

# Inhospital CRF

## Emergency department

1) Hospital

- Södersjukhuset  KS Solna  Medizinische Universität Wien  Medizinischen Universität Graz  
 Universitätsklinikum Freiburg: Uniklinikum  Universitätsmedizin Halle  Asklepios Südpfalzlinik  
Kandel  Hospital Universitario La Paz  Hospital Clinico San Carlos  Univerzitetni Klinični Ljubljana  
 Univerzitetni Klinični Maribor  Other

2) Time of hospital arrival

\_\_\_\_\_

3) ROSC sustained until hospital arrival?  
(ROSC sustained until arrival at the hospital and care has been transferred to medical staff at the receiving hospital.)

- Yes  No

4) Admitted alive?  
(Admitted with ROSC or ROC (return of circulation supported by extracorporeal CPR))

- Yes  No

5) Patient declared dead at emergency department

- Yes  No

6) ECPR (extracorporeal CPR) performed?

- Yes  No

7) Time of ROSC or ROC (return of circulation supported by extracorporeal CPR) if ROSC/ROC after hospital arrival

\_\_\_\_\_

## First registered vital functions upon arrival to hospital (in ER, ICU or other location)

8) Systolic blood pressure (mmHg)

\_\_\_\_\_

9) Diastolic blood pressure (mmHg)

\_\_\_\_\_

10) Mean arterial pressure (MAP) (mmHg)

\_\_\_\_\_

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11) Spontaneous breathing

- Yes  No
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12) Glasgow Coma Scale (GCS)

- 3  4  5  6  7  8  9  10  11  12  13  14  15
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13) Pupillary response

- Present bilaterally  
 Absent bilaterally  
 Absent unilaterally  
 Not assessed
- 

14) Tympanic temperature (°C)

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15) Time of first registered tympanic temperature

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16) Core temperature (°C) (first registered)

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17) Time of first registered core temperature

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18) Core temperature location

- Rectal  
 Bladder  
 Esophageal  
 Blood
- 

19) ECG findings (first ECG post-ROSC)

- STEMI (>1mm ST elevation in  $\geq 2$  leads)  
 New LBBB  
 ST-segment depression (>1 mm in  $\geq 2$  leads)  
 None of the above  
 Other

**First arterial blood gas available after ROSC**

20) pH

\_\_\_\_\_

Conversion of mmHg to kPa  
mmHg value \* 0.133322

21) pO2 (kPa)

\_\_\_\_\_

22) pCO2 (kPa)

\_\_\_\_\_

23) Base excess (mmol/L)

\_\_\_\_\_

24) Lactate (mg/dl)

\_\_\_\_\_

25) O2-saturation (%)

\_\_\_\_\_

26) Hb (g/dl)

\_\_\_\_\_

27) B-glucose (mmol/L)

\_\_\_\_\_

**SOFA Score**

Conversion of mmHg to kPa  
mmHg value \* 0.133322










Admission Day 1 Day 2 Day 3  
PaO2 \_\_\_\_\_  
Fraction Inspired Oxygen (%) \_\_\_\_\_  
Creatinine \_\_\_\_\_  
Glasgow Coma Scale \_\_\_\_\_  
Bilirubin (mg/dL) \_\_\_\_\_  
Platelet count ( $\times 10^9/L$ ) \_\_\_\_\_  
Cardiovascular function (check one) \_\_\_\_\_

**Patients status prior to cardiac arrest (e.g. prior to randomization)**

28) Previous (before cardiac arrest) know co-morbidity  
(Check all that apply)

- Ischeamic heart disease
- Previous myocardial infarction
- Heart failure
- Atrial fibrillation/flutter
- Hypertension
- Diabetes type 1
- Diabetes type 2
- Chronic kidney disease
- Chronic liver disease
- Cancer
- Stroke/TIA
- Chronic obstructive pulmonary disease
- HIV
- None of the above

## Clinical Frailty Scale

<p>1 Very Fit – People who are robust, active, energetic and motivated. These people commonly exercise regularly. They are among the fittest for their age.</p>	
<p>2 Well – People who have no active disease symptoms but are less fit than category 1. Often, they exercise or are very active occasionally, e.g. seasonally.</p>	
<p>3 Managing Well – People whose medical problems are well controlled, but are not regularly active beyond routine walking.</p>	
<p>4 Vulnerable – While not dependent on others for daily help, often symptoms limit activities. A common complaint is being "slowed up" and/or being tired during the day.</p>	
<p>5 Mildly Frail – These people often have more evident slowing, and need help in high order IADLs (finances, transportation, heavy housework, medications). Typically, mild frailty progressively impairs shopping and walking outside alone, meal preparation and housework.</p>	
<p>6 Moderately Frail – People need help with all outside activities and with keeping house. Inside, they often have problems with stairs and need help with bathing and might need minimal assistance (cuing, standby) with dressing.</p>	
<p>7 Severely Frail – Completely dependent for personal care, from whatever cause (physical or cognitive). Even so, they seem stable and not at high risk of dying (within ~ 6 months).</p>	
<p>8 Very Severely Frail – Completely dependent, approaching the end of life. Typically, they could not recover even from a minor illness.</p>	
<p>9 Terminally Ill – Approaching the end of life. This category applies to people with a life expectancy &lt;6 months, who are not otherwise evidently frail.</p>	

## 29) Clinical Frailty Scale before OHCA

- 1 Very Fit - People who are robust, active, energetic and motivated  
 2 Well - People who have no active disease symptoms but are less fit than category 1  
 3 Managing Well - People whose medical problems are well controlled, but are not regularly active beyond routine walking.  
 4 Vulnerable - While not dependent on others for daily help, often symptoms limit activities.  
 5 Mildly Frail - These people often have more evident slowing, and need help in high order IADLs  
 6 Moderately Frail - People need help with all outside activities and with keeping house.  
 7 Severely Frail - Completely dependent for personal care, from whatever cause (physical or cognitive)  
 8 Very Severely Frail - Completely dependent, approaching the end of life. T  
 9 Terminally Ill - Approaching the end of life.

30) Estimated pre-arrest mRS - see Follow-up manuals for more details on mRS [princess2.org/manuals](https://princess2.org/manuals)

- 0 - No neurological symptoms  
 1 - No significant neurological symptoms. Able to carry out usual activities, despite some symptoms  
 2 - Slight disability. Able to look after own affairs without assistance, but unable to carry out all previous activities  
 3 - Moderate disability. Requires some help, but able to walk unassisted  
 4 - Moderate severe disability. Unable to attend to own bodily needs without assistance or unable to walk unassisted  
 5 - Severe disability. Requires constant nursing care and attention, bedridden, incontinent

**Core variables for systemic hypothermia in the intervention group**

## 31) Cooling method

- Intravenous system  
 Surface system

## 32) Time of initiation of systemic cooling

\_\_\_\_\_

## 33) Was trans-nasal cooling interrupted prior to systemic cooling?

- Yes  
 No

## 34) If trans-nasal cooling was interrupted, please specify reason

## 35) Time of termination of trans-nasal cooling

\_\_\_\_\_

Register core temperature every 20 minutes from start of systemic cooling until target temperature is reached, if not already at target temperature when systemic cooling is initiated.

Minutes from start of systemic cooling Core temperature

Start \_\_\_\_\_  
 20 \_\_\_\_\_  
 40 \_\_\_\_\_  
 60 \_\_\_\_\_  
 80 (1 h, 20 min) \_\_\_\_\_  
 100 (1 h, 40 min) \_\_\_\_\_  
 120 (2 h) \_\_\_\_\_  
 140 (2 h, 20 min) \_\_\_\_\_  
 160 (2 h, 40 min) \_\_\_\_\_  
 180 (3 h) \_\_\_\_\_  
 200 (3 h, 20 min) \_\_\_\_\_

- 180 (3 h) \_\_\_\_\_
- 200 (3 h, 20 min) \_\_\_\_\_
- 220 (3 h, 40 min) \_\_\_\_\_
- 240 (4 h) \_\_\_\_\_
- 260 (4 h, 20 min) \_\_\_\_\_
- 280 (4 h, 40 min) \_\_\_\_\_

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36) Time of core temperature  $\leq 34$  °C

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37) Time of Core temperature  $\leq 33$  °C

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Register core temperature every hour during maintenance phase (start registration 1 hour after target temperature is reached)

Core temperature

- Hour 1 \_\_\_\_\_
- Hour 2 \_\_\_\_\_
- Hour 3 \_\_\_\_\_
- Hour 4 \_\_\_\_\_
- Hour 5 \_\_\_\_\_
- Hour 6 \_\_\_\_\_
- Hour 7 \_\_\_\_\_
- Hour 8 \_\_\_\_\_
- Hour 9 \_\_\_\_\_
- Hour 10 \_\_\_\_\_
- Hour 11 \_\_\_\_\_
- Hour 12 \_\_\_\_\_
- Hour 13 \_\_\_\_\_
- Hour 14 \_\_\_\_\_
- Hour 15 \_\_\_\_\_
- Hour 16 \_\_\_\_\_
- Hour 17 \_\_\_\_\_
- Hour 18 \_\_\_\_\_
- Hour 19 \_\_\_\_\_
- Hour 20 \_\_\_\_\_
- Hour 21 \_\_\_\_\_
- Hour 22 \_\_\_\_\_
- Hour 23 \_\_\_\_\_
- Hour 24 \_\_\_\_\_

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38) Time of termination of systemic cooling (start of rewarming)

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39) Time of core temperature  $\geq 36.5$  °C

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40) Did the patient have fever  $> 37.7$  °C during the first 72 hours (one measurement of core body temperature  $> 37.7$  °C)

- Yes    No

**Echocardiography findings**

41) LVEF (%) at 24 hours (+/- 12 hours)

- Normal (> 55%)
- Mildly reduced (45-54%)
- Moderately reduced (30-44%)
- Severely reduced (< 30%)
- Not performed

42) LVEF (%) at 72 hours (+/- 12 hours)

- Normal (> 55%)
- Mildly reduced (45-54%)
- Moderately reduced (30-44%)
- Severely reduced (< 30%)
- Not performed

**Serious adverse events within 7 days**

43) Moderate bleeding, according to the GUSTO criteria (bleeding requiring transfusion, but not resulting in haemodynamic compromise)

- Yes  No

44) Severe bleeding according to Gusto criteria (intracranial hemorrhage or bleeding resulting in haemodynamic compromise necessitating intervention)

- Yes  
 No

45) Sepsis and septic shock, according to the 3rd international consensus definitions for sepsis and septic shock?

- Yes  No

46) Arrhythmia resulting in hemodynamic compromise?

- No
- Bradycardia with need for pacing
- Ventricular tachycardia
- Ventricular fibrillation

47) Cerebrovascular lesion during ICU stay

- Yes  No

48) New cardiac arrest after enrollment (requiring CPR/defibrillation)

- Yes  
 No

49) Circulatory complications?

- No
- Cardiogenic shock requiring inotropes
- Cardiogenic shock requiring mechanical support



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50) Cooling device related adverse events

- Yes  
 No  
 Uncertain (needs adjudication)
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51) If Yes, Specify

\_\_\_\_\_

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52) Did device related or other unexpected serious adverse event occur?

- Yes (fill in safety CRF)    No
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### **Sedation**

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53) Was the patient sedated 40 h according to protocol?

- Yes    No
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54) If sedation was terminated (including wake-ups) before 40 h from cardiac arrest, describe why

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### **Lab tests (During ICU stay)**

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55) NSE at 24 hours (if applicable)

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56) NSE at 48 hours (if applicable)

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57) NSE at 72 hours (if applicable)

\_\_\_\_\_

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58) Maximum level of Troponin T within 24 hours (if used by center)

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59) Maximum level of Troponin I within 24 hours (if used by center)

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**Angiography/Revascularization**

- 60) Angiography performed
- Not performed
  - Acute within 24h after admission
  - During ICU/hospital stay

61) PCI\_performed

- Yes  No

**Delirium**

62) Symptoms of delirium at the time of ICU discharge?  
Identified by: ICD-code for delirium, or positive delirium screening with the delirium assessment instrument used at the site (E.g. the CAM-ICU, the Nu-DESC etc.), or delirium described by text in the medical journals (according to the DSM-5 criteria for delirium).

- Yes
- No
- Missing
- Not applicable

63) Symptoms of delirium at seven days or later after OHCA?  
Identified by: ICD-code for delirium, or positive delirium screening with the delirium assessment instrument used at the site (E.g. the CAM-ICU, the Nu-DESC etc.), or delirium described by text in the medical journals (according to the DSM-5 criteria).

- Yes
- No
- Missing
- Not applicable

**Organ support during ICU stay**

64) Was the patient supported by an intra-aortic ballon pump (IABP)

- Yes  No

65) Was the patient supported by ECMO?

- Yes  No

66) If yes, was the patient put on ECMO during CPR (ECPR)?

- Yes  No

67) If supported with ECPR, when was ECMO started?

\_\_\_\_\_

68) Was the patient supported by an Impella?

- Yes  No

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69) Was the patient treated with continuous renal replacement therapy?

Yes  No

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70) Deviation from protocol

Yes  No

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71) If protocol deviation = Yes, describe

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**Prognostication at 72 hours - see manual for Neurologic prognostication  
princess2.org/manuals**

72) Time for prognostication

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73) Does the patient fulfill the study criteria for a likely poor neurological outcome?

Yes  
 No

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74) What prognostic methods beyond clinical neurological assessment were used for prognostication?  
(tick all that apply)

- NSE  
 SSEP  
 EEG  
 MR/CT brain scan

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**Withdrawal of life sustaining therapies / ICU care discontinued**

75) When was intensive care terminated?

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76) What prognostic methods beyond clinical neurological assessment were used in the event that intensive care was discontinued?  
(tick all that apply)

- NSE  
 SSEP  
 EEG  
 MR/CT brain scan

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77) If intensive care was discontinued before 72 hours from randomization, describe why?

**Discharge**

78) Did patient die during hospital stay?

- Yes (fill in below)  
 No
- 

79) If yes, where did the patient die

- ICU  
 Hospital ward
- 

80) Cause of death

- Cerebral  
 Cardiac  
 Infection  
 Multi-organ failure  
 Other
- 

81) Date and time of discharge

\_\_\_\_\_

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82) mRS at hospital discharge - see follow up manual for more information of mRS [princess2.org/manuals](https://princess2.org/manuals)

- 0 - No neurological symptoms.  
 1 - No significant neurological symptoms.  
 2 - Slight disability.  
 3 - Moderate disability.  
 4 - Moderate severe disability.  
 5 - Severe disability.
- 

83) Patient discharged to

- Home  
 Rehabilitation  
 Other