Alcor A-2889
Mark Lee Miller
Case Report

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Case Report Contents:

1. Overview

Mark Lee Miller, age 60, lived in Costa Mesa, California and suffered from Amyotrophic Lateral Sclerosis (ALS). Mark was born on October 20, 1955. He served in the Army for 8 years and worked for the FBI in Orange County for 33 years. He was predeceased by his brother who also suffered from ALS.

Mr. Miller, who is also identified as Alcor member A-2889 was pronounced legally deceased on 31-Dec-2015 after suffering an unwitnessed cardiopulmonary arrest at his private home in Costa Mesa, California. The Suspended Animation Inc. (SA) team was deployed after his arrest to provide stabilization and transport support. With transit permits unavailable until after the holiday, at the request of the Alcor Life Extension Foundation (Alcor), the member received initial stabilization care and then was transported to a nearby research facility for cephalic washout and isolation performed by an experienced physician (MD).

After the washout was completed, the SA team emergently transported the member's cephalon at water ice temperatures, via ground transport to Alcor for cryopreservation.

As a new member for less than 180 days, standby could not be covered by Alcor's Comprehensive Member Standby (CMS) program and its deployment policies. Pre-arrest mobilization decisions, therefore, had to be made with regard to availability of extra funding that had to be provided.

2. Personnel

Suspended Animation Inc. (SA):
Tabitha Carvalho, RN, SA Director of Client Services; Standby Team Leader (TC)
Sayer Johanson, NREMT; Team Member, Contributed Graphs (SJ)

Alcor Life Extension Foundation (Alcor):
Aaron Drake, NREMT-P, NAEMSE, Medical Response Director; Surgeon, Organization (AD)
Hugh Hixon; Setup, Perfusion, Cooldown, Cleanup (HH)
Max More, Ph.D., Chief Executive Officer; Scribe, Organization (MM)
Linda Chamberlain, Alcor Co-Founder, Special Projects Manager; Scribe, Support (LC)

3. Pre-Deployment

**Note: Third party identifying information and protected health information has been omitted from publication.*

Medical History:
Mark Miller, Alcor member A-2889 was a 60-year-old Caucasian man, 5'11" in height, weighing approximately 80 lbs.

The member was in the advanced stages of Amyotrophic Lateral Sclerosis (ALS) and was under hospice care at his private residence. No further medical information was provided by the member's Power of Attorney (POA).

He had recently obtained his Alcor membership and had planned to relocate to Scottsdale, Arizona to be closer to the facility.

On 31-Dec-2015 at approximately 22:58 hrs PST (23:58 hrs MST), Mark suffered a sudden, unwitnessed cardiopulmonary arrest. Although family members were near his bedside, they were unsure of the actual time when he experienced respiratory arrest.

The member was pronounced legally deceased at 23:55 hrs PST (00:55 hrs MST) by the hospice nurse who had been called to the home by the family.

Patient Assessment & Pre-Deployment:
**Times are in PST and will be converted to MST (Alcor time) in the timeline below*

On 30-Dec-2015 at 19:31 hrs PST, the Alcor Deployment Committee received an e-mail from Alcor's Medical Response Director (AD) with an urgent request for a deployment decision on a newly signed member, A-2889, who was not covered by Alcor's Comprehensive Member Standby program.

The Deployment Committee received additional information from AD via e-mail on 31-Dec-2015 at 15:39 hrs. At 16:05 hrs, SA received a request from the Deployment Committee to send out an SA staff member with a pulse oximeter to gather further information about the member's respiratory status.

A home visit was arranged and at 17:20 hrs, the SA Team Leader (TC) met with the member's POA and caregivers at the member's home in Costa Mesa, California. A visual assessment was conducted, and the member and his caregivers were provided with a pulse oximeter for monitoring.

TC found the member in a hospital bed in a room accessible by passing through several narrow hallways and doors. He was an emaciated Caucasoid man who was alert and non-verbal, receiving BiPAP at 2 L/min flow via mask.

[. . . .]

The caregiver stated that the hospice nurse was visiting twice a week to assess the member. The last nurse visit had been earlier that day. He said that a hospice nurse would be visiting the next day to assess if the frequency of the nurse visits should be increased.

The POA expressed his wish to move the member to Arizona if the member was stable enough, but he was not aware that there was an additional cost to make the transfer. He expressed his concern that when the time came, there would not be a nurse available for a timely pronouncement of legal death because the nurses were 30 minutes to an hour away from the member's home.

The POA and a family caregiver were instructed on how to use the pulse oximeter and what the signs and symptoms of a low oxygen level would be. They both verbalized understanding. A recommendation was made to the POA and caregiver that they leave the pulse oximeter on continuously and notify Alcor of any changes in the member's condition.

TC then left the member's home at 18:08 hrs and the visit report was sent to the Deployment Committee on 31-Dec-2015 at 20:55 hrs PST via e-mail. The Committee determined that the member's vitals were stable, and the member should be monitored closely for signs of respiratory decline.

4. Stabilization and Transport to [Medical Laboratory].

**Times are in PST and will be converted to MST (Alcor time) in the timeline below*

At 22:58 hrs PST on 31-Dec-2015, the TC received a call from the member's POA. He stated that he thought that the member was not breathing. TC asked the POA to double-check the member for breathing signs and then to call the hospice nurse. She also provided the POA with instructions on how to cool the member after pronouncement of legal death. Following the conversation with the POA, she alerted the Deployment Committee of the member's status and requested further instructions.

Alcor's Chief Medical Advisor then received a call at 22:59 hrs PST from the patient's caregiver, stating that the patient's chest was not moving. He had just been seen by the SA Team Leader a couple of hours before and was found to have good oxygenation on 2 L/min by mask.

At 23:12 hrs, two SA team members were mobilized to respond to the member's home. This included the team leader and a second team member, TC and SJ. They scrambled to SA's headquarters to pick up the medications and equipment and then drive the mobile operating vehicle to the member's home. Alcor's Chief Medical Advisor requested via text message that Sodium Citrate be administered as a priority.

The member was pronounced legally deceased at 23:55 hrs PST on 31-December-2015 by a hospice nurse.

SA team members and equipment arrived at the patient's home at 00:12 hrs on 01-January-2016. Assessment and confirmation of legal pronouncement were made. At 00:15 hrs, manual chest compressions commenced, which provided circulation for the patient. Bagged ice was placed around the patient's head to initiate cooling.

At 00:23 hrs, manual chest compressions had to be stopped, and the patient was physically carried to the waiting Portable Ice Bath (PIB) due to the narrow hallways and sharp corners in the patient's home that could not accommodate the PIB.

The patient was placed in the PIB and the AutoPulse® cardiopulmonary support device was initiated at 00:24 hrs. At 00:25 hrs, the AutoPulse® stopped due to the patient's small chest size.

At 00:28 hrs, the patient was moved inside the SA mobile surgical vehicle. In the next 16 minutes, manual chest compressions resumed, he was covered with ice, and ice water was recirculated over him using the SA cooling mask and tubing circuit. He was also intubated with a 37 Fr. Combitube and placed on the ventilator. Intraosseous access (IO) was obtained on the left anterior-medial aspect of his tibia.

In the following eight minutes, Sodium Citrate 10 g, Propofol 200 mg, and Heparin 100,000 IU were administered via the IO access while maintaining ongoing manual chest compressions.

Due to the New Year's Holiday, a transit permit could not be obtained until Monday 04-Jan-2016. There was no SA surgeon available in the state. After much deliberation, it was decided by the Deployment Committee to do the neuroseparation and cephalic washout at [a trusted medical laboratory] and then transport the patient's cephalon emergently to Scottsdale on the night of 01-Jan-2016.

The patient's transport to the laboratory facility began at approximately 00:56 hrs with SJ driving and TC continuing manual compressions and administering medications. Cardiopulmonary Support (CPS) was stopped while the nasopharyngeal temperature probe was placed in the patient's left nostril and then immediately resumed.

CPS resumed at 01:01 hrs and stopped again one minute later to put additional ice into the PIB.

The nasopharyngeal temperature was 15.2 °C at 01:05 hrs.

Over the next 25 minutes, Streptokinase 250,000 IU in 5 mL of 0.9% Sodium Chloride was administered using a 0.2 µm filter followed by CPS for six minutes. Then Aspirin 300 mg in 5 mL of THAM was administered using a 0.2 µm filter followed by CPS circulate the medications.

CPS was stopped at 01:37 hrs due to TC's exhaustion. The patient's nasopharyngeal temperature at 01:42 hrs was 11.0 °C.

5. Field Washout

**Times are in PST and will be converted to MST (Alcor time) in the timeline below*

Cephalic Washout

The patient arrived at the laboratory facility at 01:58 hrs PST accompanied by the SA team. His nasopharyngeal temperature at this time was 9.1 °C.

At 02:05 hrs, the ventilator was turned off, and the patient was moved into a laboratory space. It was noted that the ambient temperature in the room felt quite warm. No thermostat was visible to indicate the actual room temperature.

At 02:11 hrs, the patient was moved from the PIB to a surgical table and ice placed on the patient's head at the request of the surgeon. During the transfer of the patient to the table, the nasopharyngeal probe became dislodged and then was quickly repositioned.

For the next hour, preparations were made for cephalic washout and isolation. Additional ice was placed around the patient's head. MHP-2 organ preservation solution in a 20-liter bag was removed from its Pelican transport case and set up for the washout on top of an 8-foot ladder for gravity flow delivery of perfusate. A rough perfusion circuit consisting of 48 inches by ½ inch tubing was put together to connect the perfusate bag to the patient.

At 03:15 hrs, the first incision was made to the left jugular area by the surgeon. The nasopharyngeal temperature at this time was 9.8 °C. Over the next 45 minutes, the following was done: The left common carotid artery was accessed with a 15 Fr. venous cannula at the level of the cricoid cartilage. An attempt was made to access the left external jugular vein, which perforated the rear wall.

Washout started at 04:17 hrs with 15 L of MHP-2. The bag was raised at a level of about three feet over the patient's head on a stepladder. The measured drop was 2'7" from the cannula in the neck to the bottom of a 15 L bag. The mean drop was about 3' = mean pressure of 67 Torr. (67 mmHg)

Although the perfusate was kept cold inside the Pelican case and the mobile operating vehicle, the solution began to warm in the heat of the room. Due to the placement of the perfusate bag and the limitation imposed by the tubing length of the circuit setup, placing ice around the perfusate to keep it cold was not possible.

At 04:18 hrs, the right jugular was opened with a scalpel to assist drainage. The SA team inquired if more ice should be placed on the patient. The surgeon felt that it was not necessary as cold solution was already circulating in the patient.

Blood was flowing freely from both external jugular veins. There was a noticeable lightening of the blood color after 20 minutes of perfusion, and the patient's face became paler in color. No clots were seen, but there was granular red matter in the laminar flow as usual in cold perfusion.

The 15 L bag was about 2/3 empty by 05:00 hrs. Completed washout of 15 L perfused by 05:15 hrs. Clamped below air level. The nasopharyngeal temperature at the time was 14.3 °C.

Cephalic Isolation
The Combitube was removed at 05:29 hrs PST. It was noted that one of the balloons on the Combitube was not completely deflated when it was removed. The vessels were clamped at 05:30 hrs. The isolation of the cephalon started at 05:33 hrs at the T1/T2 vertebrae. Rough dissection was subsequently moved to the C6/C7 level due to clavicle interference and no sound intervertebral discs at the lower level. The level was low enough to enter the thorax. The apex of the right lung was visualized. The isolation was completed with a surgical mallet and an osteotome at 05:44 hrs. The nasopharyngeal temperature at the time was 15.44 °C.

The patient's cephalon was immediately inverted and placed in two layers of Biohazard bags with the nasopharyngeal temperature probe still in place. The sterile metal eyehook was not used. With the bagged cephalon remaining inverted, it was put in the neuro cooler on top of a layer of free water ice. The bag was taped securely with duct tape; the temperature probe and logger were placed outside the bag. Additional bagged ice was placed around and on top of the cephalon. The nasopharyngeal temperature was 14.7 °C.

6. Transportation to Alcor

At 06:17 hrs PST, the SA team left the medical laboratory for Alcor with the patient's cephalon in the neuro cooler. During transport, at 06:37 hrs, team members noted that the temperature was dropping very slowly. To better promote cooling, bagged ice around the cephalon was removed and replaced with free water ice. The nasopharyngeal temperature was 15.0 °C.

At 12:49 hrs MST, the SA team arrived at Alcor, in Scottsdale, Arizona. The nasopharyngeal temperature on arrival was 5.4 °C. The patient's care was transferred to Alcor at 13:02 hrs MST.

7. Cryoprotective Surgery

The perfusion system had been set up for a "Whole Body" patient. Because of the holiday, it was changed to a "Neuro" patient. Filling the system and getting it started began a bit late and SA arrived a bit before their predicted ETA, so things were a bit hectic for a single perfusionist. However, the system was ready 15-20 minutes after the patient's arrival.

The data collection system was started slightly after the perfusion system was filled, so a complete record was made.

There was some residual blood in the initial washout, but no clots observed.

Perfusion was uneventful. The patient's brain began to shrink as soon as the ramp started. Total water removed was about 600 mL. The corneas appeared concave from dehydration, and the skin

was shrunken from dehydration and mottled. Brain retraction appeared about the same; about 1 cm beneath both burr holes.

Due to measurement error in December 2015, a value of 44.4 Brix was set for the desired terminal concentration of nM22 and was the goal for this cryoprotection. This endpoint was achieved, but resulted in a terminal concentration of about 86% of the correct terminal concentration of 49.9 Brix.

To clarify, nM22 denotes a cryoprotectant solution made by diluting with B1 carrier solution a stock solution consisting of 1.25x M22 in LM5 carrier solution, where 1.25x denotes M22 solutes being present at 1.25 times the concentration at which M22 is defined in published scientific literature. The desired terminal concentration of nM22 is 1.25x M22 in LM5 diluted with B1 such that M22 solutes reach 1x normal defined concentration of M22, this solution having a refractive index of 49.9 Brix.

Burr hole creation was improved by the surgeon cutting away the skin instead of simply dividing it and then using spreaders; the advantage being that spreaders frequently come loose. The skin was cut in two semi-circles to create a lens-shaped hole in the skin for the perforator.

The perfusates used were: B1 = 5 L out of a 20 L bag and 5.7 L of nM22 = 5.7 L

8. Perfusion Summary

(hh: mm)

00:56	Time from cardiac arrest to the pronouncement of legal death.
01:09	Pronouncement to arrival at the laboratory by SA (medication administration and travel time).
02:00	Approximate cannulation time (problem attempting to cannulate a jugular vein).
01:15	Approximate washout time at ~67 mmHg.
00:22	Neuroseparation.
05:30	Approximate travel time from the laboratory in Rancho Cucamonga, CA to Alcor in Scottsdale, AZ.
12:43	Cardiac arrest to arrival at Alcor.
00:22	Arrival to placement in neuro box.
00:17	Burr hole creation, including cutting away of the hair.
00:15	Cannulation.
00:10	Washout at 80 mmHg.

01:42	Cryoprotection to 50% pause (effluent) at 80 mmHg, mostly at ramp speed of 10.
00:15	Equilibration pause at 50%.
02:28	Step to equilibrium terminal concentration endpoint.
00:19	End of cryoprotection to beginning of cooldown.
05:49	Arrival to beginning of cooldown.

9. Timelines

** Note: All times in the timelines have been converted to Mountain Standard Time (MST) / Alcor Time*

Stabilization and Transport:

30-Dec-2015

20:31 hrs	E-mail from Alcor's Medical Response Director for critical deployment decision.
21:26 hrs	Conference call with Deployment Committee.

31-Dec-2015

17:05 hrs	Received e-mail to visit the patient at home with a pulse oximeter.
17:22 hrs	Contacted the patient's POA to arrange a home visit.
17:45 hrs	Departed SA headquarters for the patient's home.
18:20 hrs	Arrived at the patient's home with the pulse oximeter and conducted a visual assessment.
19:08 hrs	Left the patient's home.
21:55 hrs	Home visit report sent via e-mail to the Deployment Committee for review.
23:58 hrs	Received a call from the POA that the patient was not breathing. This became the estimated time of cardiac arrest.

01-Jan-2016

00:06 hrs Notified SA management of the patient's condition and received direction to head to the patient's home with the equipment.

00:12 hrs Notified the SA team to gather equipment and mobilize to the patient's home.

00:17 hrs Notified Alcor that SA was heading to SA headquarters to collect equipment.

00:55 hrs Hospice nurse pronounced the patient legally deceased.

**Note: Mobile operating room clock was ahead by one hour and recorded call out times reflected this. Corrected times were listed in the timeline notes by SA but the times were corrected once more to reflect MST/ Arizona time as per standard.*

01:12 hrs The SA team arrived at the patient's home.

01:13 hrs The SA team confirmed that pronouncement of legal death had occurred, and funeral home information was given to the hospice nurse.

01:15 hrs Manual chest compressions were started on the patient.

01:16 hrs Ice was placed around the patient's head.

01:23 hrs Manual chest compressions stopped. The patient was carried to the PIB.

01:24 hrs The AutoPulse® was turned on.

01:25 hrs The AutoPulse® began malfunctioning due to the patient's small size.

01:28 hrs The patient was taken to the van.

01:29 hrs Additional ice was placed on the patient.

01:32 hrs The Surface Convection Cooling Device (SCCD mask) was placed on the patient and water was circulating.

01:38 hrs The patient was intubated with a 37 Fr. Combitube.

01:39 hrs The patient was placed on the ventilator and an intraosseous device (IO) was initiated in the anterior-medial aspect of the left leg.

01:41 hrs Manual compressions restarted and continued during medication administration.

01:42 hrs Sodium Citrate 10 g was administered via the IO site.

01:45 hrs Propofol 200 mg was administered.

01:49 hrs Heparin 100,000 IU was administered.

01:56 hrs Manual compressions were stopped; the team and the patient departed the patient's home for [the laboratory].

02:01 hrs The nasopharyngeal temperature probe was inserted into the patient's left naris and manual compressions restarted.

02:02 hrs Manual compressions were stopped to add more ice to the PIB.

02:05 hrs Nasopharyngeal temperature = 15.2 °C.

02:09 hrs Streptokinase 250,000 IU in 5 mL of 0.9 % Sodium Chloride solution was administered through a 0.2 µm filter and manual chest compressions were restarted to circulate the medication.

02:11 hrs Received a text message from Alcor's Medical Response Director instructing the team to drive to [the laboratory] to do a field washout, cephalic isolation and then transport to Alcor.

02:15 hrs Manual chest compressions were stopped to prepare medication.

02:20 hrs Aspirin 300 mg mixed in THAM was administered using a 0.2 µm filter.

02:22 hrs Manual chest compressions were restarted and continued.

02:30 hrs Manual chest compressions were stopped to add more ice to the PIB.

02:33 hrs Manual chest compressions were restarted. Nasopharyngeal temperature = 13.7 °C.

02:37 hrs Manual chest compressions were stopped due to team member's exhaustion.

02:42 hrs Nasopharyngeal temperature = 11.0 °C.

02:58 hrs The team arrived at CCR. Nasopharyngeal temperature = 9.1 °C.

Medication Table:

TIME	MEDICATION NAME	DOSE	PURPOSE
01:42 hrs	Sodium Citrate	10 g	Anticoagulant; prevents blood clot formation.
01:45 hrs	Propofol	200 mg	Anaesthetic; reduces cerebral metabolic demand, reduces theoretically increased awareness during aggressive CPS.
01:49 hrs	Heparin	100,000 IU	Anticoagulant; prevents blood clot formation.
02:09 hrs	Streptokinase	250,000 IU	Fibrinolytic; dissolves existing blood clots
02:20 hrs	Aspirin in THAM	300 mg/ 5mL	Anti-inflammatory and antiplatelet; inhibits platelet aggregation.

Cephalic Isolation:

03:05 hrs The ventilator was shut off. The patient was moved into the lab.

03:11 hrs The patient was transferred to the surgical table from the PIB per the physician's request. There was ice placed on the patient's head. Nasopharyngeal temperature = 7.2 °C.

03:15 hrs The temperature probe became dislodged during the transfer of the patient from the PIB to the table.

03:16 hrs The nasopharyngeal temperature probe was reinserted into the left naris. Additional ice was added to the patient's head. The washout setup and the surgical setup were started.

04:15 hrs The first incision was made in the left jugular vein. Nasopharyngeal temperature = 9.8 °C.

04:47 hrs The left carotid artery was accessed with a 15 Fr. cannula. Nasopharyngeal temperature = 9.3 °C.

04:59 hrs An attempt was made to cannulate the left jugular vein. The vein perforated.

05:17 hrs Washout started with 15 L of MHP-2. Nasopharyngeal temperature = 11.2 °C.

05:18 hrs An incision was made in the right jugular vein.

05:47 hrs Approximately 7 L of MHP-2 infused. Nasopharyngeal temperature = 12.8 °C.

06:15 hrs MHP-2 washout was completed. Nasopharyngeal temperature = 14.3 °C.

06:28 hrs Cephalic isolation was initiated. Nasopharyngeal temperature = 14.8 °C.

06:29 hrs The Combitube was removed.

06:30 hrs The vessels were clamped.

06:31 hrs Nasopharyngeal temperature = 15.0 °C.

06:33 hrs Cephalic isolation started at vertebrae T1-T2 per MD and moved up to C6-C7.

06:42 hrs Notified AD via text message that the washout was completed, and cephalic isolation was in progress.

06:44 hrs Cephalic isolation was completed.

06:45 hrs The cephalon was inverted, placed in a neuro cooler. Nasopharyngeal temperature = 15.1 °C.

Transport to Alcor:

07:17 hrs Departed the laboratory for Alcor.

07:37 hrs Removed bagged ice around the patient's cephalon and replaced it with free ice.

Nasopharyngeal temperature = 15.0 °C.

08:30 hrs Nasopharyngeal temperature = 12.8 °C.

09:30 hrs Nasopharyngeal temperature = 11.0 °C.

10:30 hrs Nasopharyngeal temperature = 10.0 °C.

12:49 hrs Arrived at Alcor.

12:50 hrs Nasopharyngeal temperature = 5.4 °C.

13:02 hrs Report given; patient care transferred to the Alcor team.

Cryoprotective Surgery:

13:06 hrs	Removed the patient from the shipping box and placed in Alcor neuro box. Cephalon secured in the ring.
13:15 hrs	Burr hole area cleared of hair and some skin.
13:20 hrs	Nasopharyngeal temperature = 5.5 °C
13:21 hrs	Right and left burr holes drilled.
13:30 hrs	Inserted right carotid cannula.
13:31 hrs	Right carotid cannula secured new way with a 3-D printed clamp.
13:33 hrs	Pressure at 50 mmHg.
13:39 hrs	Exposed section of left carotid artery, due to the perforated area. Both sides were cannulated.
13:40 hrs	Increasing pressure. It was set initially to 100 mmHg but changed to 80 mmHg per protocol.
13:41 hrs	Left vertebral artery clamped. Right vertebral artery identified and clamped.
13:48 hrs	Mixing reservoir = 0.9 L, Concentration = 9.1, Effluent = 0, Pressure = 4 psi, Running at 80 mmHg.
13:49 hrs	The lid was placed on the box. Cooling was underway.
13:50 hrs	On recirculation. Continuing to washout; wanting more volume in the reservoir.
13:51 hrs	Mixing reservoir = 1 L; closing circuit. No longer drawing from the bladder. Ramp on. Speed = 15. Venous sampling lines not placed. (Team member asked if in-line refractometers were working well)
14:00 hrs	Effluent reading on the right side was 9.53. The baseline was 9.45.
14:02 hrs	Right venous sampling line was secured.
14:14 hrs	Mixing reservoir went from 1.0 to 1.05 L. Pulled some fluid from the patient's brain.
14:16 hrs	Inserted left venous sampling line.
14:23 hrs	Left venous sampling line secured.

14:29 hrs Mixing reservoir = 1.2 L, (200 mL pulled off). The brain was retracted.

15:32 hrs Stopped ramp at 30 Brix.

15:36 hrs Mixing reservoir = 1.45 L, 450 mL pulled off, good brain retraction noted.

15:40 hrs Switching perfusion and box temperature to -3 °C. Corneas have shrunken from dehydration. The skin appears mottled and tanned.

15:46 hrs Equilibration reached. Mixing reservoir = 1.43 L, Concentration = 7.23 L, Effluent = 1.60.

15:47 hrs Back on the high-speed part of the ramp.

15:56 hrs 45.8 Brix on closed circuit arterial. Right venous Brix = 29.45. Left venous Brix = 33.4.

16:25 hrs Speed of 28 gave us a stable concentration of 48 Brix on the arterial side.

16:29 hrs Dumping out of the return to the reservoir.

Addendum:

Mark Lee Miller, A-2889 had wanted to be a whole-body patient. However, to protect his brain from the severe damage of waiting three days for a transit permit, a decision had to be made to do a neuroseparation in California, and then send his body separately for cryopreservation after a transit permit could be obtained.

The patient's body arrived at the lab packed in water ice from the cooldown and remained that way after the cephalic isolation. Approximately 1-2 hours after the departure of the SA team with Mr. Miller's cephalon, the mortuary arrived to collect the post-cranial body. This would have been approximately 07:00 hrs to 08:00 hrs on 01-Jan-2016. They were advised by MD not to allow Mr. Miller's trunk to freeze. He was taken from the lab in a mortuary ambulance and placed in their cooler for the weekend until a transit permit could be obtained.

Details about the interim period when the patient's body was with the mortuary are limited. Due to delays in obtaining a transit permit for the body, cooling of the cephalon was paused at -80 °C for 12 days until the remaining process of cooling the body and cephalon to liquid nitrogen could be completed together.

10. Issues & Actions

**Points related to Issues & Actions derived from case report and associated video report*

Logistics:

Issue: **SA:** Sudden cardiopulmonary arrest left no time for SA surgeons and perfusionists to travel to the patient's location.

Corrective Action: **SA:** None. Due to the member signing up with Alcor less than six months prior to legal death, the case was not covered by Alcor's Comprehensive Member Standby (CMS) program. It was therefore not possible to deploy personnel days in advance of need.

Issue: **CG:** The video captured of both the SA procedures and the Alcor procedures were quite inadequate for capturing the necessary audio and video data in their entirety with precision. The SA videos had the camera pointed at the patient, but most of the prep work was done out of audio and visual range in an adjacent space. During the neuroseparation video, the audio was so muffled it was almost impossible to hear the proceedings at all. The Alcor video had numerous obstructions by personnel, and the view did not provide any visual information in terms of the surgical work. This made documentation of proceedings laborious and increased the potential for error.

Corrective Action: **CG:** Either all team members should consider wearing a body cam or fixed video capture needs to be drastically improved. At the very least, consider a fixed camera hovering over the OR table to gather detailed images of the surgical procedures as well as a panoramic or 360° camera to capture a view of the entire room. Then maintain awareness of where one is in relation to the cameras. This would ensure that all audio is captured with accuracy, and would increase the likelihood that detailed surgical images would be visible. GoPro would be recommended. They also use a fully panoramic camera that could replace the linear view presently captured by a standard video camera.

Issue: **CG:** It is not always known what type of equipment or sizes of equipment is being used or what aspect of a process is being performed. This makes case auditing, review, and report production more difficult.

Corrective Action: **CG:** As is frequently done in Code Blue- type hospital emergencies, one team member (or all members) need to narrate what they are doing

and what kind of equipment they are using. This does not mean that the entire procedure needs to be related in every detail, but pertinent interventions and tools should be identified.

Issue: **CG:** Timestamps and dates are not being identified in the videos consistently.

Corrective Action: **CG:** There needs to be a digital clock placed in a location visible to the team as well as the camera. All procedures need to be documented from the time of this clock. Time and date should be verbally confirmed at the start of every video.

Issue: **CG:** There was a significant gap in time between the first cannulation video and the cephalic isolation video. The video of the washout and cryoprotection was not provided. There was a 17-minute gap between Video #2 of the left sided cannulation and the documented activity missing with Video #3 that was not accounted for. Video #1 was of surgical preparation, and what is assumed to be Video #4 but has been labeled #3 was of the neuroseparation. There was no video data provided of the initial stabilization events at the patient's house or in the vehicle.

Corrective Action **CG:** All procedures need to be captured on video, with suitable audio. All audio and video data need to be provided for review. Any large gaps that happen during a procedure should be accounted for and documented in the field notes. A body cam would be the most efficient way to capture field video in a variety of locations at once.

Stabilization:

Issue: **SA:** The patient's emaciated chest was too small for an adult sized AutoPulse® band to function.

Corrective Action: **SA:** The AutoPulse® is not designed for use on extremely small or pediatric patients. The AMBU Cardio pump should be used to support manual chest compressions.

CG: The Lucas II is also recommended to be used in its place as it can accommodate a smaller chest circumference.

Issue: **SA:** The ambient temperature in the lab was above the optimal temperature for the procedure.

CG: An assessment of nasopharyngeal temperature readings indicates a significant patient temperature increase while at the surgical site.

Corrective Action: **SA:** Lower the thermostat temperature.

CG: Speak with the surgeon about lowering the ambient temperature. Actively advocate for patient safety.

SA/CG: Leave the patient in the PIB until the team is ready to perform surgery.

Issue: **SA:** There were limited equipment and assistance for the surgeon available at the laboratory for cephalic washout and isolation procedures.

Corrective Action: **SA:** Confirm in advance with the surgical facility that they have the equipment and staff required for field surgery and washout.

CG: If this lab should choose to assist with procedures in the future as a failsafe, it should be fully equipped to do so as a failsafe. If possible, bring what they do not have.

Issue: SA: The patient and the MHP-2 solution warmed during setup and procedure.

Corrective Action: **SA:** Keep the patient in the PIB with ice and circulating ice water until all preparations for surgery and perfusion are complete.

Place the MHP-2 in ice water bath until the surgery is complete.

Lower the thermostat serving the procedure area.

Issue: **CG:** Neither SA, Alcor nor the surgeon demonstrated anything which approached a sterile surgical field. In varying degrees, individuals made some attempt at demonstrating sterile technique, but in all cases, this effort broke down almost immediately. Examples of this include touching unsterile surfaces after donning sterile gloves, mixing sterile and unsterile

tools in the same tray, not prepping the skin prior to incision, and general hand discipline errors in terms of placement and handling of instruments. The standard set forth is to maintain a sterile surgical site during invasive procedures, both for the protection of the patient and the prevention of disease transmission to staff members.

Corrective Action: CG: It is reasonable to assume that some errors in maintaining a sterile field will occur. It is unreasonable to witness breaches made due to lack of knowledge or omission. What is strongly recommended is that all team members be re-educated on sterile technique in terms of creating a sterile operative site within a non-sterile environment. This is less labor intensive than creating an OR-level of protocol and yet achieves the same goals more realistically.

Cryoprotective Perfusion

Issue: BW: An incorrect refractive index for the target concentration of nM22 cryoprotectant was used.

Corrective Action: BW: The correct target refractive index of nM22 has been noted, and future refractive index measurements of target concentration standards will be conducted by two people independently.

Cryogenic Cooling

Issue: **BW:** Liquid nitrogen valve stuck in an open position during cooling, causing abnormal downward temperature excursion.

Corrective Action: **BW:** Modify liquid nitrogen valve assembly on the cooling system to use four valves in series/parallel configuration to provide fail safety for single valves failing in either the open or closed position.

Issue: **CG:** Due to delays in obtaining a transit permit for the body, cooling of the cephalon was paused at -80 °C for 12 days until the remaining process of cooling the body and cephalon to liquid nitrogen could be completed together.

Corrective Action: **CG:** If possible, use separate equipment to cool separate tissue, and merge storage later, so that final cooling of the brain is not paused.

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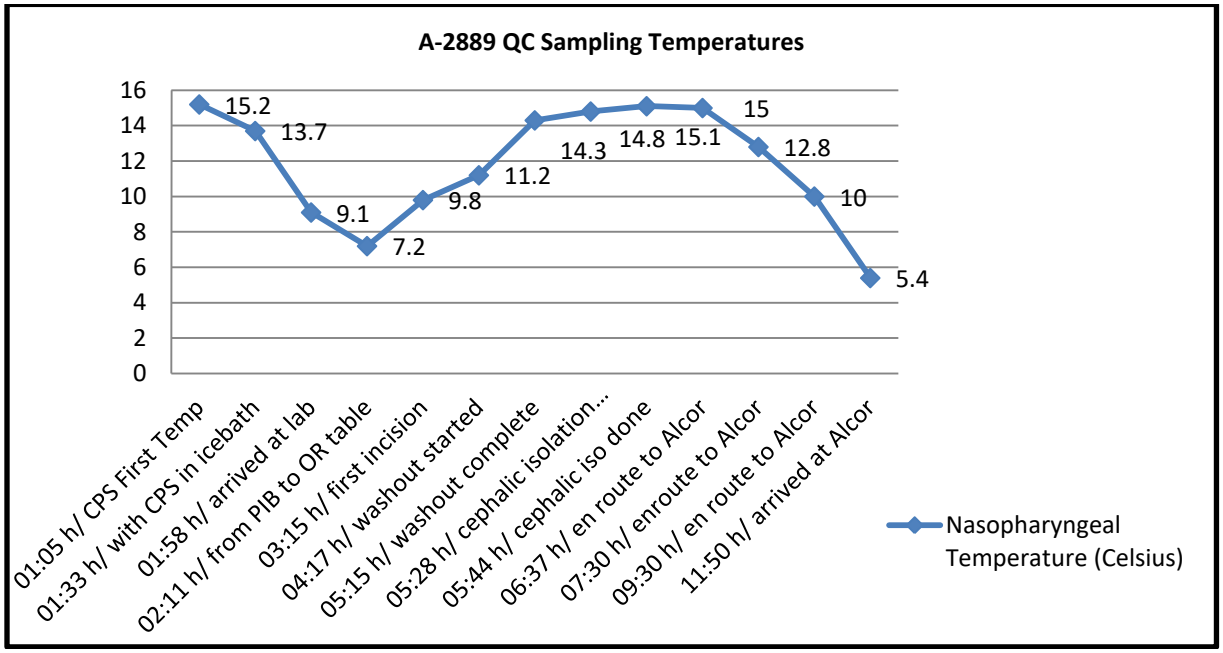
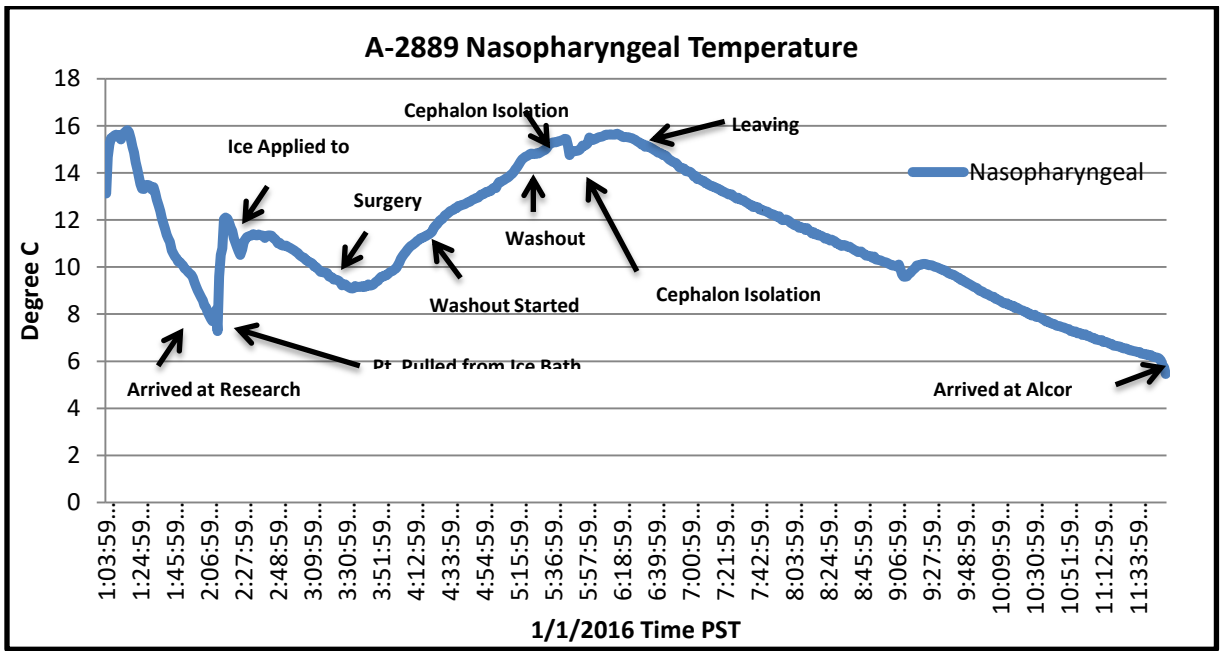
11. Graphs

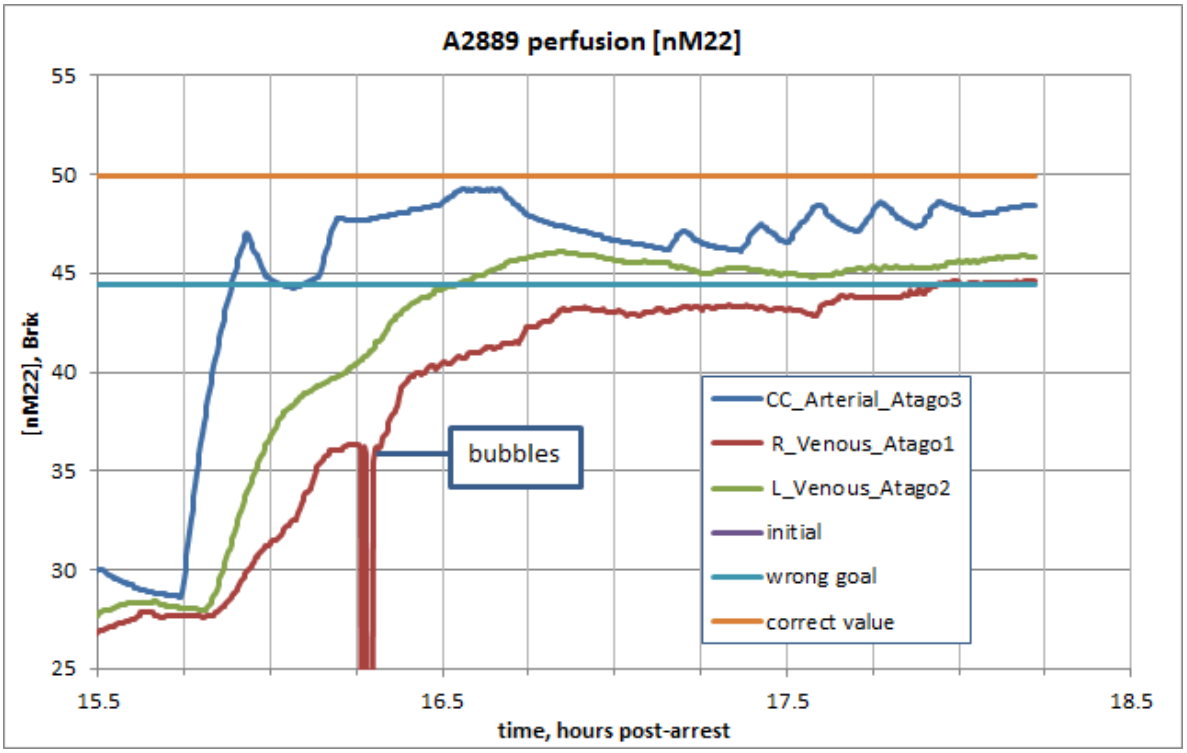
QC Sampling Temperatures



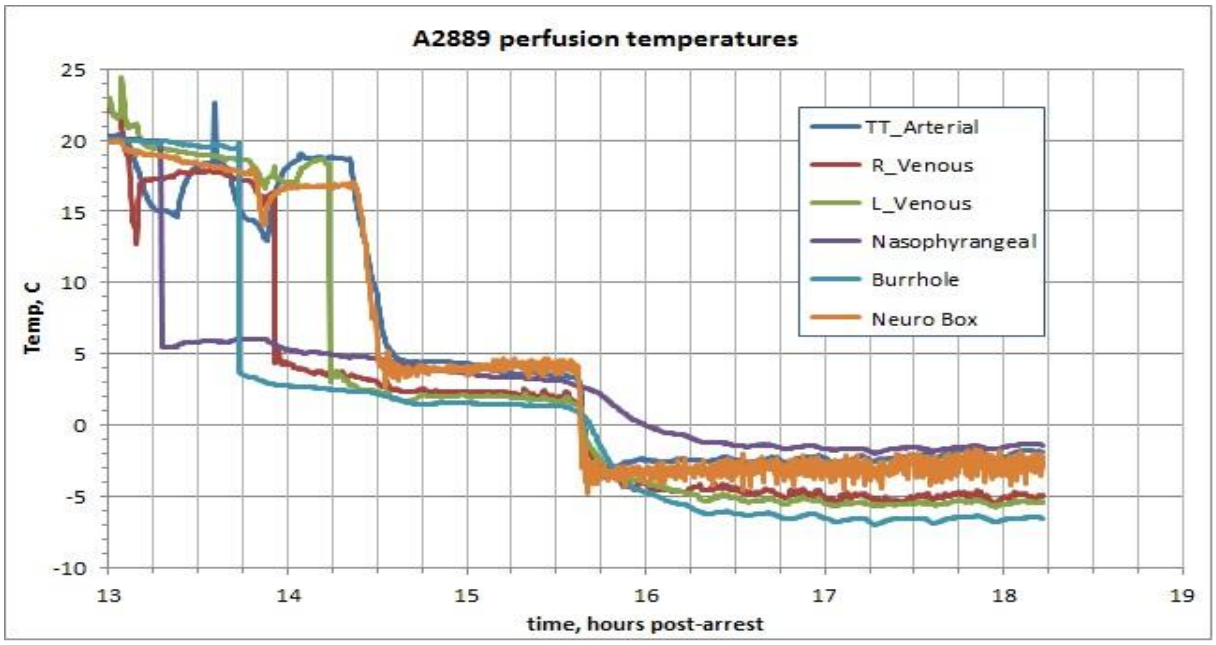
Stabilization Temperatures



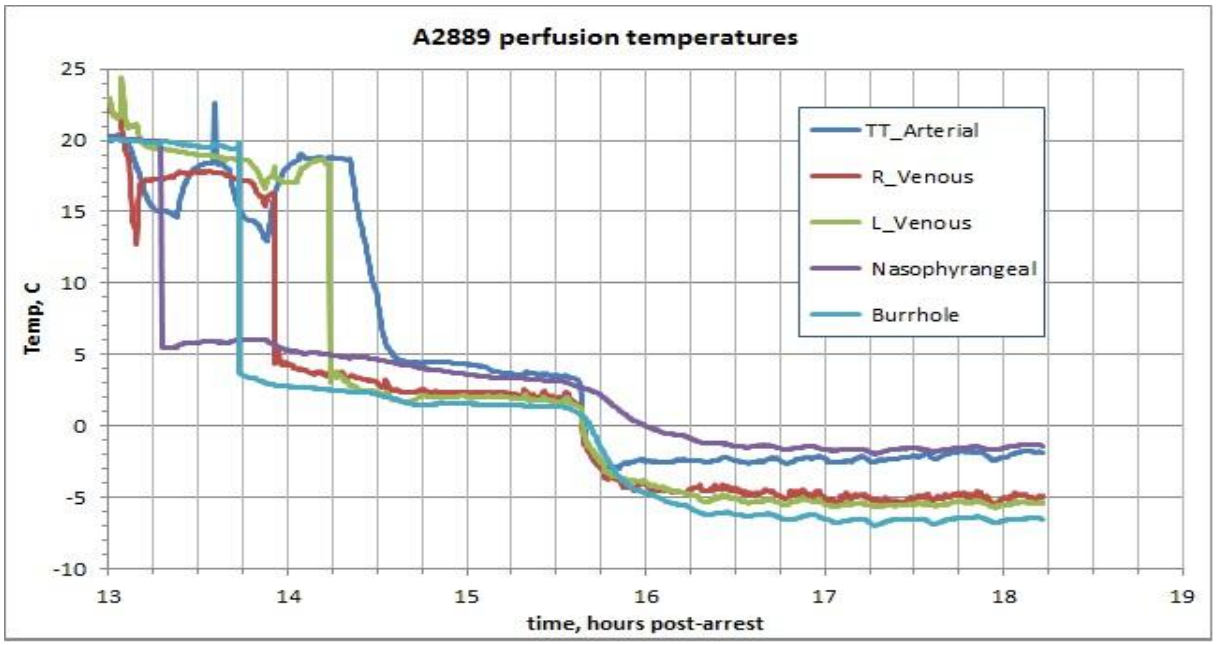
Cryoprotectant Perfusion Concentration



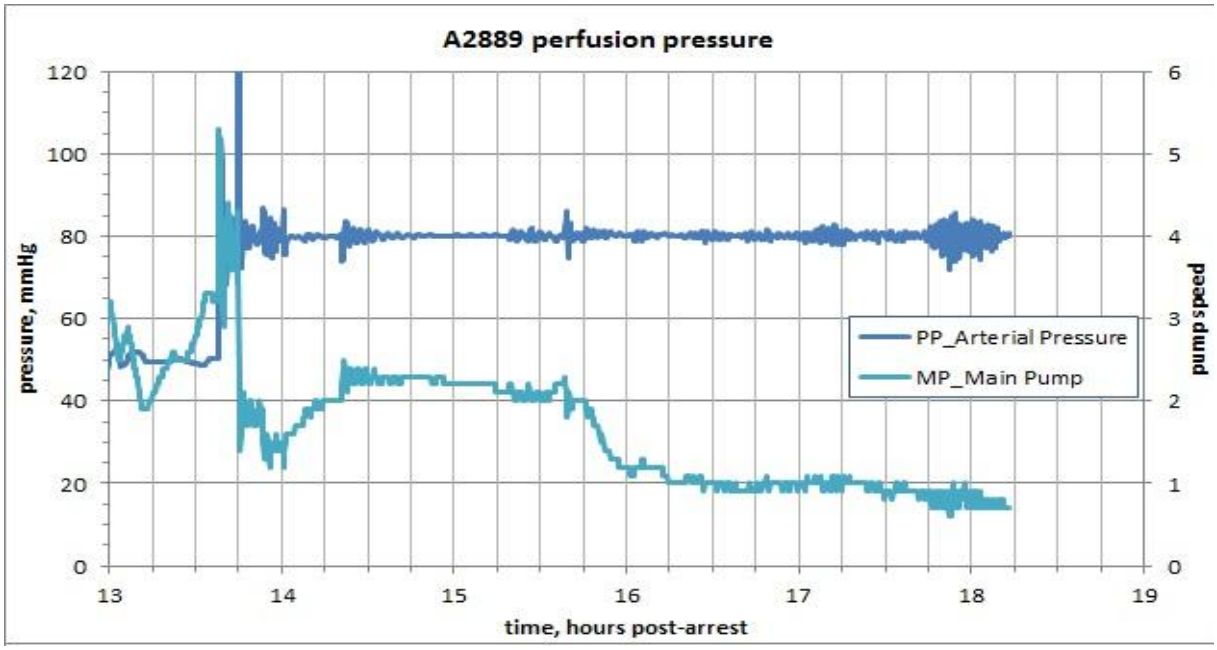
Cryoprotectant Perfusion Temperatures



Cryoprotectant Perfusion Temperatures
(Neuro Box Temperature Omitted for Clarity)

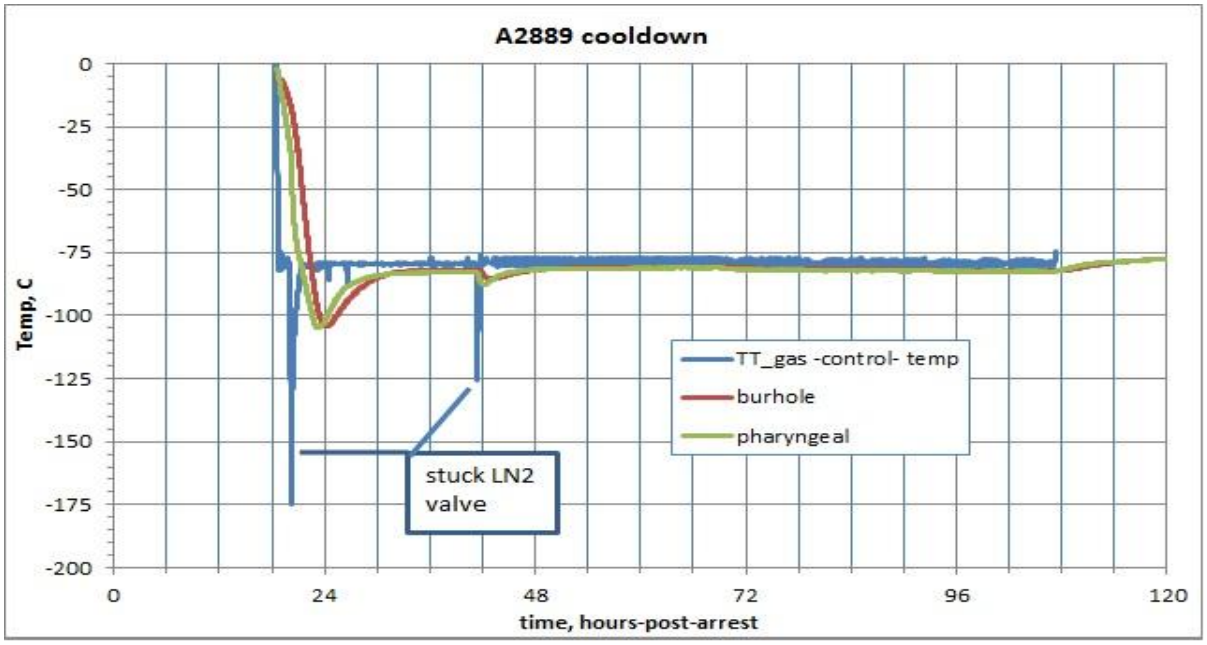


Cryoprotectant Perfusion Pressure and Flow

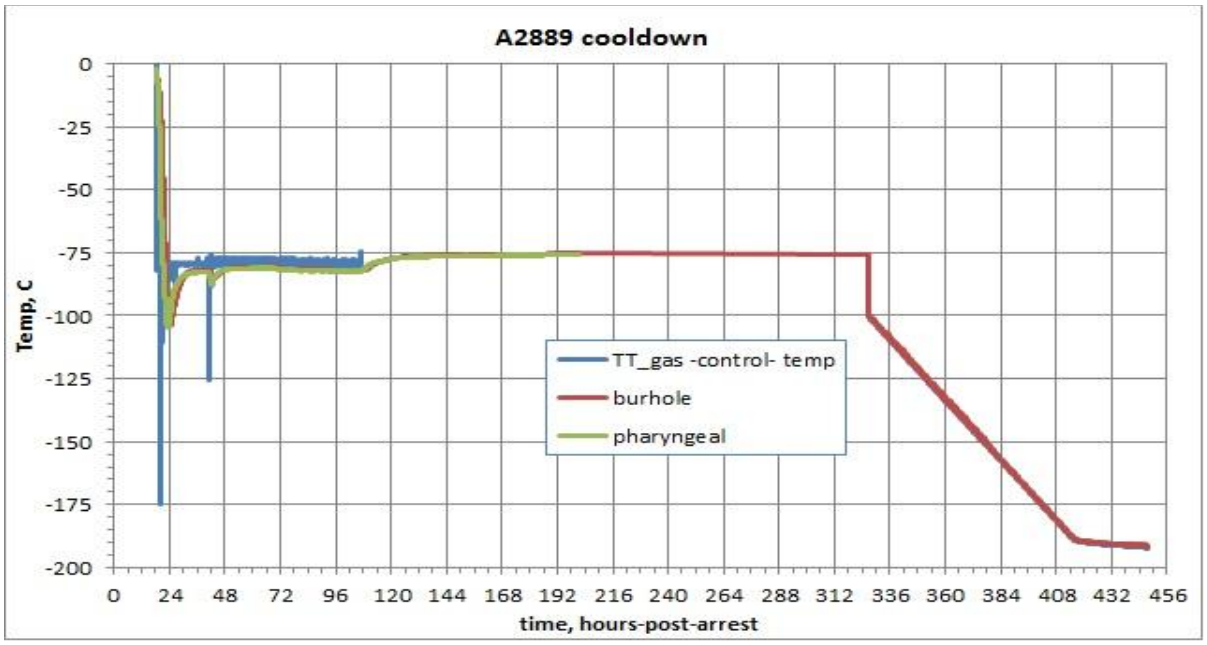


Cryogenic Cooling Temperatures

Cryogenic Cooling Temperatures



Final Cooling Temperatures



--End of report--