



Burn Navigator[®] RX

User's Manual



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Description

Burn Navigator® is a Clinical Decision Support tool to help health care providers manage IV fluid therapy for adult and pediatric severe burn patients. Each Burn Navigator device allows resuscitation of only one patient at a time.

Intended Use

The Burn Navigator is indicated for use in the care of adult patients with 20% or more Total Body Surface Area (TBSA) burned, or pediatric patients, 24 months old or older, weighing at least 10 kg with 15% or more TBSA burned, as a fluid resuscitation monitor and calculator for hourly fluid recommendations.

The Burn Navigator is intended to be used for burn patients of all ages, co-morbidities and weights from 1 to 400 kg as a fluid resuscitation monitor.

The Burn Navigator is intended to be initiated within 24 hours of the burn incident and to be used no longer than 72 hours post burn. The Burn Navigator is not intended for use in the care of patients weighing over 400kg.

Users are expected to have clinical training in emergency or critical care at a physician or nurse level.

The Burn Navigator can be used after Foley catheter insertion until the fluid resuscitation phase is complete.

The Burn Navigator is intended to be used in Burn Intensive Care Units, during patient transport and in other critical care environments where fluid resuscitation is performed.

Caution: Federal (U.S.) law restricts this device to sale by or on the order of a physician.

Safety Information

Use Warnings



The Burn Navigator® provides fluid recommendations for critically burned patients. Users should always rely on their clinical judgment when making decision regarding patient care. The Burn Navigator recommendations are not a substitute for clinical judgment.



WARNING! Gross myoglobinuria may require a high target urine output range. Consult attending physician regarding appropriate UO range.



WARNING! The Burn Navigator uses Urine Output as a surrogate for general organ perfusion. If Urine Output is not or no longer a good surrogate for organ perfusion in a particular patient, such as can happen with acute renal failure or use of diuretics, consult with attending physician for appropriate fluid therapy.



WARNING! The Weight-based protocol is not intended for patients weighing less than 10 kg, because immature kidneys may not regulate output during hypovolemia.



WARNING! Patients with inhalation injuries may need a higher rate of fluid resuscitation than the Burn Navigator algorithm recommends. Consult physician regarding appropriate fluid rates for a patient with an inhalation injury.



WARNING! Giving fluids in addition to the primary resuscitation fluid may require an adjustment to the fluid infusion rate by the user, different from the rate recommended by Burn Navigator. The attending physician should be contacted to determine the appropriate fluid infusion rate.



MR Unsafe. The Burn Navigator should **not** be used during a magnetic resonance imaging (MRI) procedure. Do **not** use the Burn Navigator in the same room or an adjacent room to the room where an MRI procedure is being performed. Consult the MRI device manual to determine the appropriate safe distance of use.



Essential Performance: The Burn Navigator provides fluid therapy recommendations for serious burn patients. If the Burn Navigator fails to generate a recommendation, clinicians will use an alternative guide to fluid resuscitation (e.g. Parkland or Modified Brooke formulas). The generation of a recommendation is not considered essential performance for patient safety. The other Burn Navigator features provide additional views to aid clinical judgment and also are not considered essential performance for patient safety.



The Burn Navigator needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in this manual.



The Burn Navigator should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, observe the device to verify normal operation in the configuration in which it will be used.



Portable and mobile radio-frequency (RF) communications equipment can affect medical electrical equipment.

Incoming Device Setup, Cleaning & Maintenance, Handling

Incoming device setup

- **Make sure the system date, time and time zone are correct.** Turn on Burn Navigator, press the System button, then press the Change Date/Time button.
- Check battery status and recharge the batteries if they are not full. The battery indicator in the top right of the screen shows four bars when full.



Cleaning & Maintenance

Cleaning and maintenance items are categorized by frequency.

During patient care:

- Disinfect the device and screen with a disinfectant wipe, such as an alcohol swab, CaviCide® wipe, Clorox Bleach® wipe or other germicidal wipe as needed.

After each patient:

- Disinfect the device and screen with a disinfectant wipe, such as an alcohol swab or CaviCide® wipe.
- If the tablet has crossed time zones during patient care, make sure the system date and time and the time zone are correct.
- Properly shut down the device.
- Recharge the Burn Navigator batteries.
- Before putting the device away, be sure to wipe off any moisture.
- Store between -10 and 50 degrees Celsius.

Quarterly:

- Make sure the system date and time and time zone are correct.
- Delete unneeded patient files.

Twice a Year:

- Adjust the time based on any daylight savings time changes.

CAUTION

- Do not use ester contained agent, strong alkaline agent, benzene or thinner since it may adversely affect the surface causing discoloration, etc. Do not use commercially-available household cleaners and cosmetics, as they may contain components harmful to the surface.
- Do not apply water or detergent directly to the computer since liquid may enter inside of the computer and cause malfunction or damage.

Operational environment

Place the computer on a flat stable surface. Do not place the computer upright or turn it over. If the computer is exposed to an extremely strong impact, it may become damaged.

Temperature: Operation: -10 °C to 50 °C {14 °F to 122 °F} (IEC60068-2-1, 2) *₁
 Storage: -20 °C to 60 °C {-4 °F to 140 °F}

Humidity: Operation: 30% to 80% RH (No condensation)
 Storage: 30% to 90% RH (No condensation)

Even within the above temperature/humidity ranges, using for a long time in an extreme environment will result in the product deterioration and will shorten the product life.

*₁ Do not expose the skin to this product when using the product in a hot or cold environment. If the computer is wet in temperatures of 0 °C {32 °F} or below, freeze damage may occur. Make sure to dry off the computer in such temperatures.

- Do not place the computer in the following areas, otherwise the computer may be damaged.
 - Near electronic equipment. Image distortion or noise may occur.
 - In extremely high or low temperature.
- As the computer can become hot during operation, keep it away from items that are sensitive to heat.

Handling cautions

This computer is designed to minimize shock to parts such as the LCD and the hard disk drive and equipped with a drip-proof keyboard, but no warranty is provided against any trouble caused by shock. Be extremely careful when handling the computer.

- When carrying the computer:
 - Turn off the computer.
 - Remove all external devices, cables, and other protruding objects.
 - Do not drop or hit the computer against solid objects.
 - Do not grip the display part.
- When you board an airplane, take the computer with you and never put it in your checked luggage. When using the device on airplane, follow the airline's instructions.
- When carrying a spare battery, put it in a plastic bag to protect its terminals.
- Be careful not to get injured by dropping or getting hit when carrying the computer.
- Be careful of computer drop resulting from the hand strap damage.
- Use only the included stylus/digitizer pen to touch the touchscreen. Do not place any object on its surface and do not press down strongly with sharp-pointed or hard objects that may leave marks (e.g., nails, pencils and ball point pens).
- Do not use the touchscreen when dust or dirt (e.g., oil) is on the screen. Otherwise foreign particles on the screen/stylus/digitizer pen can scratch the screen surface or obstruct the stylus/digitizer pen operation.
- Use the stylus/digitizer pen only for touching the screen. Using it for any other purpose may damage the stylus/digitizer pen and result in scratches on the screen.
- The cursor cannot follow the digitizer pen movement if you move the digitizer pen too quickly.

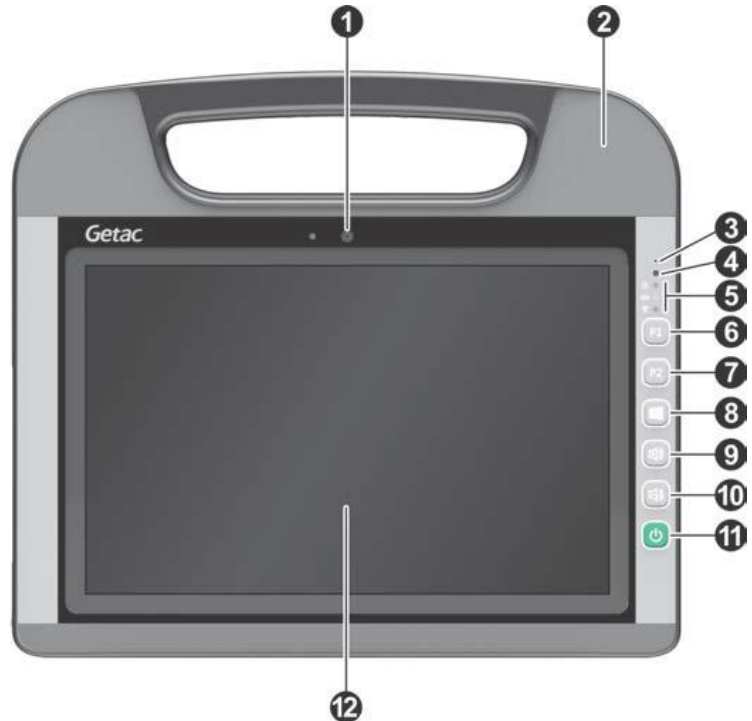
Tablet Description

The Burn Navigator RX device uses a Getac RX10h tablet computer.

Getac RX Model

Front Components

- 1 : Front Camera**
- 2 : Fingerprint Scanner**
- 3 : Microphone**
- 4 : Light Sensor**
- 5 : Power Status LED**
 - Off: Power off/Hibernation
 - Blue: Power on
 - Blinking Blue: Sleep mode
 - Amber: Charging
 - Green: Fully charged
 - Slow Red blink: battery low
 - Fast Red blink: Thermal protection problem
- 6: Programmable button one**
- 7 : Programmable button two (disabled)**
- 8 : Windows button (disabled)**
- 9 : Volume up button (disabled)**
- 10 : Volume down button (disabled)**
- 11 : Power button**
- 12 : LCD**



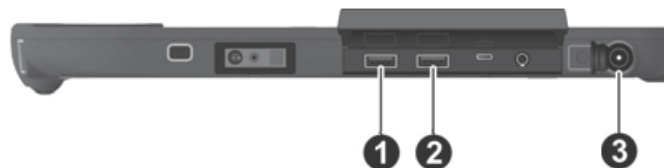
Rear Components

- 1 : Tether hole**
- 2 : Digitizer Pen**
- 3 : Bridge Battery Indicator**
- 4 : Battery Pack**
- 5 : Expansion Connector**
- 6 : Speaker**
- 7 : Back Camera**
- 8 : Camera Flash**



Left Components

- 1 : USB 3.0 port**
- 2 : USB 2.0 port**
- 3 : AC input port**



First-time Operation

AC Adapter (1)



CMP-1621

AC Power Cord (1)



CMP-1622

Battery Pack (2)



CMP-1623

Digitizer Pen and Tether (1)



CMP-1632

USB Data Drive (1)



CMP-1640

Inserting the Battery Pack

- 1 Hold the battery pack with the Getac serial number label facing the device.
- 2 Ensure that the keyed black connector is facing to the right (east).
- 3 Slide the battery pack into the back of the device at an angle so that the keyed black connector makes contact first.
- 4 Once the battery pack is in place, press on the left (west) side of the battery until it clicks into place

CAUTION

- Make sure the battery pack is securely locked in place. Otherwise the battery pack may fall when you carry the computer.
- Do not touch the terminals of the battery pack and the computer. Doing so can make the terminals dirty or damaged and may cause malfunction of the battery pack and the computer.

About the battery for this computer

The battery pack can be swapped without shutting down the device

- When the battery pack is removed, the device will remain powered on for a short amount of time.
- Ensure that the charged spare battery is nearby so that the battery can be swapped before the device shuts down
- Charge or swap the battery once the battery indicator begins to blink red.
- Full charge: Approximately 6.5 hours with 1 battery or 12 hours with 2 batteries

WARNING!

The use of accessories other than those specified above may result in increased electromagnetic emissions or decreased electromagnetic immunity of the Burn Navigator.

Using the digitizer pen

You can use Burn Navigator RX by touching screen in the same way as the mouse. Touch the screen surface with the digitizer pen (included).

Attaching the digitizer pen to the computer

- Pass one end of the tether (loop 1 in diagram) through the top of the stylus
- Pass loop 2 through loop 1 and pull it tight
- Pass loop 2 through the tether hole on the device
- Pass the pen through loop 2 and pull it tight



CAUTION

- Do not pull the tether with excessive force. The digitizer pen may hit the computer, person's body or other objects when released.

Handling the AC adaptor

- Problems such as sudden voltage drops may arise during periods of thunder and lightning. Since this could adversely affect your computer, an uninterruptible power source (UPS) is highly recommended unless running from the battery pack alone.

Turn on the computer

Press the power switch (component 11 as seen on page 8 of this manual).

The power indicator will turn on.

CAUTION

- Do not press the power switch repeatedly.
- The computer will forcibly be turned off if you press and hold the power switch for 4 seconds or longer.
- Once you turn off the computer, wait for 10 seconds or more before you turn on the computer again.
- Do not perform the following operation until the hard disk drive indicator turns off.
- Connecting or disconnecting the AC adaptor
- Pressing the power switch
- Touching the screen, external keyboard or external mouse
- When the CPU temperature is high, the computer may not start up to prevent overheating of the CPU. Wait until the computer cools down, and then turn the power on again. If the computer does not power on even after cooling down, contact Technical Support.

Precaution when Starting Up/Shutting Down

Do not do the following:

- Connecting or disconnecting the AC adaptor
- Pressing the power switch
- Touching the screen or external mouse

Using the Burn Navigator

CAUTION

Before using the Burn Navigator, assess the patient and perform any lifesaving interventions needed. The Burn Navigator is a fluid calculator and does not provide direct therapy to the patient.

Touchscreen

The Burn Navigator has a touchscreen. The touchscreen is a resistive-type screen, so it will work even if you are wearing gloves, but you may have to apply more pressure to the Burn Navigator screen than with other touchscreens you have used before.

Text Background Color

The Text Background Color indicates whether that field of text is editable by the user.

White background means you **can** edit the text field. You may be taken to a screen with a number pad or a keyboard.

Gray background means you **cannot** edit the text field.

Main Menu

The Main Menu lets you start a new patient, review an inactive patient file, or change system settings. Your hospital administrator may set a password for reviewing patient files. See the “Burn Navigator Administrator’s Manual” to change settings.

Training Mode

If you haven’t used the Burn Navigator before, you can use the Training Mode to familiarize yourself with the software and features.

To enter Training Mode, press the “Training Mode” button on the main menu, or start a new patient and enter a Patient ID that starts with “training”, e.g., training or training7Nov.

You can use all the features of Burn Navigator while in Training Mode. You will also be able to advance time to go through several hourly fluid updates in minutes.

Patient ID: TRAINING Weight: 35kg TBSA: HPB: 10:57

Select primary resuscitation fluid:
Lactated Ringer's

Select initial rate formula:
3 mL/kg/TBSA

Recommended rate: Enter new rate:
300 mL/hr 300 mL/hr

Back Enter

Patient ID: Weight: TBSA: HPB: 08:53

Burn Navigator
Main Menu

Start New Patient

Training Mode Review Patient

System Turn Off System

Device ID: BurnNav Version: V.6.1b

New Patient Setup

From the Main Menu, press “Start New Patient” or “Training Mode”.

1. Press the first white text field to enter the Patient ID.
2. You will then see a touch keyboard appear on the screen.
 - a. The “arrow” key is Caps Lock.
 - b. “Clear” deletes the last letter.
 - c. “Cancel” quits the keyboard without entering any data
 - d. “Enter” will enter the data as shown.
 - e. “Return”: If it is a multi-line text field, “Return” advances the text placement to the next line. Otherwise, it acts as the “Enter” key.
3. Next enter the patient weight.
 - a. You can enter weight in kilograms (kg) or pounds (lbs).
 - b. A number pad will appear for you to enter the weight.
 - c. The Burn Navigator will display the weight in kg for the rest of the resuscitation.

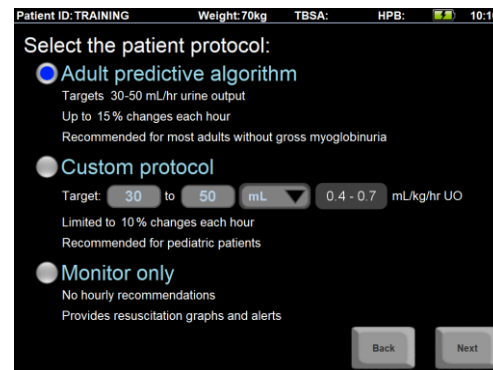
After you enter the weight, press “Next” to go to the next screen.

4. You will be asked if the patient has any confounders. Special consideration regarding resuscitation is required with the presence of any of these confounders: myoglobinuria, high blood alcohol content, hyperglycemia or end stage renal disease or congestive heart failure.

ALERT: If you answer yes to any of these questions, consult with the Attending Physician to determine appropriate fluid therapy.

5. Choose the protocol.

- a. **Adult predictive algorithm:** Targets 30-50 mL/hr Urine Output (UO). This protocol uses the Salinas algorithm developed by the US Army Burn Center (Salinas, J et al, Computerized decision support system improves fluid resuscitation following severe burns: An original study, Crit Care Med 2011, 39(9), 2031-8). The Salinas algorithm uses the trend of the last three hours of UO to recommend the next hour's IV infusion rate. The Salinas algorithm will go up to the hourly cap chosen by your medical director (e.g., 15% or 20% each hour). See the Burn Navigator Administrator's Manual for changing the hourly cap.

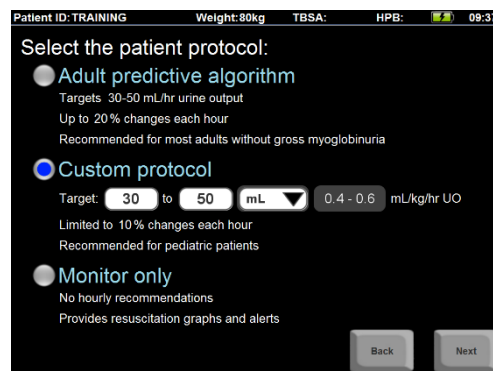


The Adult predictive protocol is recommended for most adult patients without resuscitation confounders. Consult with the attending physician before using this protocol on a patient with a confounder.

b. **Custom protocol:**

The custom protocol allows clinicians to set a target Urine Output range in **mL** or **mL/kg** each hour. The other unit (either mL or mL/kg) is calculated in gray on the right.

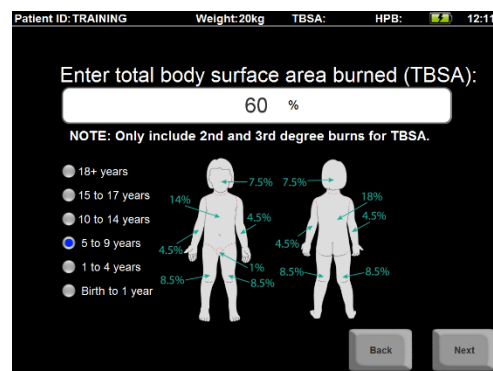
If the patient's UO is not in target, then the Custom Protocol will recommend increasing or decreasing the IV fluid rate by 10%. The custom protocol is limited to 10% changes each hour.



- c. **Monitor only:** This mode does not provide hourly recommendations, but does provide resuscitation graphs, alerts and the 24 hour fluid projection. This mode is recommended when urine output is not a good surrogate of general organ perfusion (such as acute renal failure or with diuretics), or when the physician does not want to use another protocol.

6. Enter the TBSA.

CAUTION: Only include 2nd and 3rd degree burns when calculating the TBSA!



7. Patient height is an optional field for the Adult predictive protocol.

Note: Body surface area is calculated using the Haycock algorithm.

The screenshot shows the 'Enter patient height' screen. At the top, it displays 'Patient ID: TRAINING', 'Weight: 20kg', 'TBSA:', 'HPB:', and a battery icon with the time '12:11'. The main text says 'Enter patient height: (Optional for adult predictive algorithm)'. There are two input fields: '114 cm' and '45 inches'. Below these, it shows 'Body surface area: 0.794 m²'. Further down, it displays 'TBSA: 60 %' and 'Burned surface area: 0.477 m²'. At the bottom right, there are 'Back' and 'Next' buttons.

8. Enter elapsed time since burn occurred. How long ago did the burn happen?

Note: There are two separate number fields: one for hours and one for minutes. The software will calculate the time of burn using your local time and the number of hours and minutes elapsed since the burn occurred.

The screenshot shows the 'Enter elapsed time since burn occurred' screen. At the top, it displays 'Patient ID: TRAINING', 'Weight: 20kg', 'TBSA:', 'HPB:', and a battery icon with the time '12:00'. The main text says 'Enter elapsed time since burn occurred:'. There are two input fields: '1 hours' and '-- minutes'. Below these, it shows 'Time of burn: 11:00 05-Aug-2016'. At the bottom left, there is a 'Change current Date/Time' button. At the bottom right, there are 'Back' and 'Next' buttons.

If you need to edit the time, press the “Change current Date/Time” button. See “Change Date/Time” in the “System Functions” section for a description of the Change Date/Time screen.

Note: If your Burn Navigator is configured to time sync with your network, then you cannot edit the clock time. Dock the Burn Navigator and wait a few seconds for the time sync. If you can’t dock now, just make sure the elapsed time since burn occurred (in hours and minutes) is correct, and the Burn Navigator will adjust the actual time of burn after you dock the Burn Navigator later. If you don’t see the time sync after docking the Burn Navigator, then contact your hospital IT department for help.

9. Next enter how much fluid the patient has received from the time of burn until now.
 - a. Then enter the urine output from time of burn until now.
 - b. If you don’t know either answer, you may skip the questions by pressing “Next”. You can add this data later on the Patient tab.

The screenshot shows the 'Enter fluids given until now' screen. At the top, it displays 'Patient ID: TRAINING', 'Weight: 20kg', 'TBSA:', 'HPB:', and a battery icon with the time '12:02'. The main text says 'Enter fluids given until now:'. There is an input field with '250 mL'. Below this, it says 'Enter urine output until now:'. There is an input field with '--- mL'. At the bottom right, there are 'Back' and 'Next' buttons.

10. On the Recommendation screen, you may choose the primary resuscitation fluid type. Lactated Ringer's is selected by default.
 - a. Options include albumin protocols, where the primary fluid to be titrated is composed of, e.g., 2/3 LR and 1/3 Albumin 5%. If you choose one of these protocols, you will see the calculated rate for each fluid under the "Recommended rate" and "Enter new rate" fields.
11. Based on a doctor's order and patient condition, you may select the formula for the initial rate. The recommended rate will be the value calculated by the initial formula, but only as high as 2,000 mL/hr or as low as 100 mL/hr or 20 mL/hr (based on Adult predictive or Weight-based protocols). The recommendation is shown with a gray background.
 - a. Note: the minimum rate can be changed on the Patient screen after you've started the resuscitation.
12. You may choose a different rate by pressing the white field at the bottom right. If you do change the initial rate, the software will ask you for the rationale and to provide the attending physician's name.

Patient ID: TRAINING Weight: TBSA: HPB: 12:11

Select primary resuscitation fluid:
Lactated Ringer's

Select initial rate formula:
2 mL/kg/TBSA (Consensus)

Recommended rate: 700 mL/hr Enter new rate: 700 mL/hr

Back Enter

Patient ID: TRAINING Weight: 80kg TBSA: HPB: 21:40

Select primary resuscitation fluid:
(2/3) LR + (1/3) Albumin 5%

Select initial rate formula:
4 mL/kg/TBSA (Parkland)

Recommended rate: 920 mL/hr Enter new rate: 920 mL/hr

LR 613 mL/hr Alb 5% 307 mL/hr

Back Enter

You have now completed the New Patient setup!

After starting a new patient, you will be taken to the **Home Screen**.

Patient ID: TRAINING Weight: 80kg TBSA: 50% HPB: 2 16:01

Home Patient Notes I/O Table Volume I/O Graph UO

Current primary fluid: Lactated Ringer's Next update due: 59 minutes

Current infusion rate: 620 mL/hr

Hourly Update End Decision Support Enter Notes Enter Checklist System Menu Screen Saver

Checklist

After you start a new patient, a pop-up message will ask you to complete a patient assessment checklist. Press “Yes”.

On the checklist screen you can enter vitals and labs, as well as completing extremities steps and observations.

The Checklist allows you to track other indicators of resuscitation status other than urine output. Currently, the Checklist data is not used in the recommendation protocols and is optional.

The screenshot shows the 'Checklist' screen for a patient in 'TRAINING' mode. At the top, patient information is displayed: Patient ID: TRAINING, Weight: 20kg, TBSA: 60%, HPB: 1, and a battery icon with the time 12:03. The checklist is divided into several sections: 'Enter Vitals' with fields for Systolic BP (85 mmHg), Diastolic BP (64 mmHg), CVP (--- mmHg), and Heart rate (115 bpm); 'Enter Bladder Pressure' with a field for Bladder pressure (--- mmHg); 'Enter Labs' with fields for ScvO2 (--- %), Lactate (2.1 mg/dL), Base excess (--- mEq/L), and Hemoglobin (10.5 g/dL); 'Check Extremities' with checkboxes for 'Elevate burned extremities' and 'Check for tightness', both of which are checked; and 'Check Pulses' with dropdown menus for Left upper (normal), Right upper (weak), Left lower (normal), and Right lower (weak). At the bottom right, there are 'Cancel' and 'Enter' buttons.

The software will prompt you to do a checklist when you start resuscitation and every 6 hours later. You can enter checklist data when you want by pressing the “Enter Checklist” button on the Home screen.

If you don’t know some data for the checklist, you can leave that field blank.

Note: If a pulse is detectable by Doppler only, select “weak”.

Training Mode

If you are in Training Mode, you can advance time to the next hourly update by pressing the “Next Update” button in the bottom right of the Home screen.

If you are not in Training Mode, you will see “Screen Saver” instead of “Next Update”.

Alternatively, you can press the “System Menu” button on the bottom right of the Home screen, then advance the time as needed with the Advance Time control in the bottom left part of the System Menu.

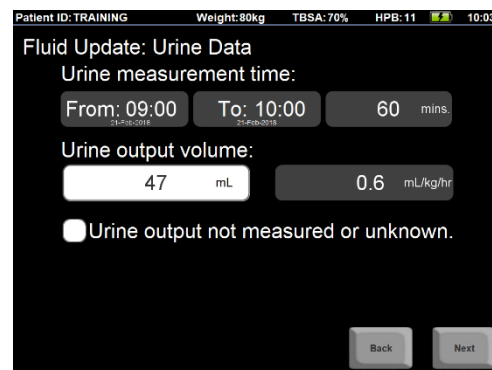
When in Training Mode the screen saver will not automatically turn on.

You can save the training patient file as other files. The file name will include the Patient ID, which starts with “training”, so you can easily distinguish the training patient files from the real patient files.

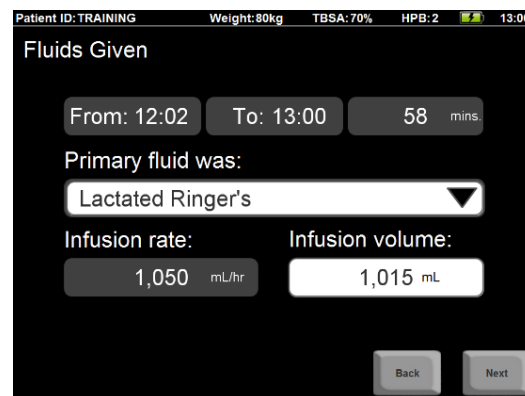
Hourly Fluid Updates

The Fluid Update Wizard (series of screens) will appear automatically when it is time to do an hourly fluid update.

The **Urine Data** screen shows the “From” and “To” times for this update.



- a. The “From:” time is the last time you entered data (new patient setup or last hourly update).
 - b. The “To:” time is the current time.
 - c. The Burn Navigator will calculate and display the number of minutes between the From and To times. The “From:” and “To:” times are not editable.
1. Enter the urine output volume for this time period.
 - a. If a urimeter was connected for nearly all (approximately 90%) of the last update period, the Burn Navigator will auto-fill the measured UO value.
 - b. If the urine output is unknown for some reason, then check the box on the bottom left.
 - c. Burn Navigator will calculate and display the urine output in mL/kg/hr.
 - d. Once you enter urine output, the “To:” time will stop incrementing with the clock time.
 2. On the **Fluids Given** screen, verify the primary fluid and the infusion volume for this time period.
 - a. The gray boxes on top show the From and To times from the last screen, as well as the time duration.
 - b. The second row shows the primary resuscitation fluid type.
 - c. On the third row, the gray field shows the primary fluid infusion **rate** based on the last setting given to Burn Navigator. The white field shows the primary fluid infusion **volume** based on the rate and time duration.



PLEASE NOTE!

- If you’ve changed the rate during the hour from the Home screen, then Burn Navigator will calculate the **volume** based on how long the Home screen pump was at Rate 1, Rate 2, etc., then calculate the average **rate** for the whole update.
- You can change the **volume** by pressing the white field. If you change the **volume**, Burn Navigator will change the average **rate** for the update accordingly.
- The Burn Navigator does not communicate with your fluid infusion pump(s), so it does not know when or by how much you may have changed pump flow rates during

the time period, unless you update the pump setting changes timely on the Home screen or provide the total volume during the fluid update.

- If a **bolus** of the primary resuscitation fluid was given, then you can add the bolus to the total **volume** given. The algorithm will include the bolus when determining the next recommendation. If you don't want the algorithm to include the bolus volume for the next recommendation, then add the bolus volume to the next screen, Additional Fluids, instead.

3. On the **Additional Fluids** screen, add any fluids given to the patient in addition to the primary resuscitation fluid.

- Press "Select fluid type..." to see a list of Additional Fluid options.
- Additional Fluids are divided into two categories: **Adjunct Fluids** and **Other Fluids**.
- Adjunct fluids are included in the volume graph.
- Other Fluids are **not** represented in the volume graph.
- Check the "Repeat" box to have that fluid type and volume show up for the next update. When repeated, Adjunct fluids are included in the and the 24-hour fluid projection, but Other fluids are not.
- You can press the red "X" to delete the fluid type.
- If you don't see the fluid you gave on this screen, then choose the bottom option, "Any Other Fluids," and write a note to identify the fluid type.

Note: Provide all additional fluids as a **volume** for the time period.

Patient ID: TRAINING Weight: 90kg TBSA: 25% HPB: 6 09:00

Additional Fluids

Fluid Type	Volume	Repeat
Select fluid type...		
Adjunct fluids category:		
Lactated Ringer's		
Normal Saline		
Plasma-lyte		
5% Albumin		

Total Additional Fluids: --- mL

Back Next

Patient ID: TRAINING Weight: 75kg TBSA: 35% HPB: 11 18:02

Additional Fluids

Fluid Type	Volume	Repeat
Select fluid type...		
Other fluids category:		
LR + 5% Dextrose		
Tube Feeds		
IV Medications		
Other Fluids		

Total Additional Fluids: --- mL

Back Next

4. You may or may not see the **Safety Questions** screen. This screen asks if the patient is hypotensive, hyperglycemic, on pressors or on diuretics. These questions are asked when the algorithm recommends decreasing fluids.

ALERT: If you answer yes to any of these questions, consult with the Attending Physician to determine appropriate fluid therapy.

CAUTION: Use clinical judgment to determine if your patient is hypotensive.

CAUTION: If the patient is on pressors, ask the attending physician if the pressors can be reduced rather than decreasing the primary fluid rate.

The screenshot shows the 'Safety Questions' screen. At the top, patient information is displayed: Patient ID: TRAINING, Weight: 80kg, TBSA: 33%, HPB: 5, and a battery icon with the time 16:00. The screen contains four questions, each with 'Yes' and 'No' radio button options:

- Is patient hypotensive? ☐ Yes ☐ No
- Is patient hyperglycemic? ☐ Yes ☐ No
- Is patient on pressors? ☐ Yes ☐ No
- Is patient on diuretics? ☐ Yes ☐ No

At the bottom right, there are 'Back' and 'Next' buttons.

5. Next, you'll see the **New Rate** screen. This screen shows you the previous rate and the recommended rate with a percent change indicator. **You may enter a different fluid rate by pressing the white box indicating "New rate."**

- a. In Monitor Only mode, you won't see a recommendation. You will see a red message reminding you that you are in Monitor Only mode. Press the white box to enter the new rate.

The screenshot shows the 'New Rate' screen. At the top, patient information is displayed: Patient ID: TRAINING, Weight: 20kg, TBSA: 60%, HPB: 2, and a battery icon with the time 13:11. The screen displays the following information:

- Previous infusion rate: 230 mL/hr
- Fluid type: Lactated Ringer's (selected from a dropdown menu)
- Recommended rate: 253 mL/hr with a 10% increase indicated by a blue upward arrow.
- New rate: 270 mL/hr with a 17% increase indicated by a blue upward arrow.

At the bottom right, there are 'Back' and 'Enter' buttons.

Adult Predictive Algorithm mode

6. If you enter a rate different from the recommendation, the Burn Navigator will ask you to enter the rationale, the attending physician's name and your own name. The Burn Navigator will create a note (on the Status screen) with the rationale you select. The rationale screen does not show up in Monitor Only mode.

- a. Note: In Monitor Only mode there is no UO-based recommendation.

Patient ID: TRAINING Weight: 80kg TBSA: 46% HPB: 11 06:06

New Rate

Previous infusion rate: 922 mL/hr

Fluid type: Lactated Ringer's

Recommended rate: --- mL/hr ---% New rate: 800 mL/hr 13% ↓

No recommendations during Monitor only protocol.

Back Enter

Monitor Only mode


You have now completed the Hourly Fluid Update! You will be taken to the Home screen.

Patient Resuscitation Screens

The patient resuscitation screens show a top bar, a row of six tabs to select the six patient resuscitation screens, and a row of functional buttons along the bottom of the first three screens.

Top Bar & Battery Indicator

The top bar shows the Patient ID, patient weight and TBSA, the current Hour Post Burn (HPB), the battery indicator, and the current time.

Patient ID: TRAINING Weight: 80kg TBSA: 70% HPB: 2  12:13

Hours Post Burn (HPB)

Hours Post Burn (HPB) is a measure of time, in hours, after a burn has occurred. The HPB count is iterated at the top of the hour (e.g., 04:00, 11:00), so one HPB represents a clock hour (e.g. 04:00 – 04:59). The clock hour in which a patient is burned is considered HPB 0. For example, if a patient's burn occurred at 07:20, the HPBs would be numbered:

07:00 – 07:59 HBP 0

08:00 – 08:59 HBP 1

09:00 – 09:59 HBP 2, and so on.

Battery Indicator

The battery indicator has six icons. When the Burn Navigator is plugged into the wall, you will see the charging icon. When running on batteries, you will see one of the four battery bar icons. As the battery levels decrease, you will see fewer bars. If the battery state is unknown for some reason, you will see the unknown icon.







You will see a low battery pop-up alert when the battery level is approximately 20%, and then a *critically* low battery pop-up alert when the battery level is approximately 15%.

Note: When you see the *critically* low battery message, immediately plug in the Burn Navigator, insert a fresh battery, or transfer your data to another Burn Navigator device. At 10% battery level, the Burn Navigator saves your data and shuts down to preserve integrity of the data.

Screen Tabs

Immediately below the top bar are six tabs to select the six patient resuscitation screens: Patient, Home, Status, I/O Table, Volume, I/O Graph.

Patient ID: TRAINING Weight: 20kg TBSA: 60% HPB: 4  15:30

Home	Patient	Notes	 I/O Table	 Volume	 I/O Graph
------	---------	-------	---	---	---

Functional Buttons

Along the bottom of the Home, Patient and Notes screens is a row of Functional buttons.



If “Enter Notes” feature is disabled in “Admin Settings”, then the Enter Notes button will not show on this row.

If you are in “Training Mode”, then the far right button will be “Next Update” rather than “Screen Saver”.

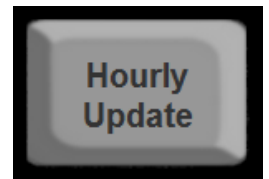
Note that for an inactive patient file, you cannot enter hourly updates, notes, or checklists.



Hourly Update

The first button, “Hourly Update” provides two functions.

- 1) If it is time for an hourly fluid update, pressing this button will take you through the Hourly Fluid Update screens.
- 2) If you have entered an Hourly Fluid Update within the last 10 minutes (the “grace period”) and another hourly fluid update is not due, then you can press this button to redo the last fluid update. You will be given a new fluid recommendation if you use this button. If you redo an update and you enter new values, those values will not show up as edited in the I/O Table.



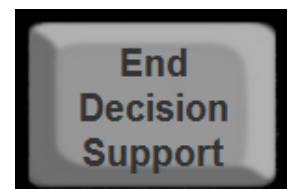
If an hourly update is not due and it has been more than 10 minutes from your last hourly update when you press this button, then you will see a message saying it is not yet time for a new hourly update and more than 10 minutes have passed since the last hourly update.

Note: To edit past hourly fluid updates, go to the I/O Table and touch the column representing the time period you want to edit.

End Decision Support

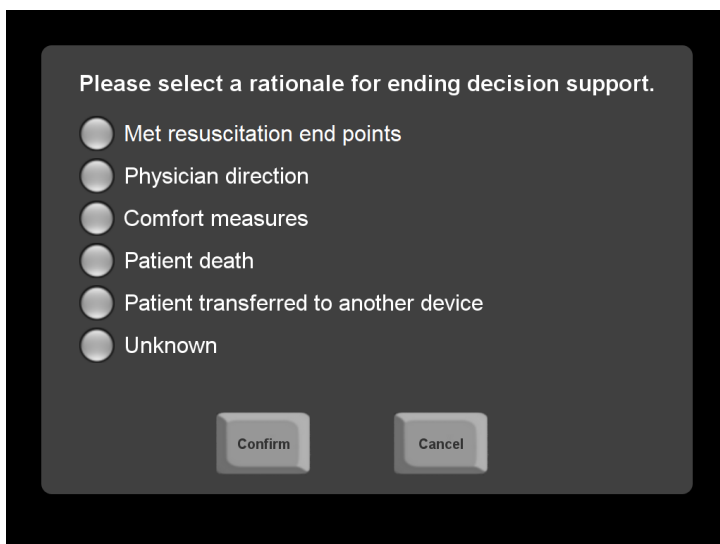
The End Decision Support button will close the patient file.

CAUTION: Once decision support has been ended for this patient, you will not be able to perform any new hourly fluid updates or change any information!



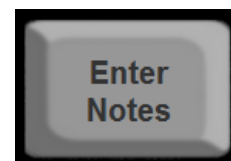
When you press the End Decision Support button, you will be asked twice to confirm ending decision support for this patient.

When you press the End Decision Support button, you will be asked to select a rationale for ending decision support.



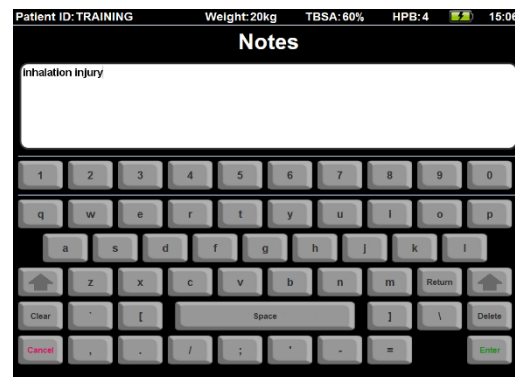
Enter Notes

Pressing the Enter Notes button takes you to a keyboard screen for entering notes.



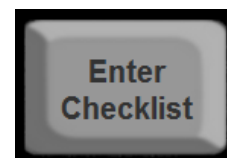
- This text field is multi-line, so you can enter more than one line of notes at a time.
- The notes will appear on the Status screen.

This button will not appear if disabled in “Admin Settings”.



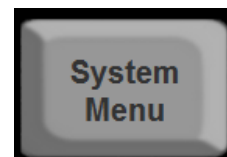
Enter Checklist

Pressing the Enter Checklist button will take you to the checklist screen. See the “Checklist” section above.



System Menu

This button takes you to the System Menu screen. See the System Functions section, below.

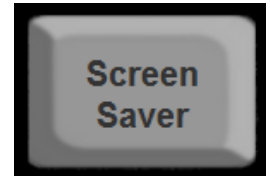


The last button will be either “Screen Saver” or “Next Update”:

Screen Saver

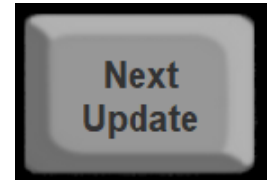
The screen saver button will darken the screen, helping preserve battery life.

NOTE: When an hourly fluid update is due or there is another alert message, the screen saver will end and you will see the message.



Next Update

When you are in “Training Mode”, you will see “Next Update” instead of “Screen Saver”. Press “Next Update” to advance the clock to the next hourly update.

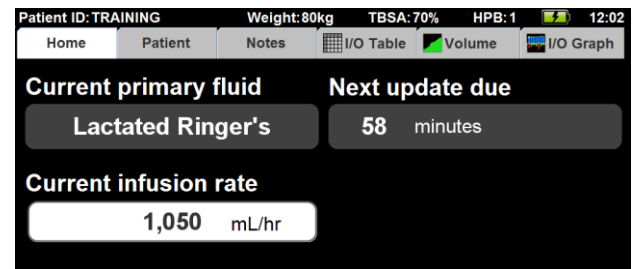


NOTE: The screen saver does not automatically turn on when in Training Mode.

Home

The Home screen shows:

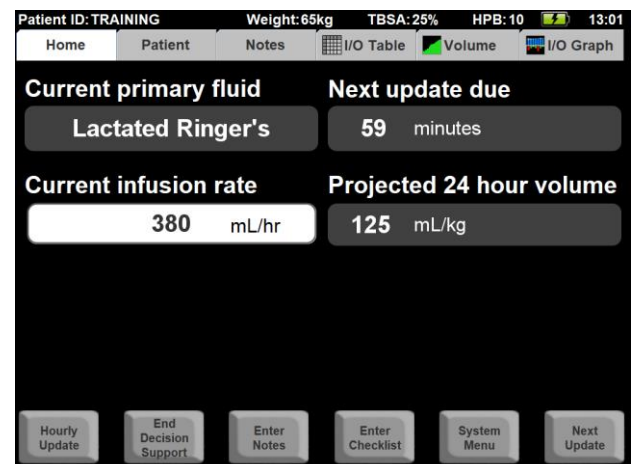
- 1) The current primary fluid
- 2) The current infusion rate
- 3) When the next update is due
- 4) By hour post burn 10, the Projected 24 hour volume.



The Next Update Due will show a number of minutes until the update is due, or it will show “NOW” if the update is due.

Updating Pump Rate

When you change the pump rate in between hourly updates, update the Burn Navigator on the Home screen by pressing the “Current infusion rate” field. The software will calculate the total volume for the next hourly update based on how long the pump was at each rate. **Note:** The Burn Navigator does not communicate with any pumps.



Patient

The Patient screen shows the Information you entered in the New Patient Setup. You may change the data in the white fields, except for the Protocol.

The Burn Navigator start time (“BurnNav started”) is time stamped when you complete the New Patient Setup. The BurnNav started time cannot be changed. The elapsed time since burn is calculated based on the original calculated time of burn.

On the Patient tab, select the **Minimum rate** field to see the Minimum rate screen.

The **Minimum rate** screen shows the lowest recommendation the Burn Navigator will provide for a patient.

- a. First 8 hours post burn (HPB): the minimum rate is determined by the 2mL/kg/TBSA formula.
- b. After 8 HPB: you can choose either a formula or choose “Manual” and type in the minimum rate. The formulas are:
 - i. The 4-2-1 weight formula is: (4 mL/kg/hr for the first 10 kg) + (2 mL/kg/hr for the next 10 kg) + (1 mL/kg/hr for weight above 20 kg).
 - ii. Burn Surface Area formula is:
 3750 mL/m² Burn Surface Area per day (burn related losses)
 + 1500 mL/m² Body Surface Area per day (maintenance fluids)

Notes

The Notes screen has two sections.

The **Notes** section on the left shows any notes that have been entered through the “Enter Notes” button, as well as various Burn Navigator-generated notes.

The first note, “Resuscitation Plan” is automatically added based on the options chosen in the new patient setup.

The most recent note will always be at the top of the section. Scroll down to see progressively older notes.

The **Checklist** section on the right displays checklist data provided through the “Enter Checklist” button and screen. Note that any item not addressed in the checklist screen will be displayed blank (as “---”) in the Checklist section.

The most recent checklist will always be at the top of the section. Scroll down to see progressively older checklists.

The screenshot displays the Burn Navigator interface with the following details:

- Header:** Patient ID: TRAINING, Weight: 80kg, TBSA: 70%, HPB: 4, 15:16.
- Tabs:** Home, Patient, Notes (selected), I/O Table, Volume, I/O Graph.
- Notes Section (Left):**
 - Entered rate: 1000 mL/hr
 - Physician: MD
 - Caregiver: RN
 - Rationale: Patient is tachycardic
 - 06-Aug-2016 12:02 HPB: 1
 - Resuscitation Plan:
 - Adult predictive protocol
 - Target UO 30-50 mL/hr
 - Initial formula: 3 mL/kg/TBSA
 - Initial formula rate: 1050 mL/hr
 - Max recommendation: 2000 mL/hr
 - Min recommendation 1-8 HPB: 700 mL/hr
 - Min recommendation 9+ HPB: 100 mL/hr
 - Recommendation changes: up to 25%
 - Burn Navigator Version: V.5.1a
- Checklists Section (Right):**
 - 06-Aug-2016 12:02 HPB: 1
 - Checklist
 - Systolic BP = 88 mmHg
 - Diastolic BP = 56 mmHg
 - CVP = --- mmHg
 - Heart rate = 127 bpm
 - Bladder pressure = --- mmHg
 - Lactate = 2.1 mg/dL
 - ScvO2 = --- %
 - Base excess = --- mEq/L
 - Hemoglobin = 10.5 g/dL
 - Left upper pulses = weak
 - Right upper pulses = normal
 - Left lower pulses = weak
 - Right lower pulses = normal
 - Burned extremities elevated
 - Tightness checked
- Bottom Buttons:** Hourly Update, End Decision Support, Enter Notes, Enter Checklist, System Menu, Screen Saver.

I/O Table

The I/O Table shows all the fluid information for the patient.

On the left of the screen is a list of fluids and other information: the UO (in mL and in mL/kg/hr), Recommended Rate for that time period, Actual Primary Fluids given to the patient, Total Adjunct Fluids, and Total Other Fluids. The bottom rows show whether the patient is hypotensive, on pressors, or on diuretics, if those safety questions were asked during the fluid update.

Note: the safety questions are not asked each hour; they are asked only when the recommendation algorithm wants to decrease the fluid rate.

The legend in the top right explains abbreviations and symbols used in the table:

LR: *Lactated Ringer's*

PL: *Plasma-lyte*

NS: *Normal Saline*

^ (yellow carat symbol):

Pre-Burn Navigator values

* (red asterisk): *Edited value*

(): *Projected value*

Note: the projected value only applies to the time period after the most recent HPB update.

There are two views of the I/O Table: Hourly Averages and Actual Times

Hourly fluid updates should happen at the top of each hour (when the clock reads __:00), but you may be a few minutes late. The Burn Navigator will accept data even if it the data is not at the top of the hour. We generate two views of the I/O Table:

- 1) **Hourly Averages** (on the right) indicates where the software averages the data you provide to fit into the fixed 60-minute hour post burn periods, e.g., from 02:00 to 03:00, 03:00 to 04:00, etc.

Patient ID: TRAINING

Weight: 90kg

TBSA: 25%

HPB: 4

07:01

Home

Patient

Notes

I/O Table

Volume

I/O Graph

Actual Times (Edit)

Hourly Averages

Legend:

▲ - Pre-Burn Nav.

● - Edited Value

() - Projected Value

LR - Lactated Ringer's

PL - Plasma-lyte

NS - Normal Saline

Hours Post Burn (HPB)	HPB0	HPB1	HPB2	HPB3	HPB4
Clock Hour	3 - 4	4 - 5	5 - 6	6 - 7	7 - 8
Urinary Output (mL)		8	36	44	
Urinary Output (mL/kg/hr)		0.1	0.4	0.5	
Recommended Rate (mL/hr)		280	280	280	(280)
Actual Primary Rate (mL/hr)		65	280	280	
Actual Primary Volume (mL)		65	280	280	
Lactated Ringer's (mL)		65	280	280	
Total Adjunct Fluids (mL)		9	41		
5% Albumin (mL)		9	41		
Total Resus. Fluids (mL)		75	321	280	
Total Other Fluids				20	
IV Medications (mL)				20	
All Fluids In (mL)		75	321	300	
Cumulative All Fluids In (mL)		75	395	695	

*Select Actual Times to edit columns

In the Hourly Averages view, each column represents exactly 60 minutes, matching clock hours.

2) **Actual Times** (on the right) indicates the values entered for the actual time period of the update. For example, the screen on the right shows one fluid update period ending at 11:01, one minute after the top of the hour.

In Actual Times view, a column might represent any number of minutes (60, 72, 53, etc.) depending on when the updates were actually entered.

Actual Times	04:46	06:00	07:00	08:00	(09:00)
Urinary Output (mL)		44	44	36	
Urinary Output (mL/kg/hr)		0.4	0.5	0.4	
Recommended Rate (mL/hr)		280	280	280	(280)
Actual Primary Rate (mL/hr)		280	280	280	
Actual Primary Volume (mL)		345	280	280	
Lactated Ringer's (mL)		345	280	280	
Total Adjunct Fluids (mL)		50		100	
5% Albumin (mL)		50			
Oral Resus. Solution (mL)				100	
Total Resus. Fluids (mL)		395	280	380	
Total Other Fluids			20		
IV Medications (mL)			20		
All Fluids In (mL)		395	300	380	
Cumulative All Fluids In (mL)		395	695	1,075	

Actual Times (clock times view)

Note: The I/O Graph screen shows the values from the **Hourly Averages** view of the I/O Table.

Editing Data

If you notice an error in the I/O Table, you can correct it only in the **Actual Times (edit)** view. Press the column representing the time period you want to edit.

The volume graph shows the cumulative volume of all fluids (Primary and Adjunct resuscitation fluids) that the patient has received since the burn occurred.

Note: The Cumulative Volume graph includes only primary and adjunct fluids. Other fluids are not included.

There are four or five lines overlaying the volume graph:

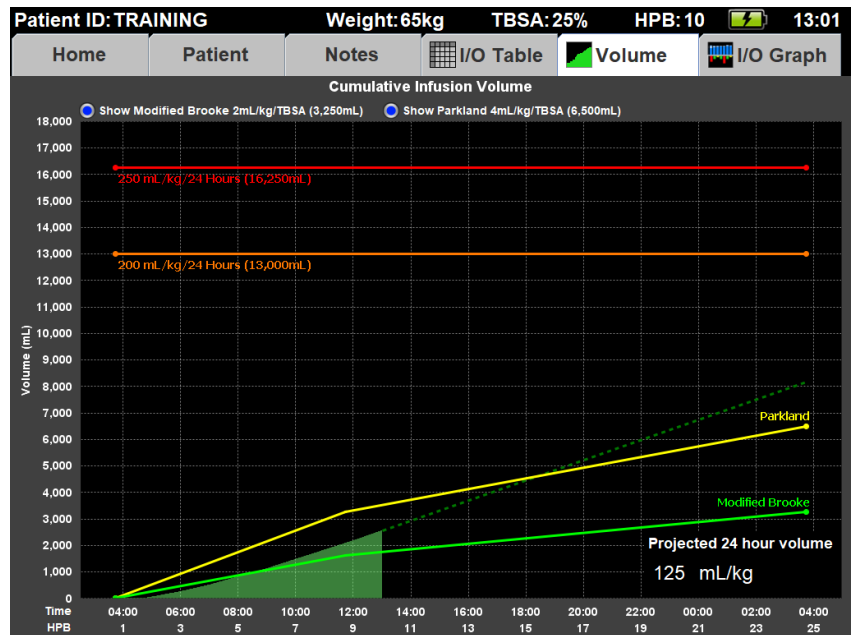
Green: Modified Brooke formula (2 mL/kg/TBSA in 24 hours)

Yellow: Parkland formula (4 mL/kg/TBSA in 24 hours)

Cyan (Blue): Galveston pediatric burn surface area formula (may show with Custom protocol)

Orange: 200 mL/kg/24 hours alert limit

Red: 250 mL/kg /24 hours alert limit



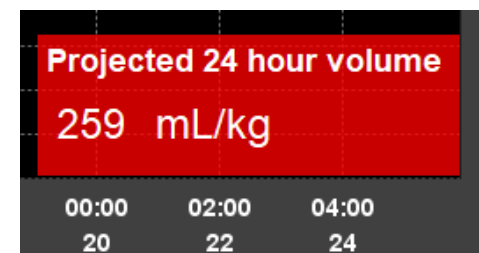
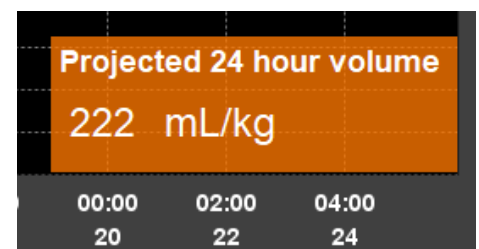
The total volumes for the Modified Brook and Parkland lines are calculated and shown at the top of the graph. The two radio buttons at the top allow you to turn these two lines on or off.

The total volumes for 200 mL/kg/24 hours and 250 mL/kg/24 hours are calculated and shown next to the line representing that volume. When the cumulative volume passes the orange and red lines, the graph will change from green to orange, then to red at the times when each alert level is passed.

24 hour fluid projection

By 10 HPB, a 24 hour volume projection will be displayed in the lower right hand corner. The projection is based on the current rate of the Primary Resuscitation Fluid, plus all repeated Adjunct Fluids. (The projection does not include Other Fluids.) The projection label will turn orange if the projection is over 200 mL/kg, and it will turn red if the projection is over 250 mL/kg (as seen on the right).

A dashed line will also be displayed on the graph to visualize the projection.

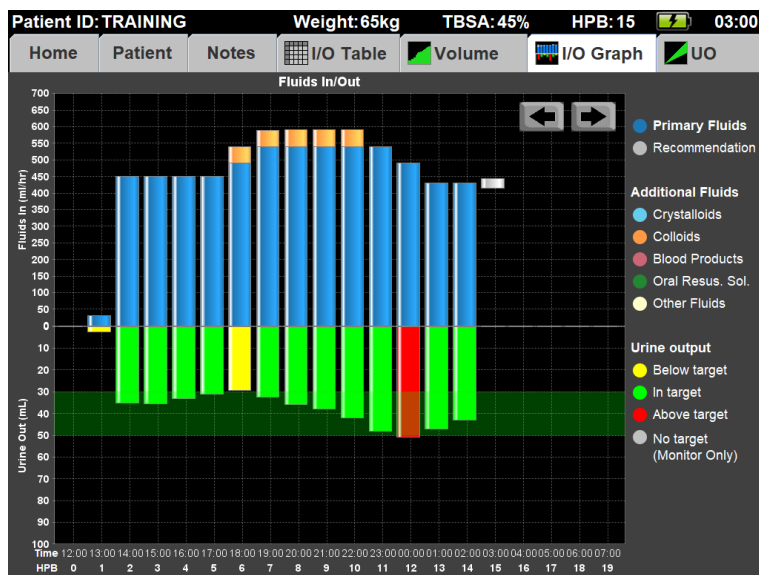


I/O Graph

The I/O Graph indicates Fluids In on top portion of the graph and Urine Output on the bottom.

Each bar is one clock hour (each hour post burn (HPB)). The data seen in the I/O Graph is the **Hourly Averages** data from the I/O Table.

The y-axis of the Fluids In graph on top shows the average infusion rate for each HPB. The y-axis of the Urine Out graph on bottom is inverted (so that the zero value for both graphs is the center of the screen). The Urine Out graph shows the average volume for each HPB (mL for the Adult predictive protocol and mL/kg for the Weight-based protocol).



The pre-Burn Navigator fluids are shown with diagonal stripes on the bars. The pre-Burn Navigator bars, if any, will always be on the far left of the graph.

The Fluids In graph shows the primary resuscitation fluids in blue, Adjunct Fluids in different colors based on type (crystalloids, colloids or blood products) and Other Fluids. The last recommendation is shown as a gray bar after all the other columns.

The Urine Out graph colors the urine bars based on whether the urinary output is on target or not:

- Green bars mean the urine output was in target range.

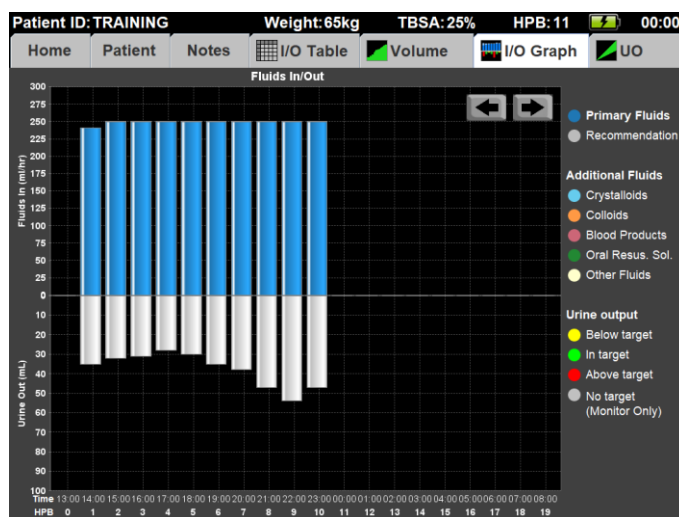
- Yellow bars mean the urine output was below (less than) the target range.

- Red bars mean the urine output was above (greater than) the target range.

The target UO range is shown as a dark green stripe in the background of the graph.

Note: In Monitor Only mode the urine output bars are light gray, since no UO target is set in that mode (as seen on the right).

The I/O Graph shows only 24 hours (bars) at a time. When there are more than 24 hours of data, use the arrows in the top right of the graph to scroll the graph.



Urimeter Connectivity

The Burn Navigator can connect to a urimeter device to collect UO data. Currently, the following devices are supported:

<u>Manufacturer</u>	<u>Device Name</u>
Adaptec	SensicaUO

You may connect a compatible urimeter at any time, before or after starting Burn Navigator. We suggest connecting the urimeter to Burn Navigator as soon as possible.

The following features will appear if Burn Navigator is configured for urimeter connectivity:

- The urimeter connection status indicator will be visible on the Home tab.

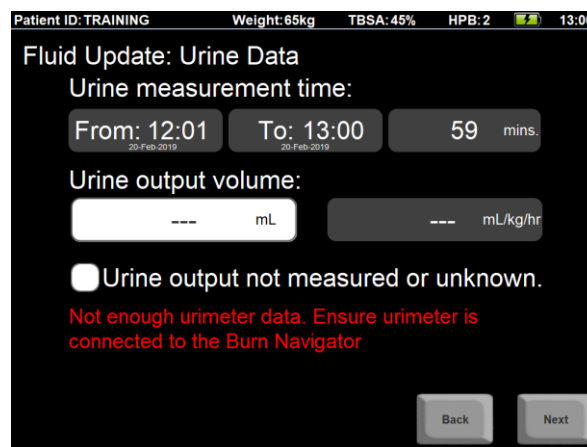
✓ Urimeter Connected

— Urimeter Not Connected

- The Continuous UO Graph tab will be visible. Selecting it will display the Continuous UO Graph, described below.



When a urimeter is connected, the Burn Navigator will try to auto-fill the UO volume for each fluid update based on the measured data. However, if there is not enough urimeter data for the update, then the field will be left blank, as shown, and you will need to enter the UO volume manually.

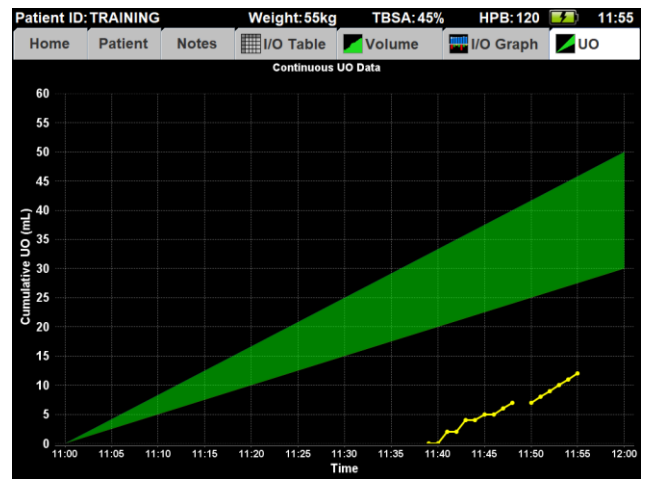
The screenshot shows the 'Fluid Update: Urine Data' screen. At the top, it displays patient information: 'Patient ID: TRAINING', 'Weight: 65kg', 'TBSA: 45%', 'HPB: 2', and a battery icon with the time '13:00'. The main section is titled 'Fluid Update: Urine Data'. Below this, it says 'Urine measurement time:' followed by 'From: 12:01' (with '20-Feb-2019' below it), 'To: 13:00' (with '20-Feb-2019' below it), and '59 mins.'. Then, it says 'Urine output volume:' followed by two input fields: one with '--- mL' and another with '--- mL/kg/hr'. Below these fields is a checkbox labeled 'Urine output not measured or unknown.' which is currently unchecked. Underneath the checkbox, there is a red text message: 'Not enough urimeter data. Ensure urimeter is connected to the Burn Navigator'. At the bottom right, there are 'Back' and 'Next' buttons.

Note: In general, the Burn Navigator cannot guarantee the accuracy of data from connected devices. We recommend you confirm the reported UO volume by visual inspection at each fluid update.

Continuous UO Graph

The Continuous UO Graph tab will be visible only if your Burn Navigator is configured for urimeter connectivity. This graph displays the cumulative UO volume, as measured by the urimeter, over the current clock hour.

Each point on the graph shows when UO data is collected. Gaps may appear where there is no UO data for a given minute (e.g. if the urimeter does not send data, or is not connected.)



The green overlay indicates the target UO range, according to the active resuscitation protocol.

Note: The Continuous UO Graph will be cleared and reset to zero at the top of each clock hour; however, the Burn Navigator will still remember the previous urimeter data, and will count it in the auto-filled UO volume on the next fluid update when appropriate.

Safety Features

The Burn Navigator comes with a number of safety features to help ensure the patient is getting adequate fluid resuscitation without excessive fluids.

There are several safety rules included in the recommendation algorithm. For example:

- The recommendations won't change more than 40% from the last infusion rate.
- The maximum recommendation is 2,000mL/hr, or $28.6 \times \text{weight(kg)}$, rounded down, whichever is lower. For example:
 - 40kg: 1,140mL/hr is the maximum recommendation
 - 50kg: 1,430mL/hr
 - 60kg: 1,710mL/hr
 - 70kg or more: 2,000mL/hr
- If the maximum recommendation is given twice in a row, the next recommendation will not go above 1,750mL/hr (or $28.6 \times \text{weight(kg)}$, whichever is lower) and the recommendation after that will not go above 1,500mL/hr (or $28.6 \times \text{weight(kg)}$, whichever is lower).
- During the first 8 hours post burn (HPB), the minimum rate is determined by the 2mL/kg/TBSA formula.
- After 8 HPB, Burn Navigator will not make a recommendation lower than the Minimum rate shown on the Patient tab.
- Between 9 and 24 HPB: Burn Navigator will not recommend increasing the rate if the projected 24-hour volume would overshoot the configurable projection cap. If the projection at the last infusion rate already exceeds the cap, Burn Navigator will recommend a rate decrease of at least 7% until the cap is no longer exceeded.

The Burn Navigator also includes several safety alerts, such as:

- If the recommended rate exceeds +/- 25% from the last rate and is at least 100 mL/hr change.
- When the infusion rate has been over 1,000 mL/hr for 6 or more hours

The Volume graph has the Modified Brooke and Parkland resuscitation guidelines, as well as the 200 mL/kg/24 hours and 250 mL/kg/24 hours alert lines. The Volume graph also changes colors when the two alert levels are reached. The 24 hour volume projection can be used as a safety trigger to start an intervention, such as albumin or plasmapheresis, to avoid over-resuscitation.

The I/O Graph displays urine output data so that it is easy to see whether the urine output has been too low or too high.



The Checklist function provides periodic reminders for checking patient vital signs, physiological parameters, lab values, and extremity care, which are secondary indicators for adequate or excessive fluid resuscitation. One checklist item, bladder pressure, provides a check to see if a low urine output may be caused by some other reason than inadequate fluid resuscitation.

The Status screen allows the user to see how the patient's checklist values (such as vital signs and lab results) have improved or decreased over time.

CAUTION!

Periodic communication with the attending physician and your own clinical judgment is expected. Do not rely solely on the Burn Navigator recommendations and safety features.

CAUTION!

- **The Burn Navigator recommendations are not a substitute for clinical judgment. No medical decision should be based solely on the recommendations provided by the Burn Navigator.**
- **The recommendations are only as useful as the data is accurate.**
- **Use the patient assessment checklist for other indicators of adequate, under-, or over-resuscitation.**

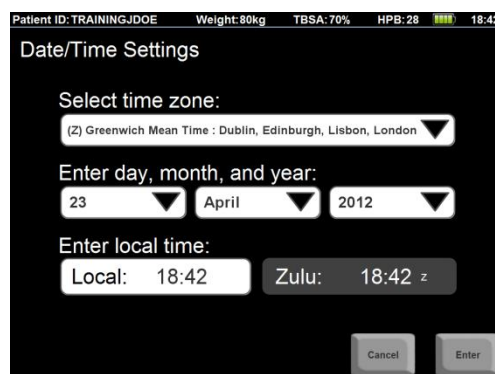
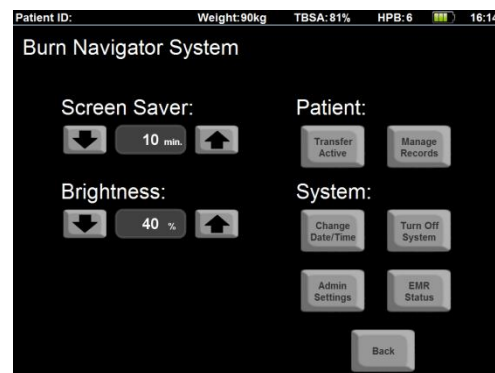
System Functions

The System Menu includes:

- **Screen Saver time.** This is the number of minutes of inactivity before the screen saver starts. (Note that the screen saver will not automatically start when in Training Mode)
- **Brightness.** The brightness controls lets you brighten or dim the screen. Press the up and down arrows to change the brightness. Set the brightness to 20% or less for longest battery life.
- **Advance Time.** The advance time control only appears in Training Mode. Press the “+10 min” button or the “+1 min” button to advance the time. The clock in the upper-right hand corner shows the time.
- **Transfer Active patient file.** This button allows you to transfer your active patient data file from one Burn Navigator tablet to another Burn Navigator tablet. Note that the file is not automatically deleted from the first Burn Navigator system.
- **Manage records.** This button take you to a Patient Record Management screen where you can “archive” (or transfer) inactive patient files from this Burn Navigator. The Patient Record Management screen will also let you delete patient files from this Burn Navigator.

***TIP:** on the Patient Record Management screen, scroll down to the bottom of the “Select patient record” drop down box to select all records that have not yet been archived.*

- **Change Date/Time.** This button takes you to the Date/Time Settings screen, where you can change your time zone and set the current Time, Day, Month, and Year. The “Zulu” time is set by the Manufacturer and can only be changed by biomedical engineering or technical support.
 - **Note:** If your Burn Navigator is configured to time sync with your network server, you won’t be able to access this menu. Dock the Burn Navigator and 5 seconds to time sync.
- **Turn Off System.** This button will properly down off the Burn Navigator device.
- **Admin Settings.** This button leads to administrative settings for the Burn Navigator. This button is password protected. See the “Burn Navigator Administrator’s Manual”, Manual 1120A, to change settings.



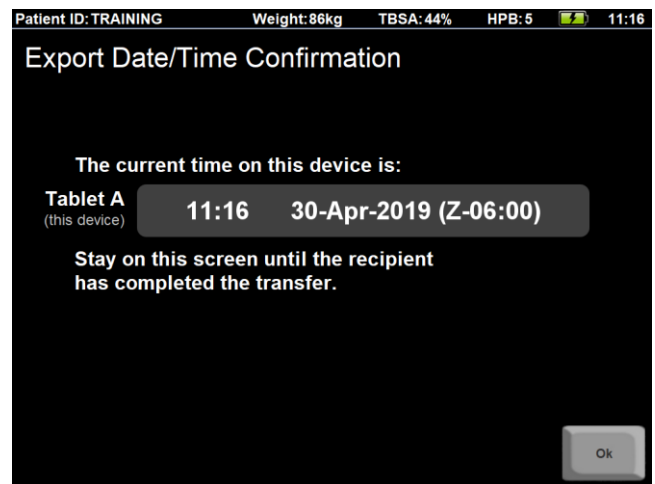
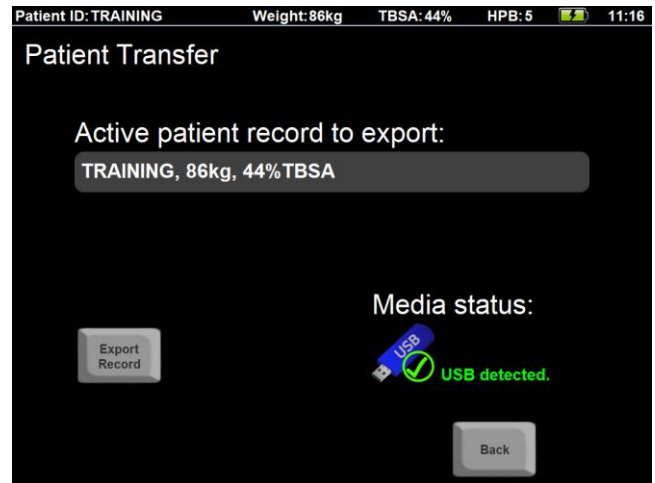
- **EMR Status.** This button will take you to the EMR Status screen.
Note: EMR connectivity requires additional IT setup. Please contact Arcos regarding EMR connectivity.

Transfer Active Patient

To transfer an active patient from one Burn Navigator (“Tablet A”) to another Burn Navigator (“Tablet B”), do the following:

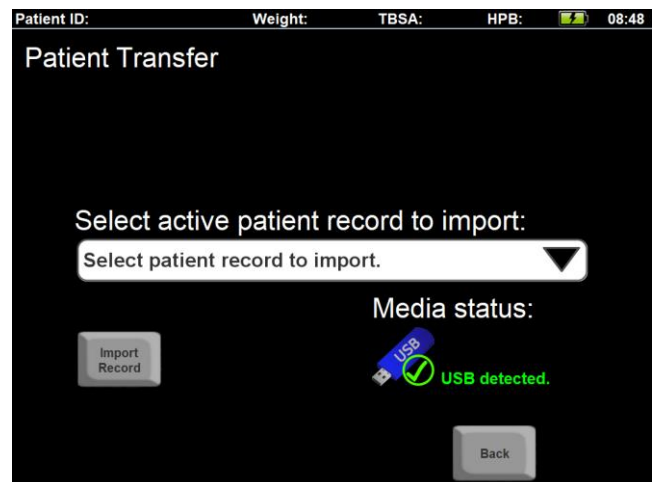
Exporting the patient (Tablet A)

- 1) Insert a Burn Navigator® Data Drive into the USB port on Tablet A.
- 2) Select the “Transfer Active” button from the System menu. You should see “USB detected” in the bottom right corner of the patient transfer screen.
- 3) Your current active patient is shown in the gray background.
- 4) Press "Export Record" and confirm.
- 5) You will see the Export Date/Time Confirmation screen. You may remove the Data Drive from Tablet A at this point.
 - a. **Note!** It is OK if the date and time shown are not the actual current time. For example, you may have advanced the time in training mode.
- 6) When Tablet B has finished importing, press “OK” and confirm.



Importing the patient (Tablet B)

- 1) Insert a Data Drive containing an active patient into Tablet B. Ensure that Tablet B does not have an active patient.
- 2) Select the “Transfer Active” button from the System menu. You should see “USB detected” in the bottom right corner of the patient transfer screen.
- 3) Select the desired patient from the dropdown list and press the “Import Record” button.



- 4) You will see the Import Date/Time Confirmation screen. You will need to enter the current time as shown on Tablet A. Select the “Tablet A” field and enter the correct values.

You may also change your system time by selecting the “Tablet B” field.

Note! For non-training patients, you cannot enter a time for Tablet A which is earlier than the time of the last fluid update.

Patient ID: Weight: TBSA: HPB: 08:48

Import Date/Time Confirmation

Transferring patient from Tablet A to Tablet B
Please enter the date and time for Tablet A below.

Tablet A (other device)

Tablet B (this device) 08:48 30-Apr-2019 (Z-06:00)

Clock offset:

Back Import

Patient ID: Weight: TBSA: HPB: 08:49

Import Date/Time Confirmation

Transferring patient from Tablet A to Tablet B
Please enter the date and time for Tablet A below.

Tablet A (other device) 08:36 30-Apr-2019 (Z-06:00)

Tablet B (this device) 08:49 30-Apr-2019 (Z-06:00)

Clock offset: +0:13

To correct for the clock error, all dates and times in the patient record will be offset by the above value.

Back Import

5) Select “Import”.

Note! The existing patient file data will be adjusted to correct for the difference between the clocks on Tablet A and Tablet B. A note will be generated after import to document this.

6) At this point the transfer process is complete. You may remove the Data Drive from Tablet B.

FAQ – Frequently Asked Questions

1. Why is the first bar in the Fluids I/O graph so short?

- The first bar represents the entire clock hour (e.g., 4:00 to 4:59am) in which the patient was burned. If the patient wasn't burned exactly at the beginning of that hour (e.g., burned at 4:50am), then the patient didn't receive fluids the whole hour. Because the width of each bar is 60 minutes, the bar represents the fluid in *volume* received. For example, if a fluid rate of 1,000mL/hr was given starting at 8:54am, you would see a bar height of only 100mL (6 minutes' time at 1,000mL/hr) for the first bar (representing all of 8:00 to 8:59am).

2. Are additional fluids included in the algorithm?

- No, additional fluids are not included in the algorithm. The list of additional fluids includes many types of colloids, which do not have a consistent ratio (e.g., 1 to 2 or 1 to 3) for replacing crystalloids during the first 24 hours as patient capillary leak changes. Additional fluids are shown in a magenta color on the Fluids I/O Graph.
- If you are consistently giving one type and rate of additional fluid, and that fluid has a consistent effect on patient urine output, then the algorithm will adapt to the new amount (and projected amount) of urine output and the primary resuscitation fluid recommendations will be lower.
- On the other hand, if you anticipate a one-time large volume of additional fluid for a particular hour, then you should discuss with the attending physician about lowering the primary resuscitation fluid below the recommendation for the hour

of large additional fluids, then increasing the primary resuscitation fluid above the recommendation for the next hour when the large additional fluids are no longer given.

3. What if the doctor orders a bolus of my primary resuscitation fluid?

- a. There are two ways to include a bolus of the primary fluid, e.g. Lactated Ringer's:
 - 1) When you perform the hourly fluid update, on the 'primary infusion rate' screen, press the "Select box if primary rate was changed" box and then add the bolused volume to the volume the patient already received; or,
 - 2) When you perform the hourly fluid update, on the "Additional Fluids" screen, enter the volume of the bolus.
- b. If you add the bolus as a total volume (way #1 above), it will show blue on the I/O Graph and will be used for the next recommendation. If you add the bolus as an Additional Fluid (way #2), it will show as magenta on the I/O graph and the bolus value will not be used for the next recommendation.

4. My patient's pulse is detectable by Doppler only, how should I describe the pulse in the Checklist?

- a. Select "weak".

5. How do I update the pump setting when it is not time to do an hourly fluid update?

- a. Go to the Home screen and press the big white field labeled, "Current Infusion Rate". When you change the pump setting here, the software will automatically calculate the infusion volume based on the time spent at the last rate and the time with the new rate.

6. Do the recommendations expire?

- a. Yes. The recommendations are only intended until the next top of the hour (e.g., until 4:00pm, 5:00pm, etc.). It is important to check the patient's urine output and other resuscitation indicators at the top of each hour. If a fluid update time period ends within the last 15 minutes of a clock hour (e.g., from 3:45 to 3:59pm), then the software will wait until the top of the next full clock hour for another hourly fluid update (e.g., 5:00pm).

7. Can I use CaviCide® or similar disinfectant wipes on the screen and device?

- a. Yes, the Burn Navigator screen and device can withstand repeated use of CaviCide wipes, Clorox Bleach® wipes, or similar disinfectant wipes. After the CaviCide dries, there tends to be a residue visible on the screen. You can remove the residue with a clean moist paper towel.

Starting Up

Cannot start up. The power indicator or battery indicator is not lit.	<ul style="list-style-type: none">• Connect the AC adaptor.• Insert a fully charged battery.• Remove the battery pack and the AC adaptor, and then connect them again.• If a device is connected to the USB port, disconnect the device.
The power is turned on but “Warming up the system (up to 30 minutes)” appears.	<ul style="list-style-type: none">• The computer is warming up before start up. Wait for the computer to start up (takes up to 30 minutes). If, “Cannot warm up the system” is displayed, the computer failed to warm up and does not start. In this case, turn off the computer, leave it in an environment of 5 °C {41 °F} or higher temperature for about an hour, and then turn on the power again.
Cannot turn on the computer.	<ul style="list-style-type: none">• Leave it in an environment of 5 °C {41 °F} to 35 °C {95 °F} for about an hour, and then turn on the power again.
Other startup problems.	<ul style="list-style-type: none">• Remove all peripheral devices.

Shutting Down

Windows does not shut down.	<ul style="list-style-type: none">• Remove any USB device.• Wait one or two minutes. It is not a malfunction.• Remove the computer from the Cradle.
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Display / Interface

The screen is too dark.	<ul style="list-style-type: none">• Push harder on the screen (the screen saver may be on).• Go to the System Menu and then increase the brightness setting:<ul style="list-style-type: none">○ Reduce the amount of light on the device to help you navigate the menus (turn off the room lights or put a drape over the screen).○ If you just started the device, press the “OK” button in the middle of the bottom of the screen (just above the bottom edge of the display). You will either be taken to the Main Menu or to an open patient file:<ul style="list-style-type: none">▪ Main Menu: the System button is the third from top of four buttons (it is about 1 inch above where you just pressed “OK”).▪ Open Patient File: the System Menu button is the second to the right on the bottom (about 2 inches from the right edge of the device, along the bottom).○ Once you are in the System Menu, you should see two white fields in the left half of the screen. The brightness setting is the bottom field. Press the up arrow, which is just to the right of the brightness setting.• If the Power Status LED is blinking blue, then the device has entered sleep / stand-by mode<ul style="list-style-type: none">○ Press the Power button. If the system doesn’t wake up, then turn the device power off and then back on:<ul style="list-style-type: none">▪ Press and hold the power button on the top right of the display for four seconds or longer to shut down the computer. Wait 10 seconds, and then turn it back on. If you receive a Windows message saying that Windows was not properly shutdown, select “start Windows normally”.
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I see the Windows log-in screen	<ul style="list-style-type: none"> Select the “BRDSS” log-in. If you don’t see the “BRDSS” log-in option, press the “Cancel” button. Note: you will see the Windows log-out screen if you accidentally hit the ‘key’ functional button.
Battery	
The battery indicator lights are red.	<ul style="list-style-type: none"> Connect the AC adaptor to charge the battery.
Time Sync	
Burn Navigator doesn’t time sync after being docked for 10 seconds.	<ul style="list-style-type: none"> Contact your hospital IT/IS department for support.

Software Warnings, Alerts, and Messages

The Burn Navigator displays warnings, alerts, and messages during patient care. Below is a list of the Warnings, alerts, and messages along with their triggering events.

Cause of Warning	Warning Text
Myoglobinuria indicated by user	WARNING! Gross myoglobinuria may require a high target urine output range. Consult attending physician for appropriate UO range.
User selects Weight-based protocol with a patient weighing less than 10 kg	WARNING! The Weight-based protocol is not intended for patients weighing less than 10 kg, because immature kidneys may not regulate output during hypovolemia.
User enters additional fluids (beyond the primary resuscitation fluid)	“ WARNING: Giving fluids in addition to the primary resuscitation fluid may require an adjustment to the fluid infusion rate by the user, different from the rate recommended by Burn Navigator. The attending physician should be contacted to determine the appropriate fluid infusion rate.”

Cause of Alert or Message	Alert or Message Text
User selects a known confounder other than myoglobinuria (high blood alcohol/EtOH, hyperglycemia, end stage renal disease, CHF)	Confer with attending physician regarding resuscitation.
User presses End Decision Support button	“Are you sure you want to stop Burn Resuscitation Decision Support for this patient?”
User selected ‘yes’ to the first End Decision Support confirmation screen	“PLEASE CONFIRM: Are you sure you want to stop Burn Resuscitation Decision Support for this patient?”

Cause of Alert or Message	Alert or Message Text
User selects a patient file to delete	Conditional text: "Data from the previous patient will be erased. Data has/HAS NOT been archived. Are you sure you want to proceed?"
User selects 'yes' to the first "Deleting patient record when the record has not been archived" screen	"PLEASE CONFIRM: Data from the previous patient will be erased. Data has/HAS NOT been archived. Are you sure you want to proceed?"
72 hours post burn has been reached	"It has been 72 hours post burn. Fluid decision support for this patient has ended."
System error	"NOTICE! The Burn Navigator has experienced a system error. Please contact Technical Support for further assistance."
Upon starting a new patient, periodically, and when reaching certain cumulative volume levels	"It is time to complete the patient checklist. Please complete the checklist and notify the attending physician. Do you want to go to the checklist now?"
User tries to access or move data to a memory device (USB thumb drive)	"No memory drive was detected. Please insert a memory drive and try again."
User enters elapsed time of burn over 24 hours from current time	"This product is not intended for patients burned over 24 hours ago. DO NOT USE!"
User enters a patient weight of less than 40kg (in adult only mode) or 1 kg , or greater than 400kg	"This product is not intended for patients under 40kg or over 400kg. DO NOT USE!" (message in adult only mode) "This product is not intended for patients under 1kg or over 400kg. DO NOT USE!" (message otherwise)
User enters a patient weight of less than 40kg when Weight-based protocol is enabled	"The adult protocol is not intended for patients weighing less than 40 kg. Use only if attending physician has given approval."
When Monitor Only protocol is selected	"The protocol cannot be switched during resuscitation."

Cause of Alert or Message	Alert or Message Text
It has been over 24 hours post burn and the patient has been at minimum fluid rate for at least 6 hours	"Patient has been on minimum fluid rate for 6 or more hours and it is past 24 hours post burn. If all other parameters of adequate tissue perfusion are normal, you may end decision support for this patient now."
User presses the Turn Off System button	"Are you sure you want to turn off the Burn Navigator?"
User tries to load a past patient file when an active patient file is open	"A patient resuscitation is currently active."
User enters a TBSA of less than 15%	"The Burn Navigator is intended for patients with 15% or greater TBSA. The attending physician must provide approval to use the Burn Navigator with this patient. "
User enters a height of less than 16 cm or more than 256 cm	"The value entered is out of range! The minimum permitted value is 16. The maximum permitted value is 254.
User enters a height of less than 6 inches or more than 100 inches	"The value entered is out of range! The minimum permitted value is 6. The maximum permitted value is 100.
User updates the TBSA (to 20% or more) after decision support began	"Notify attending physician that the patient TBSA has been revised and the resuscitation of this patient should be reviewed"
User changes the infusion rate from the Home screen (not in the hourly fluid update)	"Please consult with the attending physician before changing the infusion rate. Do you want to change the rate?"
In the hourly fluid update, the user indicates the urinary output is unknown	"You have not recorded a urinary output. Are you sure you want to proceed?"
User selects normal saline as the primary resuscitation fluid type	"Normal Saline is not typically used as a primary resuscitation fluid because it could contribute to patient hypernatremia."
User changes the system date or time	"The system date/time has been changed. Are you sure you want to proceed?"
User changes the time zone	"The local time-zone has been changed. Are you sure you want to proceed?"

Cause of Alert or Message	Alert or Message Text
User changes the system date or time as well as the time zone	"The system date/time and the local time-zone have been changed. Are you sure you want to proceed?"
48 hours post burn has been reached	" Alert! It has been 48 hours post burn. Please end fluid decision support for this patient now."
User enters a urine output of 0 mL during an hourly fluid update	" Alert! If there is no urine output, check the Foley catheter for obstruction and check bladder pressure. Consult the attending physician if bladder pressure is abnormal (>20 cm H ₂ O, or >15 mmHg) or if urine output is zero for more than one hour after ruling out mechanical obstruction.
When using Weight-based protocol and the user enters a urine output that is less than the target UO range	"Flush Foley w/ 10mL sterile water. Check UO next hour."
When using Weight-based protocol and the user enters a urine output that is greater than 4.0 mL/kg/hr	"UO was > 4 mL/kg/hr. Notify attending and assess patient's blood glucose, BP, HR, CVP and Hb before lowering rate."
When using Weight-based protocol, after the user enters a urine output that is greater than 4.0 mL/kg/hr, for the 'bottom of the hour' recommendation	"Protocol recommends decreasing at the bottom of the hour, from [current rate] to [new rate] mL/hr. Do you accept this new rate?"
After 8 hours post burn (HPB) and either: <ul style="list-style-type: none"> The HPB average Primary Fluids In have increased each hour for two hours in a row (comparing three hours in a row) and UO remains less than 30mL for the same 3 hours, or The HPB average Primary Fluids In has been at or above the maximum recommended fluid rate for two hours in a row and the UO is less than 10mL for both hours. 	" Alert! Urinary output is not responding to fluid therapy. Check Foley catheter for obstruction and check bladder pressure. Patient may be a fluid "non-responder." Contact attending physician."
The user indicates that the patient is hypotensive, hyperglycemic, on pressors or on diuretics when the algorithm <i>recommends</i> a decrease in fluid rate	"Alert! Consult with attending physician about an appropriate fluid rate during presence of hypotension, hyperglycemia, pressors or diuretics."

Cause of Alert or Message	Alert or Message Text
The new recommendation exceeds +/- 25% from the current infusion rate and is at least a 100 mL/hr change	“Alert! The new recommendation exceeds +/- 25% of the current rate and is at least a 100 mL/hr change. Notify the attending physician.”
The infusion rate has averaged over 1,000mL/hr for the last six hours	“Alert! The infusion rate has averaged over 1,000 mL/hr for the last 6 hours. Notify the attending physician.”
User adjusts the fluid rate to less than the minimum recommendation (Maintenance Rate)	“Alert! The adjusted rate is below the Maintenance Rate of 100 mL/hr.”
The user adjusts the fluid rate to more than the maximum recommendation of 2,000 mL/hr	“Alert! The adjusted rate is above 2,000 mL/hr. Consult with attending physician regarding this rate.”
24 hour projection is or exceeds 200 mL/kg.	“Alert! 24 hour projection is [200] mL/kg. Review the Volume and I/O graphs. Consult with attending physician. Consider albumin or other intervention.
The patient has received a cumulative volume of 200mL/kg within 24 hours.	“Alert! The patient has received more than 200mL/kg in 24 hours and may be over-resuscitated. Complete the patient checklist and notify the attending physician. Do you want to go to the checklist now?”
The patient has received a cumulative volume of 250mL/kg within 24 hours.	“Alert! The patient has received more than 250mL/kg in 24 hours and may be over-resuscitated. Complete the patient checklist and notify the attending physician. Do you want to go to the checklist now?”
72 hours post burn has been reached.	“Alert! The 72hr HPB resuscitation period has ended. The patient will be set to inactive and no new data entry will be allowed.”
Battery charge status reaches a low level	“Alert! Low battery level detected. Please charge or change the battery.”
Battery charge status reaches a critically low level	“Alert! Critical battery level detected. System will shutdown if the battery is not charged or changed immediately.”
The user enters a volume (possibly bolus) of the primary resuscitation fluid in the additional fluids screen	“Alert! You entered additional volume for the primary resuscitation fluid!”

Cause of Alert or Message	Alert or Message Text
The user presses the Hourly Update button, but it is too late to redo the last hourly update and it is not yet time for a new hourly update.	<p>“It is not yet time to do the hourly fluid update or the 10 minute edit window has expired.</p> <p>To update the pump setting, go to the Home screen and select the “Current Infusion Rate” field.”</p>
An hourly fluid update is due. (Occurs at the top of the hour __:00 unless there is less than 15 minutes of fluid data to enter)	“A Fluid Update is due. Would you like to enter the data now?”
User ends resuscitation on a patient.	“Please clean the device using a disinfectant wipe, such as an alcohol swab, to prevent infection.”
The user changes the patient’s TBSA to a value of less than 20% in the patient screen after decision support has begun.	“The TBSA has been revised and is less than 15%. The Burn Navigator is intended for patients with 15% or greater TBSA. The minimum recommended infusion rate will be [minimum rate] mL/hr. The attending physician must review the resuscitation and agree to continue using the Burn Navigator with this patient.”
When importing a patient file, the system time on the importing device is more than 30 minutes ahead or behind of the device that exported the patient file	“The current time appears to be out of sync with the patient data record. Please update the current time first.”
When the EMR successfully acknowledges a fluid update (or new patient information).	“Fluid update accepted by EMR.”
When the EMR server receives a fluid update (or new patient info) but responds with an error.	<p>“EMR returned an error. Press “Resend Data” to try again. If you get this error again, contact your hospital IT support.</p> <p>You can try again later by going to the System menu, pressing the “EMR Status” button, and then pressing the “Resend Data” button. The error message will show on the EMR Status screen.”</p>

Cause of Alert or Message	Alert or Message Text
When the EMR server receives a fluid update (or new patient info) and sends a “rejected” response.	<p>“EMR rejected the update. Press “Resend Data” to try again. If you get this error again, contact your hospital IT support.</p> <p>You can try again later by going to the System menu, pressing the “EMR Status” button, and then pressing the “Resend Data” button. The error message will show on the EMR Status screen.”</p>
When the Burn Navigator tries to send a fluid update (or new patient info) to the EMR, but cannot communicate with the EMR.	<p>“No connection to EMR. Dock the Burn Navigator and press “Resend Data” to try again. Or press “Ok” now and try again later by going to the System menu, pressing the “EMR Status” button, and then pressing the “Resend Data” button.”</p>
When the Burn Navigator tries to send a fluid update (or new patient info) to the EMR, but the EMR does not provide a response within the time limit. [Note: the time limit is set in the Admin Settings.]	<p>“Connection to EMR timed out. Press “Resend Data” to try again. If you get this error again, contact your hospital IT support.</p> <p>You can try again later by going to the System menu, pressing the “EMR Status” button, and then pressing the “Resend Data” button. The error message will show on the EMR Status screen.”</p>
When the EMR messaging is not enabled in the Admin Settings and the user tries to manually send data with the “Resend Data” button.	<p>“EMR not enabled.”</p>
When the user presses “End Decision Support” and not all fluid updates have been uploaded to the EMR yet.	<p>“Alert! Not all fluid updates have been uploaded to the EMR. Press “Resend Data” to try again. Or, press “Ok” to continue ending decision support. You will need to enter the data in the EMR manually.”</p>
When Burn Navigator is set to automatically time sync with your network and the time adjusts by more than 10 minutes.	<p>Alert! Burn Navigator clock time has changed by more than 10 minutes to match the network time. Be sure the patient’s time of burn is correct.</p>

Cause of Alert or Message	Alert or Message Text
When Burn Navigator is set to automatically time sync with your network and you try to manually change the time or date.	Alert! The Burn Navigator is configured to automatically time sync with your server. Dock the Burn Navigator to sync the time. If you cannot dock now, just make sure the elapsed time since burn (in hours and minutes) is correct. Burn Navigator will update the time of burn when you dock the device later. If it fails to sync after docking, then contact your hospital IT for support.
When user selects “yes” for presence of gross myoglobinuria. [This message shows on the recommendation screen]	ABLS guidelines recommend starting at 4mL/kg/TBSA for adults with electrical injuries.
On the new patient setup, recommendation screen: When the initial formula exceeds 2,000 mL/hr.	Initial formula exceeds 2,000 mL/hr. Recommending 2,000 mL/hr.
On the new patient setup, recommendation screen: When the initial formula is below 100 mL/hr.	Initial formula is below 100 mL/hr. Recommending 100 mL/hr.
On the fluid update wizard: When increasing the recommended infusion rate would cause the patient’s projected 24 hour volume to be too high.	High 24 hour volume projected! Fluid increase not recommended.
On the fluid update wizard: When maintaining the current infusion rate would cause the patient’s projected 24 hour volume to be too high.	High 24 hour volume projected! Fluid decrease recommended.
Exactly 4 hours have passed since decision support started.	Please confirm that the TBSA ([45%]) is correct. If not, edit the TBSA on the Patient tab.

Hardware Information

Federal Communications Commission Radio Frequency Interference Statement

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

Warning

To assure continued compliance, use only shielded interface cables when connecting to a computer or peripheral. Also, any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment.

This device complies with Part 15 of the FCC Rules.

Operation is subject to the following two conditions:

- (1) This device may not cause harmful interference, and
- (2) This device must accept any interference received, including interference that may cause undesired operation.

FCC Responsible Party: Getac Technology Corporation

5F., Building A, No. 209,

Sec. 1, Nangang Rd.,

Nangang Dist., Taipei City

11568, Taiwan, R.O.C.

Phone: +886-2-2785-7888

6-M-1

For USA-California Only
This product contains a Coin Cell Lithium Battery which contains Perchlorate Material - special handling may apply.
See
www.dtsc.ca.gov/hazardouswaste/perchlorate/

38-M-1

USA Only: Disposal may be regulated in your community due to Environmental considerations. For disposal or recycling information, please visit Getac website: <https://us.getac.com/aboutgetac/environment.html> or call 1-888-769-0149

65-M-2

Wireless LAN / Bluetooth

The Wireless LAN / Bluetooth on this device has been disabled. Arcos is not responsible for any radio, television, or third party equipment interference caused by unauthorized modification of this product. Arcos and its authorized resellers or distributors are not liable for damage or violation of government regulations that may arise from failing to comply with these guidelines.

26-M-1

Lithium Battery!

This computer contains a lithium battery to enable the date, time, and other data to be stored. The battery should only be exchanged by authorized service personnel.

Warning!

A risk of explosion from incorrect installation or misapplication may possibly occur.

15-E-1

Information for Users on Collection and Disposal of Old Equipment and used Batteries

If you wish to discard this product, please contact your local authorities or dealer and ask for the correct method of disposal.

53-M-1

If a Hardware Malfunction or Trouble Occurs, Immediately Stop Use

If Any of These Hardware Malfunctions Occur, Immediately Unplug the AC Plug and the Battery Pack.

- The device is damaged
- Foreign object inside the device
- Smoke emitted
- Unusual smell emitted
- Unusually hot

Continuing to use this product while any of the above conditions are present may result in fire or electric shock.

- If a malfunction or trouble occurs, immediately turn the power off and unplug the AC plug, and then remove the battery pack. Then contact your technical support office for repair.

During thunderstorms, use the device only on battery power (not plugged into the wall) or plugged into a surge protector.

Otherwise, electric shock may result.

Do Not Connect the AC Adaptor to a Power Source Other Than a Standard AC Outlet

Otherwise, a fire due to overheating may result. Connecting to a DC/AC converter (inverter) may damage the AC adaptor. On an airplane, only connect the AC adaptor/charger to an AC outlet specifically approved for such use.

Do Not Do Anything That May Damage the AC Cord, the AC Plug, or the AC Adaptor

Do not damage or modify the cord, place it near hot tools, bend, twist, or pull it forcefully, place heavy objects on it, or bundle it tightly. Continuing to use a damaged cord may result in fire, short circuit, or electric shock.

Do Not Pull or Insert the AC Plug If Your Hands Are Wet

Electric shock may result.

Clean Dust and Other Debris of the AC Plug Regularly

If dust or other debris accumulates on the plug, humidity, etc. may cause a defect in the insulation, which may result in a fire.

- Pull the plug and wipe it with a dry cloth.
- Pull the plug if the computer is not being used for a long period of time.

Insert the AC Plug Completely

If the plug is not inserted completely, fire due to overheating or electric shock may result.

- Do not use a damaged plug or loose AC outlet.

Close the Connector Cover Tightly When Using This Product Where Is a Lot of Water, Moisture, Steam, Dust, Oily Vapors, etc.

The entry of foreign matter may cause a fire or electric shocks.

- If foreign matter has found its way inside, immediately turn the power off and unplug the AC cord, and then remove the battery pack. Then contact your technical support office.

Do Not Disassemble This Product

The high-voltage areas inside may give you an electric shock, or foreign matter may enter and result in a fire.

Do Not Place This Product on Unstable Surface

If balance is lost, this product may fall over or drop, resulting in an injury.

Avoid Stacking

If balance is lost, this product may fall over or drop, resulting in an injury.

Do Not Leave This Product in High Temperature Environment for a Long Period of Time

Leaving this product where it will be exposed to extremely high temperatures such as near fire or in direct sunlight may deform the cabinet and/or cause trouble in the internal parts. Continued use in such a resulting condition may lead to short-circuiting or insulation defects, etc. which may in turn lead to a fire or electric shocks.

Hold the Plug When Unplugging the AC Plug

Pulling on the cord may damage the cord, resulting in a fire or electric shock.

Do Not Move This Product While the AC Plug Is Connected

The AC cord may be damaged, resulting in fire or electric shock.

- If the AC cord is damaged, unplug the AC plug immediately.

Use Only the Specified AC Adaptor With This Product

Using an AC adaptor other than the one supplied (supplied with the unit or one sold separately as an accessory) may result in a fire.

Do Not Subject the AC Adaptor to Any Strong Impact

Using the AC adaptor after a strong impact such as being dropped may result in electric shock, short circuit, or fire.

Take a Break of 10-15 Minutes Every Hour

Using this product for long periods of time may have detrimental health effects on the eyes or hands.

Do Not Use with Exposing the Skin to This Product for a Long Period of Time

Using this product with exposing the skin to the heat source of this product or AC adaptor for a long period of time can cause a low-temperature burn.

Do Not Expose the Skin to This Product When Using the Product In a Hot or Cold Environment.

Burns, low-temperature burns or frostbite may result.

- When it is necessary to expose the skin to this product such as to scan a fingerprint, perform the operation in the shortest time possible.

Do not place the computer near a television or radio receiver.

Keep the computer away from magnets. Data stored on the hard disk may be lost.

Precautions (Battery Pack)

Do Not Use with Any Other Product

The battery pack is rechargeable and was intended for the specified product. If it is used with a product other than the one for which it was designed, electrolyte leakage, generation of heat, ignition or rupture may result.

Do Not Charge the Battery Using Methods Other Than Those Specified

If the battery is not charged using one of the specified methods, electrolyte leakage, generation of heat, ignition or rupture may result.

Do Not Throw the Battery Pack into a Fire or Expose It to Excessive Heat

Generation of heat, ignition or rupture may result.

Avoid Extreme Heat (Near the Fire, in Direct Sunlight, for Example)

Electrolyte leakage, generation of heat, ignition or rupture may result.

Do Not Insert Sharp Objects into the Battery Pack, Expose It to Bumps or Shocks, Disassemble, or Modify It

Electrolyte leakage, generation of heat, ignition or rupture may result.

- If this product is subjected to a strong impact, stop using it immediately.

Do Not Short the Positive (+) and Negative (-) Contacts

Generation of heat, ignition or rupture may result.

- Do not place the battery pack together with articles such as necklaces or hairpins when carrying or storing.

Do Not Use This Product with a Battery Pack Other Than the One Specified

Use only the specified battery pack with your product. Use of battery packs other than those manufactured by Getac or supplied by Arcos may present a safety hazard (generation of heat, ignition or rupture).

When the battery pack has deteriorated, replace it with a new one

Continued use of a damaged battery pack may result in heat generation, ignition or battery rupture.

- Do not touch the terminals on the battery pack. The battery pack may no longer function properly if the contacts are dirty or damaged.
- Do not expose the battery pack to water, or allow it to become wet.
- If the battery pack will not be used for a long period of time (a month or more), charge or discharge (use) the battery pack until the remaining battery level becomes 30% to 40% and store it in a cool, dry place.
- This computer prevents overcharging of the battery by recharging only when the remaining power is less than approx. 95% of capacity.
- The battery pack is not charged when the device is first purchased. Be sure to charge it before using it for the first time. When the AC adaptor is connected to the computer, charging begins automatically.
- Should the battery leak and the fluid get into your eyes, do not rub your eyes. Immediately flush your eyes with clear water and see a doctor for medical treatment as soon as possible.

CAUTION:

Risk of Explosion if Battery is replaced by an Incorrect Type.

Dispose of Used Batteries According to the Instructions.

58-E-1

NOTE

- The battery pack may become warm during recharging or normal use. This is completely normal.
- Recharging will not commence if internal temperature of the battery pack is outside of the allowable temperature range (0 °C to 50 °C {32°F to 122 °F}). Once the allowable range requirement is satisfied, charging begins automatically. Note that the recharging time varies based on the usage conditions. (Recharging takes longer than usual when the temperature is 10 °C {50 °F} or below.)
- In high-temperature environments, the battery takes longer to fully recharge and the operating time is shorter. Only use the computer within the allowable temperature range.
- This computer has a high temperature mode function that prevents the degradation of the battery in high temperature environments. A level corresponding to a 100% charge for high temperature mode is approximately equivalent to an 80% charge level for normal temperature mode.
- The battery pack is a consumable item. If the amount of time the computer can be run by using a particular battery pack becomes dramatically shorter and repeated recharging does not restore its performance, the battery pack should be replaced with a new one.
- When transporting a spare battery inside a package, briefcase, etc., it is recommended that it be placed in a plastic bag so that its contacts are protected.
- Always power off the computer when it is not in use. Leaving the computer on when the AC adaptor is not connected will exhaust the remaining battery capacity.

A lithium ion battery that is recyclable powers the product you have purchased. Please call 1-800-8-BATTERY for information on how to recycle this battery.



Tablet Specifications

Model No.

RX

Main Specifications

CPU	Intel® Core™ M-5Y10c 0.8GHz processor Turbo Boost Technology up to 2.0GHz 4MB*1 Intel Smart Cache
Video controller	Intel HD Graphics 5300
Main Memory	4GB*2 LPDDR3 expandable to 8GB
Hard Disk Drive	128GB*3 / 256GB SSD*3
Interface	USB ports (USB 3.0 x 1 and USB 2.0 x 1)*4 10.1" TFT LCD FHD (1920x1200) 800 NITs LumiBond® 2.0 sunlight readable LED display with multi-touch technology Optional digitizer
Button	Application x 5, Power
Power Supply	AC adaptor or Battery pack
AC Adapter*5	AC adaptor (100-240VAC, 50/60Hz) Medical Power Supply AC Adapter (Option) 4
Battery Pack	Li-Ion battery (15.2V, 2160mAh) LifeSupport™ hot-swappable battery technology
Operating Time*6	Approx. 6.5 hours for one battery, Approx. 12 hours with two batteries
Charging Time*7	Power on Approx. 2.5 hours Power off Approx. 2.5 hours
Power Consumption*8	65 W*9 maximum
Dimensions and Weight	11" x 9.65" x 0.74" (280 x 245 x 18.8mm)

Weight*10	2.65lbs (1.2kg)
Operation Environment	-5.8°F to 131°F / -21°C to 55°C Humidity: 95% RH, non-condensing
Storage Environment	-40°F to 160°F / -40°C to 71°C Humidity: Humidity: 95% RH, non-condensing
Installed OS*12	Genuine Windows® 10 Professional 64-bit / Genuine Windows® 7 Professional

Notes

*1 1 KB = 1,024 bytes / 1 MB = 1,048,576 bytes / 1 GB = 1,073,741,824 bytes

*2 A segment of the main memory is allotted automatically depending on the computer's operating status.

The size of the Video

Memory cannot be set by the user. The size of Video memory is allotted depending on the operating system.

*3 1 MB = 1,000,000 bytes / 1 GB = 1,000,000,000 bytes. Your operating system or some application software will report as fewer GB.

*4 Does not guarantee operation of all USB-compatible peripherals.

*5 <Only for North America>

The AC adaptor is compatible with power sources up to 240 V AC adaptor. The unit for North America (identified by the suffix 'M' on the model number) is supplied with a 125 V AC compatible AC cord. 20-M-1

*6 Measured based on low brightness and quick screen saver settings. Varies depending on the usage and conditions.

*7 Varies depending on the usage conditions.

*8 Approx. 0.6 W when the battery pack is fully charged (or not being charged) and the computer is OFF.

<When using with 115 V AC>

Even when the AC adaptor is not connected to the computer, power is consumed (Max. 0.5 W) simply by having the AC adaptor plugged into an AC outlet.

*9 Rated power consumption 23-E-1

*10 Average value. May differ depending on models.

*11 Do not expose the skin to this product when using the product in a hot or cold environment. When using in hot or cold environment, some peripherals may fail to work properly. Check the operation environment of the peripherals. Using this product continuously in a hot environment will shorten the product life. Avoid use in these types of environments. When using in low temperature environment, startup may become slow or battery operation time may become short.

*12 Operations of this computer are not guaranteed except for the pre-installed OS.

Guidance and manufacturer's declaration - electromagnetic emissions

The Burn Navigator® is intended for use in the electromagnetic environment specified below. The customer or the user of the should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Burn Navigator® uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The Burn Navigator® is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	NOTE the emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-

frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Guidance and manufacturer's declaration - electromagnetic immunity


The Burn Navigator® is intended for use in the electromagnetic environment specified below. The customer or the user of the Burn Navigator® should assure that it is used in such an environment.

Immunity test	IEC 60601-1-2:2014 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output Lines	± 2 kV for power supply lines ± 1 kV for input/output Lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV AC Main line(s) to line(s) ± 2 kV AC Main line(s) to earth ± 1 kV DC input line(s) to line(s) ± 2 kV DC input line(s) to earth	± 1 kV AC Main line(s) to line(s) ± 2 kV AC Main line(s) to earth ± 1 kV DC input line(s) to line(s) ± 2 kV DC input line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % U_T (100 % dip in U_T) for 0.5 cycle at 0, 45, 90, 135, 180, 225, 270 and 315 degrees 0 % U_T (100 % dip in U_T) for 1 cycle, and 70% U_T (30 % dip in U_T) for 25/30 cycles at single phase at 0 degrees 0 % U_T (100 % dip in U_T) for 5 s	0 % U_T (100 % dip in U_T) for 0.5 cycle at 0, 45, 90, 135, 180, 225, 270 and 315 degrees 0 % U_T (100 % dip in U_T) for 1 cycle, and 70% U_T (30 % dip in U_T) for 25/30 cycles at single phase at 0 degrees 0 % U_T (100 % dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Burn Navigator® requires continued operation during power mains interruptions, it is recommended that the Burn Navigator® be powered from an uninterruptible power supply or a battery.
Power frequency magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE U_T is the a.c. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration – electromagnetic immunity

The Burn Navigator® is intended for use in the electromagnetic environment specified below. The customer or the user of the Burn Navigator® should assure that it is used in such an environment.

Immunity test	IEC 60601-1- 2:2014 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the Burn Navigator®, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1.2 \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m 80 MHz to 2.7 GHz	$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.7 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, ^a should be less than the compliance level in each frequency range. ^b Interference may occur in the vicinity of equipment marked with the following symbol: <div style="text-align: center;">  </div>

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Burn Navigator® is used exceeds the applicable RF compliance level above, the Burn Navigator® should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Burn Navigator®.

^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the Burn Navigator®

The Burn Navigator® is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Burn Navigator® can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Burn Navigator® as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

The Burn Navigator RX did not require a deviation from the IEC 60601-1-2: 2014 product standard. Only U.S. power ranges were tested (110-120 V, 60 Hz).

Service & Technical Support

Please report any system malfunctions immediately. Write down as much information as you can about the event. Contact Arcos at:

support@arcosmedical.com
or 877-542-8025

If any part of the system needs manufacturer servicing, please email or call to request a Returned Material Authorization (RMA) number at

support@arcosmedical.com
877-542-8025

Shipping information will be provided.

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Arcos, Inc.
4714 Riverstone Blvd Ste 200
Missouri City, TX 77459
USA
support@arcosmedical.com
877-542-8025

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