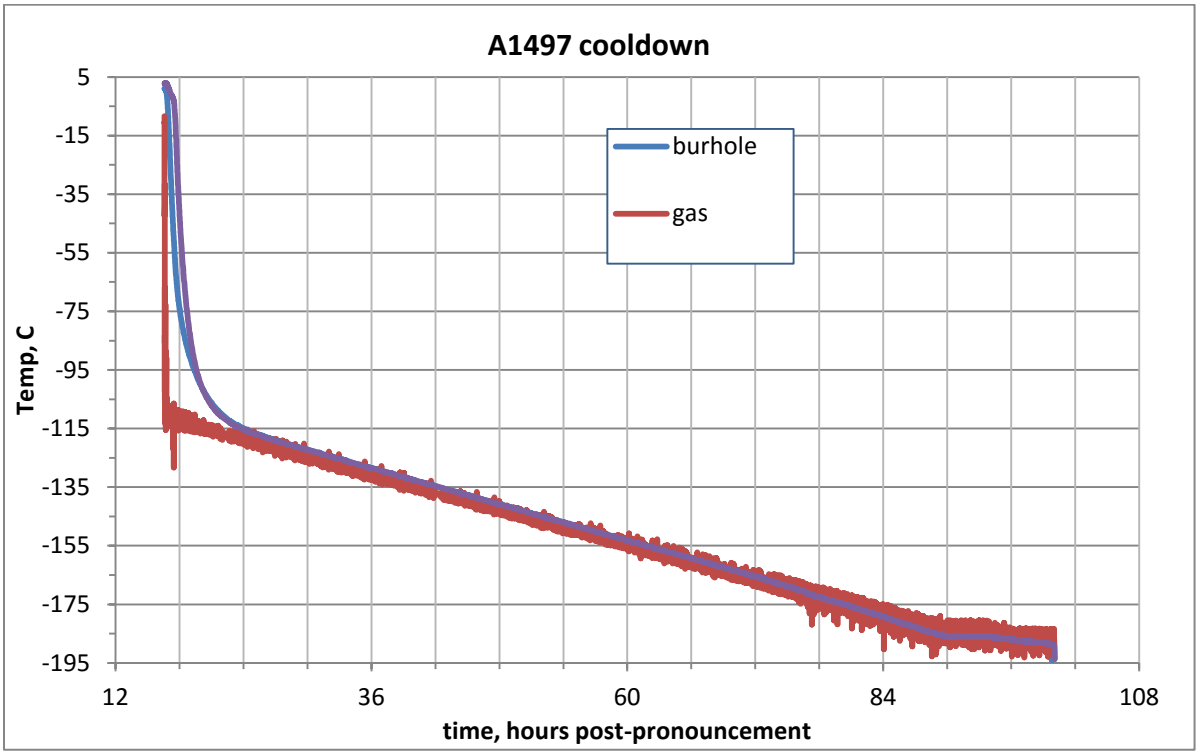

A-1497 Washout and Transport Temperatures
Temp, C
time, hours post-pronouncement
arterial
nasal
abdominal
30
25
20
15
10
5
0
-5
0
1
2
3
4
5
6
7
8
9
10
11
12

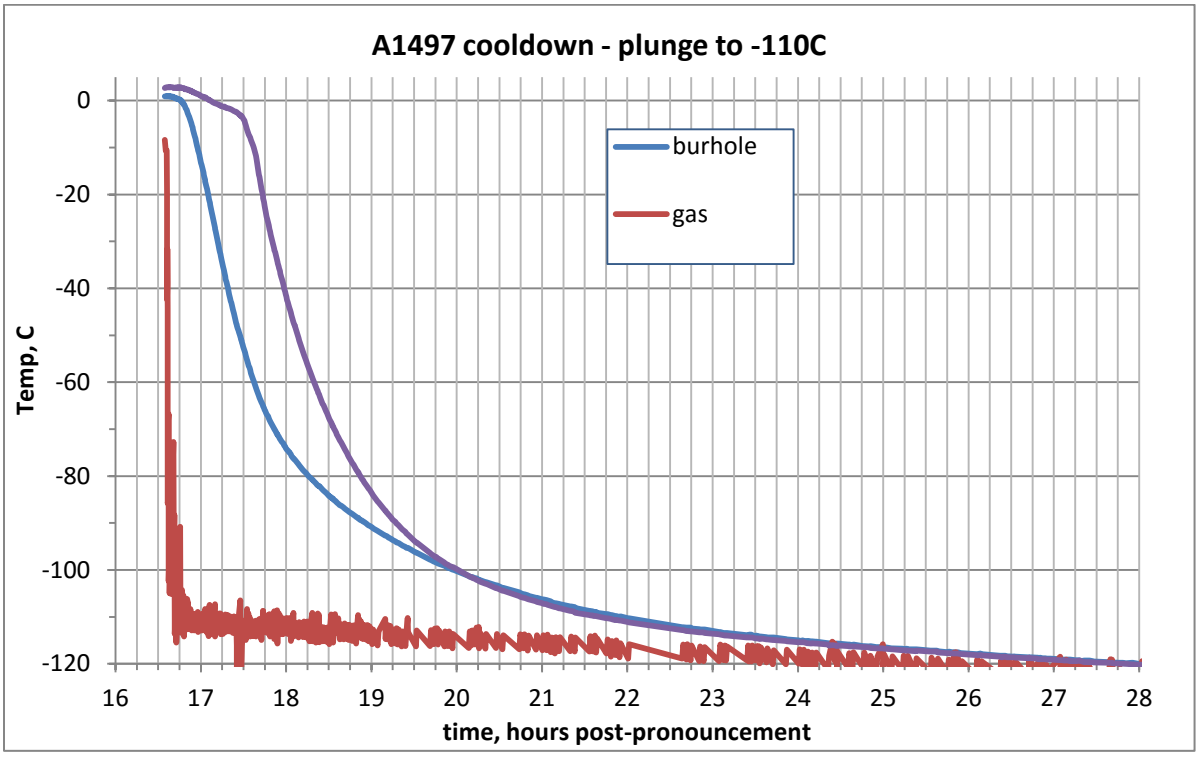

A-1497 Washout Temperatures
Temp, C
time, hours post-pronouncement
arterial
nasal
abdominal
30
25
20
15
10
5
0
-5
0.0
0.5
1.0
1.5
2.0
2.5

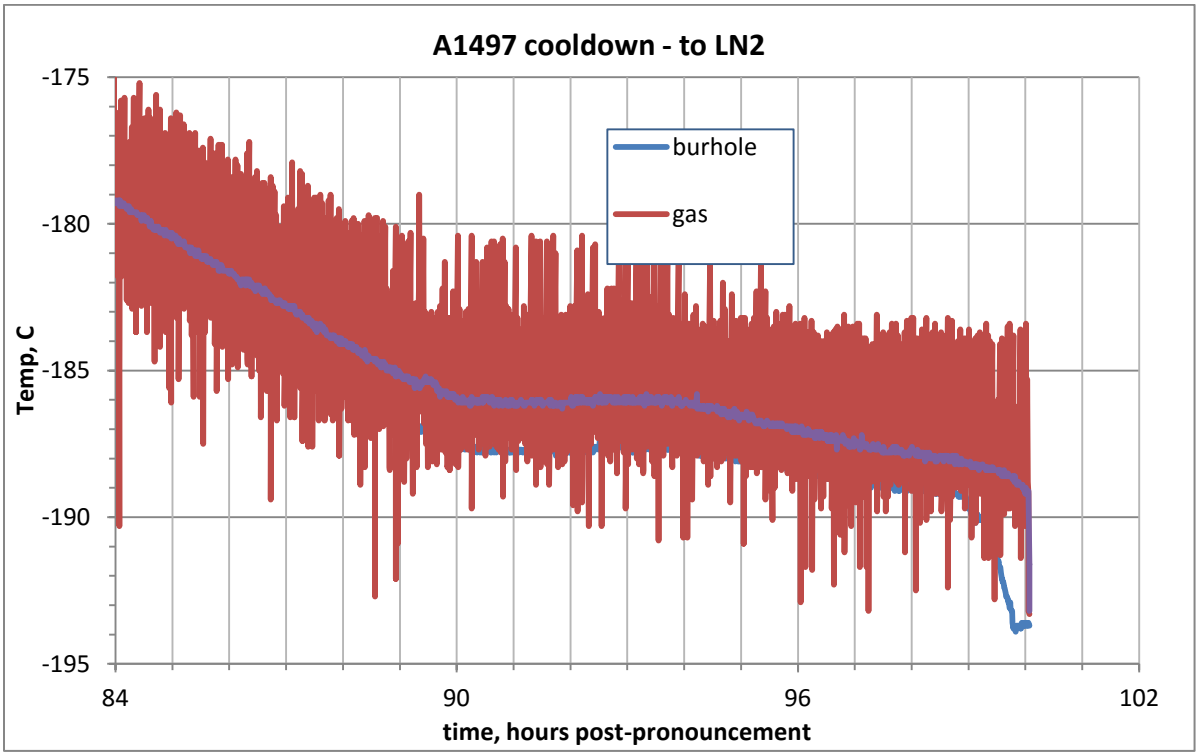

A1497 cryoprotectant - [M22]
[M22] - Brix
time, hours post-pronouncement
12:11 hrs:
begin ramp
CC_Arterial_Atago3
R_Venous_Atago1
L_Venous_Atago2
B1 washout
terminal


A1497 cryoprotection - temperatures
Axis Title
time, hours-post-pronouncement
12:11 hrs:
begin ramp
TT_Arterial
R_Venous
L_Venous
Nasophyrangeal
Burhole
Neuro Box


A1497 cryoprotection - pressure and pump speed
pressure, mmHg
pump speed
time, hours post-pronouncement
arterial pressure
pump speed
12:11 hrs:
begin ramp
300
250
200
150
100
50
0
6
5
4
3
2
1
0
-1
10
11
12
13
14
15
16
17


A1497 cooldown
Temp, C
time, hours post-pronouncement
burhole
gas
5
-15
-35
-55
-75
-95
-115
-135
-155
-175
-195
12
36
60
84
108





--End of report--