Burn Navigator® Active

User's Manual

Contents

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.

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

- **Connect to the internet via Wi-Fi to check for updates and ensure you have the latest software version.** The product will also automatically synchronize its clock when connected to the internet.
- **Enable Bluetooth and location if desired.** Bluetooth must be enabled in order to send patient files to other devices. To receive patients, location must also be enabled. ***The Burn Navigator software does not use, save, or transmit location data.***
- **Check battery status and recharge the battery if needed.** The battery level will be shown when the device is powered off or on standby while connected to the charger. To check the battery level during use, press the Menu key and note the battery icon at the top right of the screen.
- Go to Settings > Admin Settings within the app, and select the patient identifier field label.

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, connect to the internet via Wi-Fi to synchronize the date, time and time zone. ***No patient data is transmitted by this process.***
- Properly shut down the device.
- Recharge the Burn Navigator batteries.
- Before putting the device away, be sure to wipe off any moisture.

Quarterly:

- Connect the device to the internet to synchronize the clock and check for software updates.
- 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.
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 tablet is designed to minimize shock to parts such as the LCD, but no warranty is provided against any trouble caused by shock. Be extremely careful when handling the tablet .

- When carrying the tablet:
  - Turn off the display.
  - Remove all connected peripheral devices and cables.
  - Do not drop or hit the tablet against solid objects.
- When traveling by aircraft, take the tablet in your carry-on bag rather than checked luggage. When using the device aboard an airplane, follow all airline policies and instructions from crew.
- When in a moving vehicle, keep the tablet inside a protective bag or case while not in use. When the tablet is in use, ensure it is sufficiently secured to prevent sliding and/or dropping.
- Do not attempt to operate the tablet while driving.
- 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 tablet.
- Use only your finger, gloves, or the included stylus to operate 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 can scratch the screen surface or obstruct the stylus pen operation.
- Use the stylus pen only for touching the screen. Using it for any other purpose may damage the stylus and result in scratches on the screen.

Tablet Description

The Burn Navigator Active device uses a Samsung Galaxy Tab Active Pro tablet.

Front

1. Display
2. Back key
3. Home key
4. Menu key

Back

5. Camera
6. Stylus receptacle

Top

7. Power key
8. Volume Up/Down keys
9. Active key
10. Microphone

Bottom

11. Docking connector

Right

12. 3.5mm audio jack
13. USB 3.1 Type-C port
14. Microphone
15. Speaker

First-time Operation

AC-USB 3.1 Adapter (1)
& USB A-to-C 3.5’ Cable (1)

CMP-1805

Protective Cover (1)

CMP-1803

Battery Pack (1)

CMP-1806

Stylus (1)

CMP-1804

Installing or Replacing the Battery

The tablet ships with a battery pre-installed. To replace the battery, do the following:

1. Power off the tablet.
2. Remove the protective cover from the tablet.
3. Remove the battery compartment cover.
4. Remove the old battery if present.
5. Insert the new battery with the label facing up and the battery terminals aligned with the contact pins on the device.
6. Replace the battery compartment cover and protective cover.

CAUTION

- Make sure the battery compartment cover is securely snapped in place when carrying the device.
- Do not expose the battery to water or any other liquid.
- Do not attempt to charge the battery using methods other than specified. Do not short the battery terminals. Do not attempt to overcharge the battery.
- Do not touch the terminals on the battery pack or the tablet. Doing so can make the terminals dirty or damaged and may cause malfunction of the battery pack and/or the tablet.
- Monitor the device for signs of battery failure, such as frequent overheating, or swelling of the battery pack. Continued use of a failing battery may cause permanent damage to the tablet, and creates risk of fire. Stop use of the tablet immediately and replace the battery if failure is suspected.

About the battery for this tablet

- Check the battery level regularly. Charge the battery as needed or when the battery level drops below 20 percent. To extend the lifetime of the battery, disconnect the charger once the battery level is above 80 percent.
- Time to full charge: Approximately 3 hours
- Rechargeable batteries will degrade and lose capacity over time. This battery is designed to withstand about 300 to 500 full charge cycles before capacity loss becomes significant. We recommend replacing the battery every 2 to 5 years depending on frequency of use.

WARNING!

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

Handling the AC adapter

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

Turn on the tablet

Press and hold the Power button (item 6 on page 7 of this manual) until the boot screen is displayed and wait for the device to boot. The Burn Navigator software will launch automatically.

Powering off the tablet

Press and hold the Power button for 1 second to display the shut down menu.

Accessing Android settings

To perform tasks such as connecting to Wi-Fi, you will need to access the Android system settings. To do this, navigate to the Admin Settings tab in the Burn Navigator app, and press the “Open Android Settings” button.

Task list

Press the Menu key to display the Android task list, which shows the apps that are currently open. You can switch to an app by tapping it, or close it by swiping it up and off the screen.

NOTE: The Burn Nav app will always be present. Closing it will cause the app to restart. Restarting the app this way will lose all data in entry screens, forms, or wizards not yet completed; however, data already entered (e.g. fluid updates previously completed) will not be lost.

Using the Burn Navigator App

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.

Splash screen

When the app starts, you will see the splash screen. Press "OK" to close the splash screen and go to the main menu.

Main Menu

The main menu shows a list of patient records stored on the device. Active patients (blue rows) are those currently being resuscitated; inactive patients (orange rows) are those whose resuscitation has ended. Burn Navigator supports up to 6 active patients at one time. There is no maximum number of inactive patient records.

To switch between the lists of active and inactive patients, press the "Review Records" / "Active Patients" button.

Select a patient record in the list to view it. If an active patient has a pending alert that requires attention, an alert icon will be displayed next to it.

The icon indicates that the patient record has been previously exported as either a CSV or DAT file.

To delete an inactive patient record, press the delete icon (⊗) next to it. You will be asked to confirm. If you are sure you want to delete the record, select "Yes". **Deleted records are gone forever and cannot be recovered.**

The **Android Settings** button will open the system settings app, where you can configure network, Bluetooth, time, and display options. **CAUTION:** Changing system settings may affect the performance, usability, or security of the Burn Navigator app.

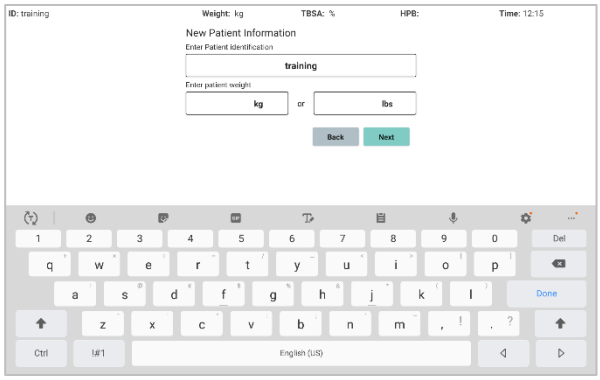
Training Mode

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.

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.

New Patient Setup



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

1. If you chose “Training Mode”, there will be an automatically generated patient ID. Otherwise, select the patient ID field and enter the patient ID using the touch keyboard that appears.

   If you enter a patient ID that starts with “training”, then the new patient will be started in training mode.

   ALERT: To protect the patient’s privacy, we recommend against using the patient’s name, MRN, or any other personally identifying information (PII) as the patient ID.

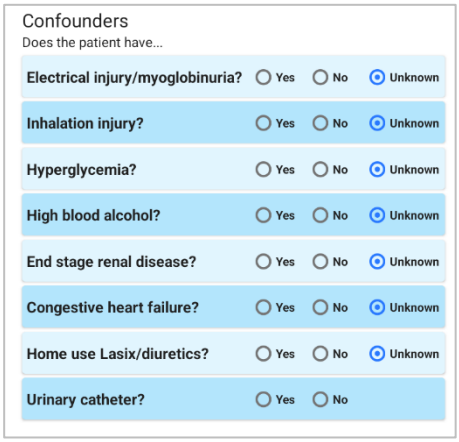
2. Next enter the patient weight.
   a. You can enter weight in kilograms (kg) or pounds (lbs).

   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.

3. You will be asked if the patient has any confounders. Special consideration regarding resuscitation is required with the presence of any of these confounders:
    - electrical injury / myoglobinuria
    - inhalation injury
    - hyperglycemia
    - high blood alcohol
    - end stage renal disease
    - congestive heart failure
    - home use Lasix / diuretics

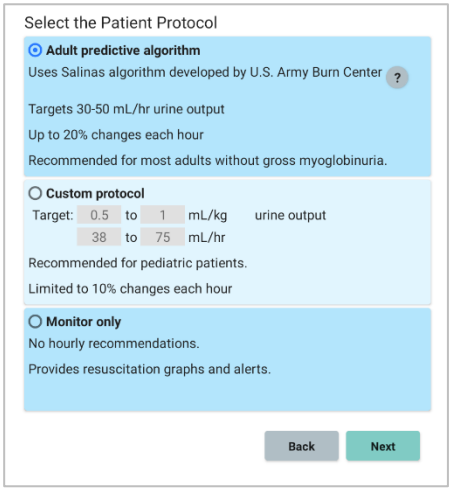


ALERT: If you answer yes to any of these questions, consult with the Attending Physician to determine appropriate fluid therapy.

You will also be asked if the patient has a urinary catheter. Since the Burn Navigator relies on urine output measurements to make fluid recommendations, we recommend using it in **monitor only** mode if no catheter is present.

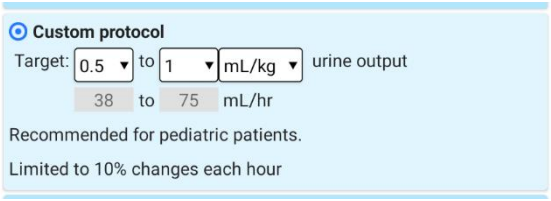
4. Choose the protocol.

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/kg or mL) is calculated in gray below.

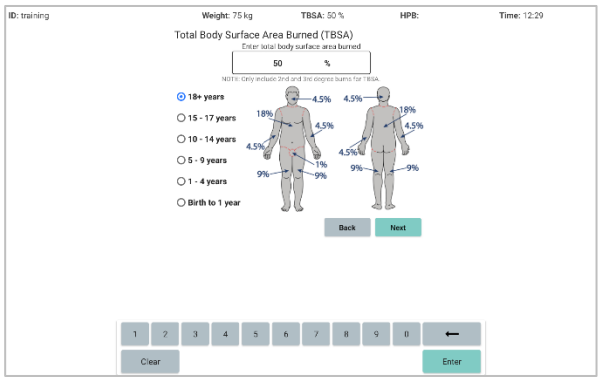


If the patient's UO is not in target, then the Custom Protocol will recommend increasing or decreasing the IV fluid rate by 10%. The custom protocol is limited to 10% changes each hour.

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), when there is no urinary catheter present, or when the physician does not want to use another protocol.

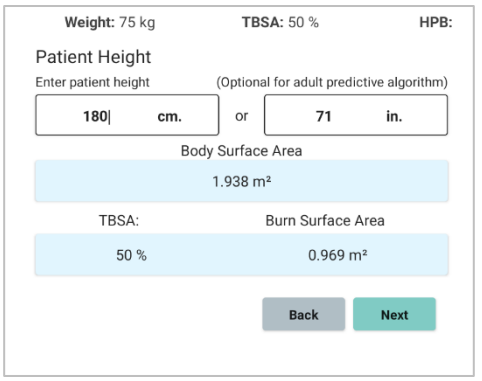
5. Enter the total burned surface area (TBSA). Diagrams are provided for reference. Use the age group radio buttons change the displayed diagram.

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



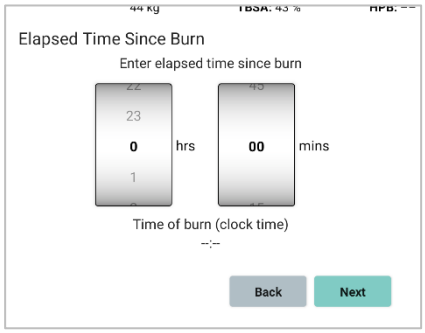
6. Patient height is an optional field, unless the default **initial rate formula** is set to "Galveston Pediatric" or the **minimum rate formula** is set to "Burn Surface Area".

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



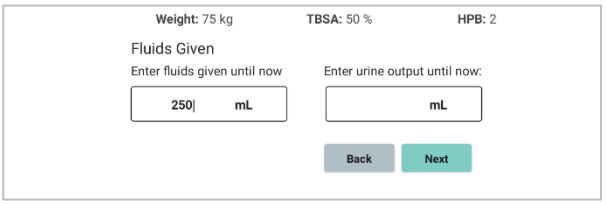
7. Enter elapsed time since burn occurred. How long ago did the burn happen?

   Note: There are two separate fields: one for hours and one for minutes. You can select any elapsed time up to 23 hours 45 minutes, in 15 minute increments.

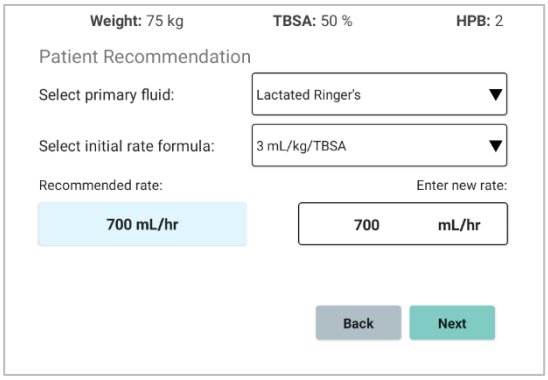


   The software will calculate the time of burn using your local time and the number of hours and minutes elapsed since the burn occurred.

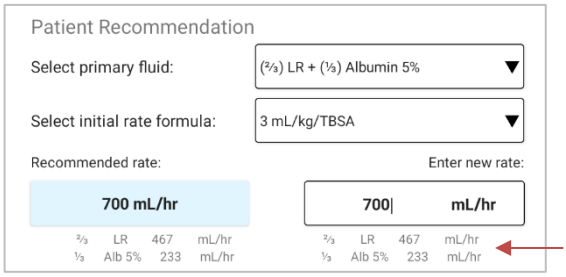
8. Next enter how much fluid the patient has received from the time of burn until now.
   a. Then enter the urine output from time of burn until now.
   b. If you don't know either answer, you may skip the questions by pressing "Next". You can add this data later on the Patient tab.



9. 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.



10. 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.



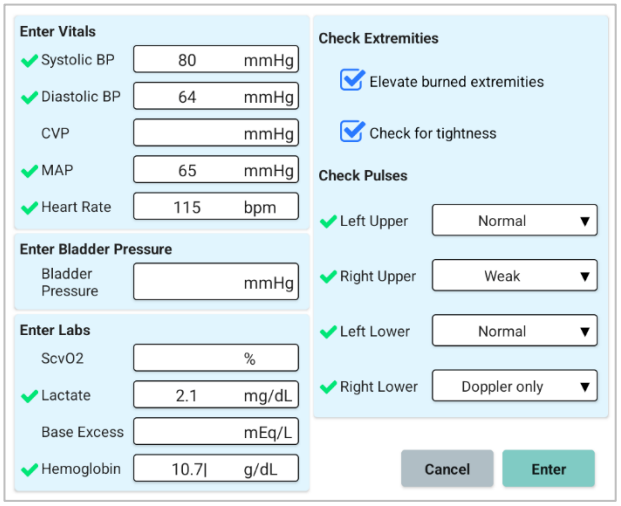
11. You may choose a different rate by pressing the white field at the bottom right.

You have now completed the New Patient setup!

After starting a new patient, you will be taken to the resuscitation tabs.

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 software will prompt you to do a checklist when you start resuscitation and every 6 hours thereafter. 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.

Training Mode

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.

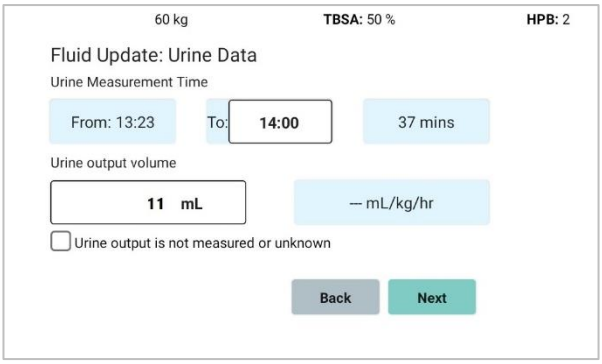
When you load a Training Mode patient, the clock will advance automatically to the time of the last fluid update or infusion rate change, if it is in the future compared to real time. **The clock will reset to the correct time when you close the training patient file.**

Screen Saver

Burn Navigator app must stay active in order to provide the hourly reminder chime to do fluid updates. After 2 minutes of inactivity, a screen saver will appear showing the number of minutes until the next update is due. You can change the screen saver timeout in Clinical Settings.

Note: If you click the hardware button to turn off the screen, that button will also put the app to sleep and Burn Navigator will not provide the hourly reminder chime.

Hourly Fluid Updates

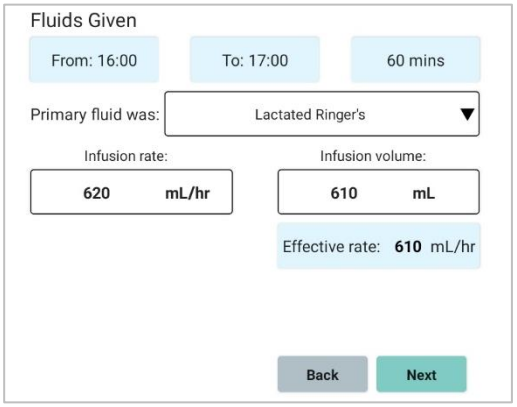


The Fluid Update Wizard (series of screens) will appear automatically when it is time to do an hourly fluid update.

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 defaults to the current time, but it can be edited. The "To" time must be entered in 24-hour format. You cannot enter a "To" time that is later than the current time, or earlier than 12 minutes after the "From" time.
c. The Burn Navigator will calculate and display the number of minutes between the From and To times.

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. The "To:" time will be frozen after the urine output is entered. Before this, it will continue to increment with the current time.



2. On the **Fluids Given** screen, verify the primary fluid and the infusion volume for this time period.
   a. The blue 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 white fields show the primary fluid infusion **rate** and **volume** based on the last setting given to Burn Navigator. The infusion volume is editable so that you can enter the exact infused volume reported by the pump.

      • If you edit the infusion volume, a blue field will appear below the Infusion volume to show the Effective rate based on the entered infused volume and time duration.

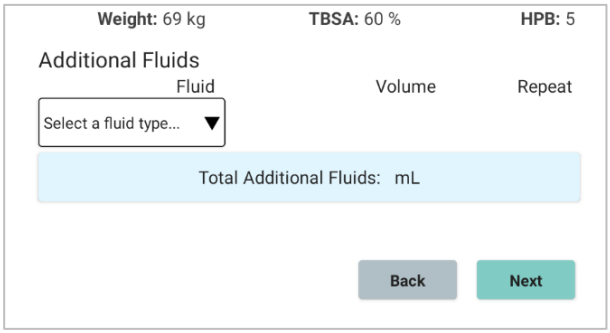
PLEASE NOTE!

- The **rate** entered on this screen is used to calculate the recommended rate for the next hour.

- The default **rate** will always be the current rate displayed on the Home screen. If you've changed the rate during the hour, then Burn Navigator will calculate the **volume** based on how long the Home screen rate was at Rate 1, Rate 2, etc., then calculate the average **rate** for the whole update. The calculated average rate will be shown below the Infusion Rate field.

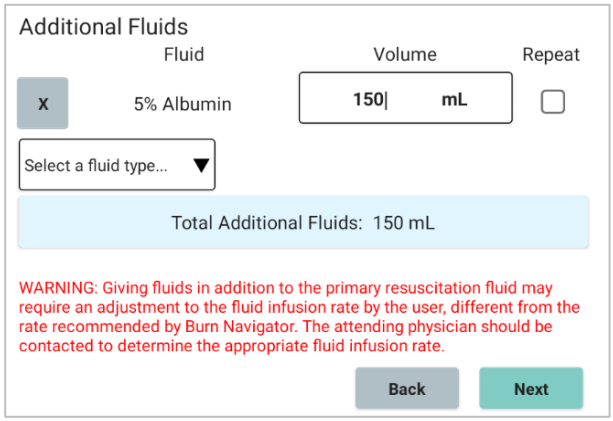
- You can change the **rate** by pressing the white field. If you change the **rate**, Burn Navigator will change the **volume** for the update accordingly.

- 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 infusion 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 data 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.
   a. Press "Select fluid type…" to see a list of Additional Fluid options.
   b. Check the "Repeat" box to have that fluid type and volume show up for the next update. Repeated additional fluids are included in the 24-hour projection.
   c. You can press the "X" to delete the fluid type.
   d. If you don't see the fluid you gave on this screen, then choose the bottom option, "Other Fluids," and write a note to identify the fluid type.



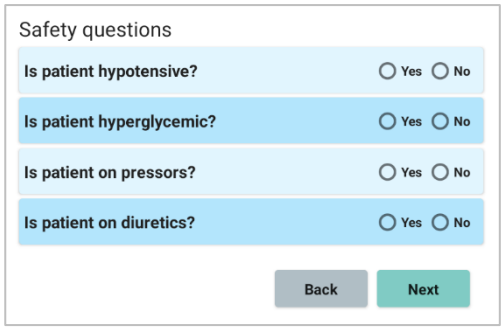
Note: Provide all additional fluids as a **volume** for the time period.

Note: Additional fluids are classified as follows:

Adjunct Resuscitation fluids		Non-resuscitation fluids
<u>Crystalloids</u>	<u>Blood Products</u>	LR + 5% Dextrose
Lactated Ringer's	Packed Red Blood Cells	IV Medications
Normal Saline	Plasma	Tube Feeds
Plasma-Lyte	Pathogen Reduced Plasma	Other
<u>Colloids</u>	Whole Blood	
5% Albumin	<u>Oral Resuscitation Solution</u>[1]	
25% Albumin		

4. Only *primary* and *Adjunct* fluids are included in the volume graph and the 24-hour projection. The *primary* fluid(s) are those titrated on the New Rate screen (below).

5. You <u>may or may not</u> 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. You must answer Yes or No to each question to proceed.



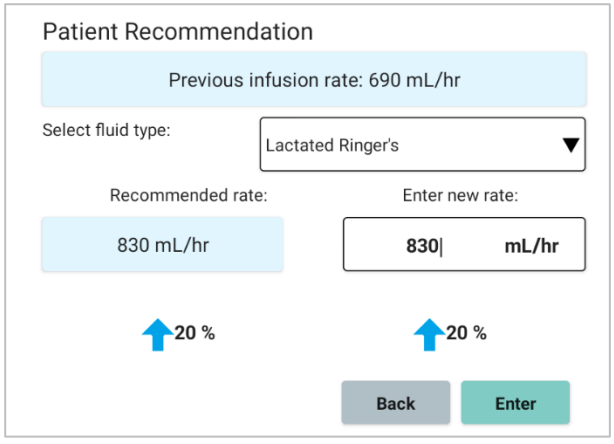
ALERT: If you answer yes to any of these questions, consult with the Attending Physician to determine appropriate fluid therapy.

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.

6. 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.

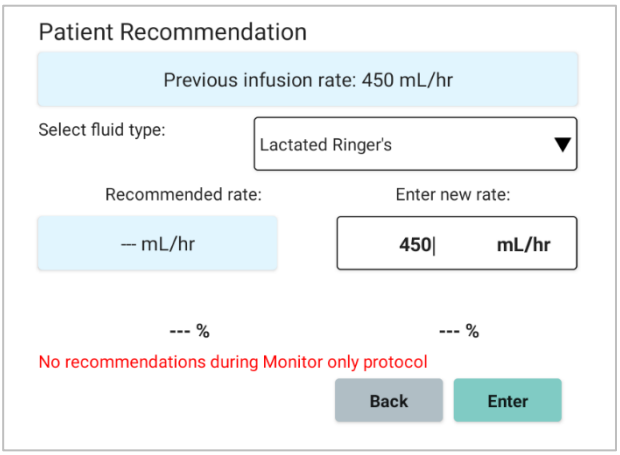


Adult Predictive Algorithm mode

[1] ORS is classified as a crystalloid for purposes of the Burn Quality Improvement Program (BQIP) note. The BQIP note is generated automatically when ending a resuscitation after 24 HPB.

7. 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.



Monitor Only mode

<u>You have now completed the Hourly Fluid Update!</u> You will be taken back to the resuscitation tabs.

Patient Resuscitation Screens

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

Top Bar

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

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.

Android System Status Bar

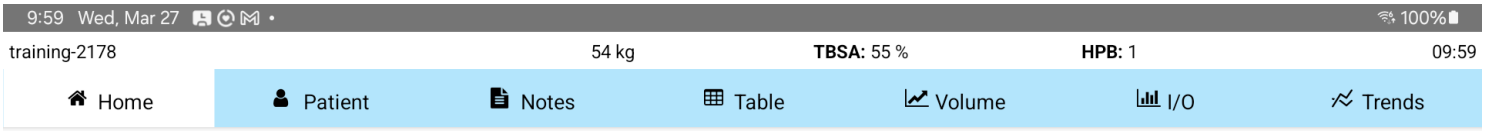
The system status bar displays the current time, battery level, Wi-Fi connection status, and Bluetooth status.

You will see a low battery pop-up alert when the battery level is approximately 15%.

Note: When you see the low battery message, immediately plug in the Burn Navigator or transfer your data to another Burn Navigator device.

Screen Tabs

Immediately below the top bar are tabs for the patient resuscitation screens:
Home, Patient, Notes, I/O Table, Volume, I/O Graph, Trends.



Functional Buttons

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

The "Next Update" button is visible only in Training Mode.

Note that for an inactive patient file, the only available action is Main Menu:

Hourly Update

The first button, "Hourly Update" provides two functions.

1) If it is has been at least 12 minutes since the last 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. <u>You will be given a new fluid recommendation if you use this button.</u> If you redo an update and you enter new values, those values will <u>not</u> show up as edited in the I/O Table.

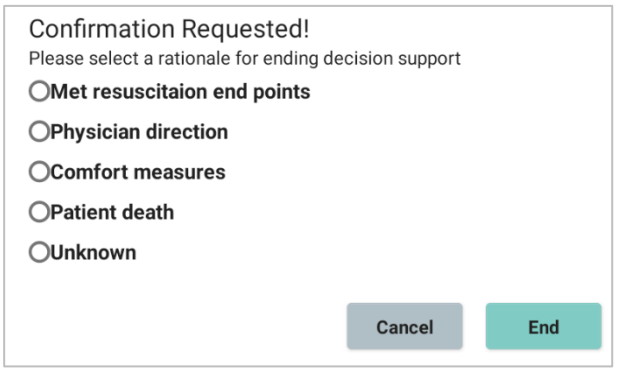
Note: To edit past hourly fluid updates, go to the I/O Table and touch the column representing the time period you want to edit.

Stop Burn Navigator

The "Stop Burn Navigator" button will end decision support for the current patient. Once decision support has ended, the patient will be moved to the **inactive patients** list.

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!

If "Rationale required when ending decision support" is enabled in Admin Settings, then when you press the Stop Burn Navigator button, you will be asked to select a rationale for ending decision support, as shown.

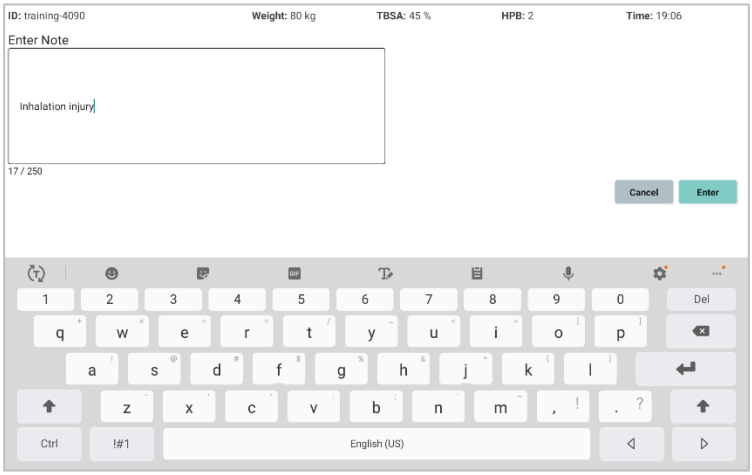


Otherwise, you will simply be asked twice to confirm ending decision support for this patient.

Enter Notes

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

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



ALERT: To protect the patient's privacy, we recommend you avoid entering personally identifying information into notes.

Enter Checklist

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

Next Update

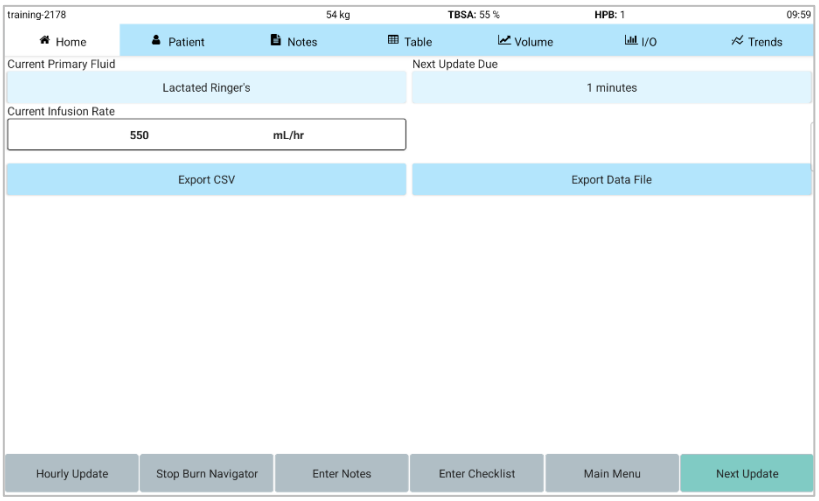
In Training Mode, press "Next Update" to advance the clock to the next hourly update.

If an update is currently due, pressing "Next Update" will not advance time, instead acting like the "Hourly Update" button.

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.

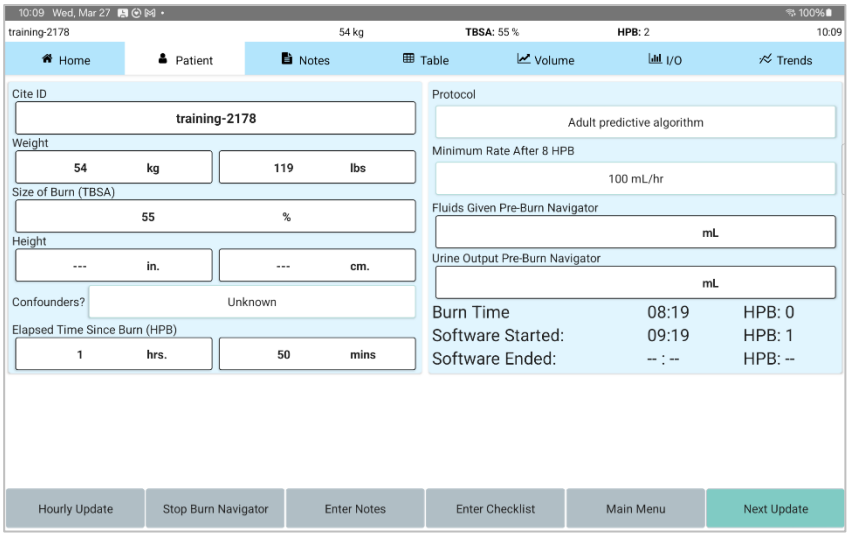
Updating Pump Rate

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

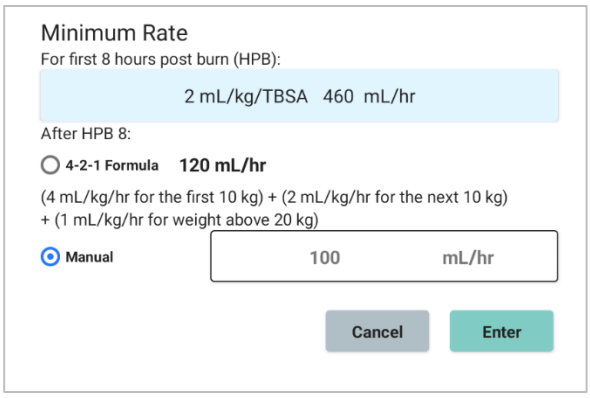
The Patient screen shows the Information you entered in the New Patient Setup. You may change the data in the white fields.

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



For inactive patients, the "Burn Nav ended" time records the time that decision support was ended.

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



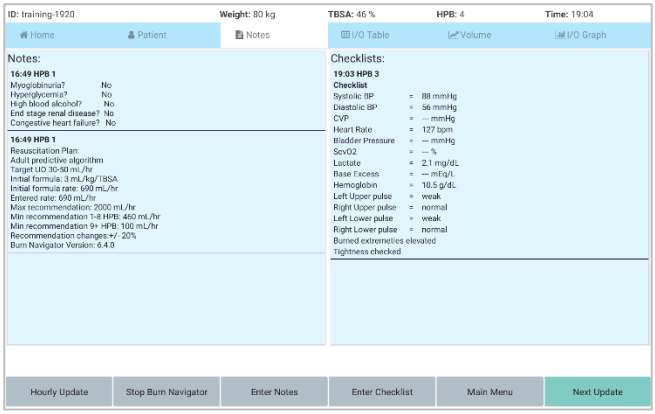
The **Minimum rate** screen shows the lowest recommendation the Burn Navigator will provide for a patient.

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/m^2 Burn Surface Area per day (burn related losses)
   + 1500 mL/m^2 Body Surface Area per day (maintenance fluids)

   NOTE: The Burn Surface Area formula only appears if it has been set as the default in Clinical Settings.

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.

I/O Table

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

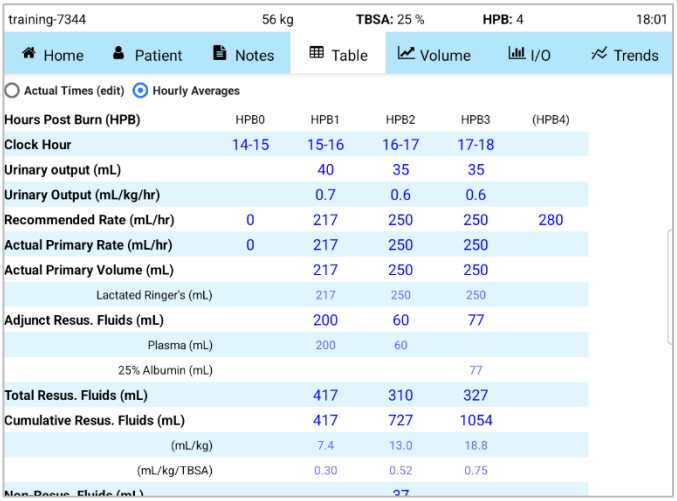
On the left of the screen is a list of fluids and other information: the UO (in mL and in mL/kg/hr), Recommended Rate for that time period, Actual Primary Fluids given to the patient, Adjunct Resuscitation fluids, and Non-Resuscitation fluids. The bottom rows show whether the patient is hypotensive, 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.

There are two views of the I/O Table: <u>Hourly Averages</u> and **<u>Actual Times</u>**
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 is not at the top of the hour.

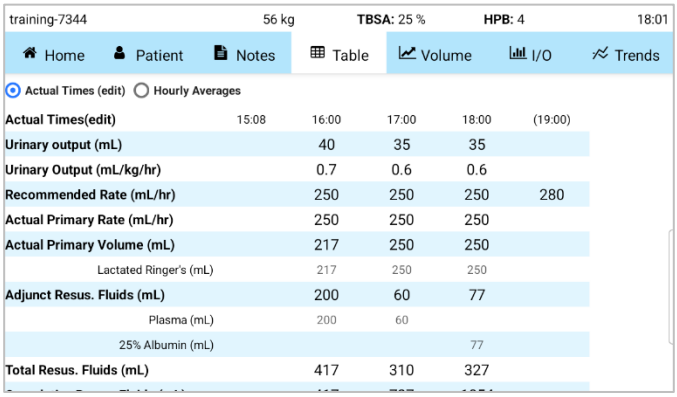
1) **Hourly Averages** (on the right) indicates where the software averages the data you provide to fit into the fixed 60-minute hour post burn periods, e.g., from 02:00 to 03:00, 03:00 to 04:00, etc.

   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.



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 in the **Actual Times (edit)** view. Press the column representing the time period you want to edit.

The first column records the pre-Burn Nav fluid measurements as entered during patient setup. This column cannot be edited from the I/O table. It should be edited from the Patient tab.

The last column represents the current time period and cannot be edited from the table. Data for this column should be entered at the next hourly fluid update.

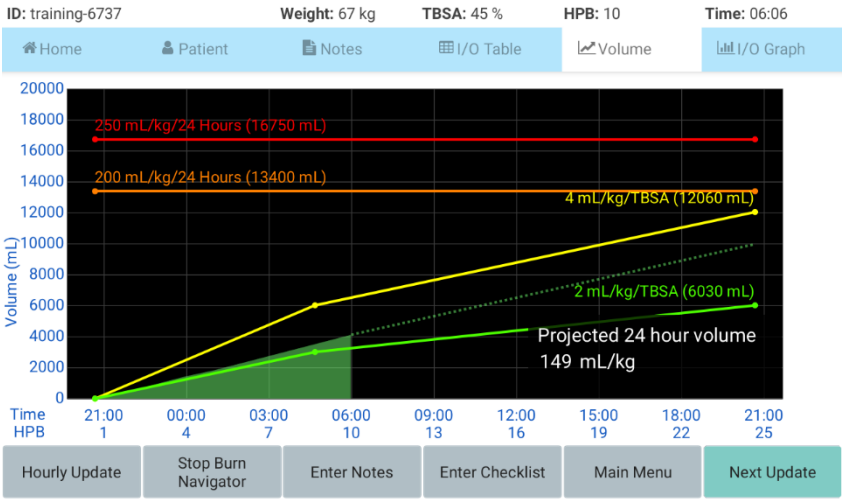
Note: The software will provide an updated recommendation when editing the last fluid update (second-to-last column) within the 10 minute grace period. You can also edit the "To" time of the last update during this window. In all other cases, you cannot edit "To" times of previous updates, and the software will not provide new recommendations.

Volume

The volume graph shows the cumulative volume of all *primary* and *adjunct* fluids that the patient has received since the burn occurred.

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.

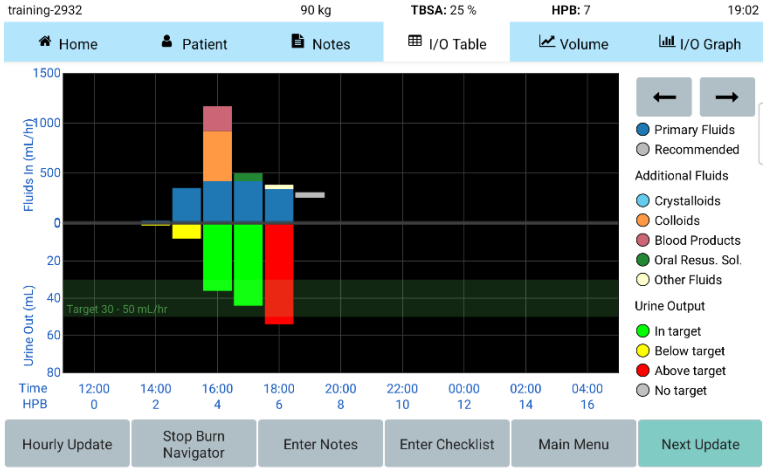
24 hour fluid projection

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 custom 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.

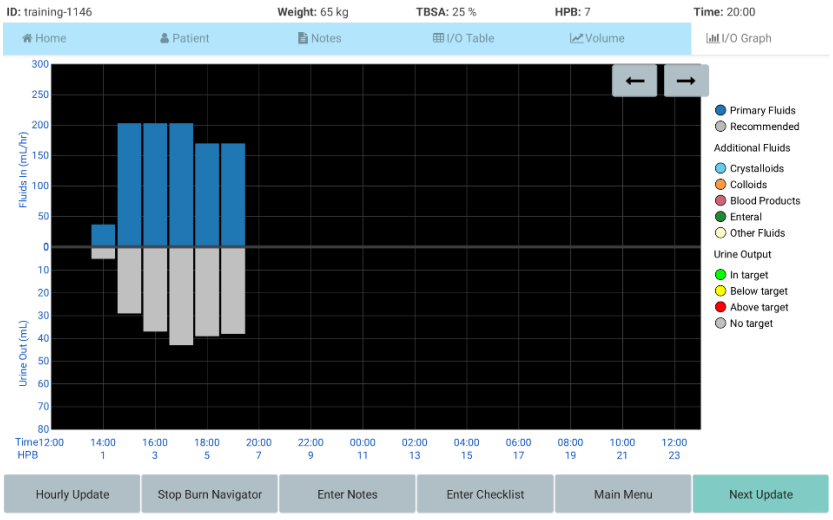
The Fluids In graph shows the primary resuscitation fluids in blue, Adjunct Fluids in different colors based on type (crystalloids, colloids or blood products) and Other Fluids. The last recommendation is shown as a gray bar after all the other columns.

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.

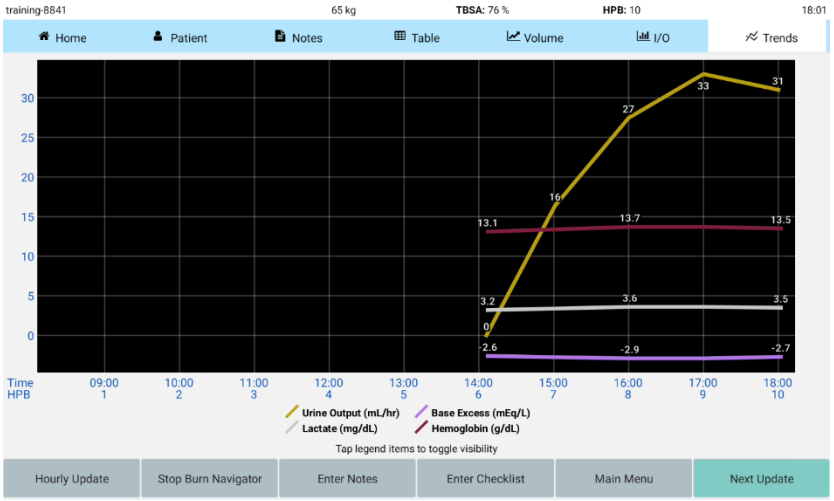
Note: In Monitor Only mode the urine output bars are light gray, since no UO target is set in that mode (as seen on the right).



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.

Trends Graph

The Trends graph plots urine output from each fluid update, together with some Checklist values, over time.



The graph displays:

- Urine output (mL/hr)
- Lactate (mg/dL)
- Base Excess (mEq/L)
- Hemoglobin (g/dL)

You can toggle the visibility of each series by pressing its label in the legend.

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.

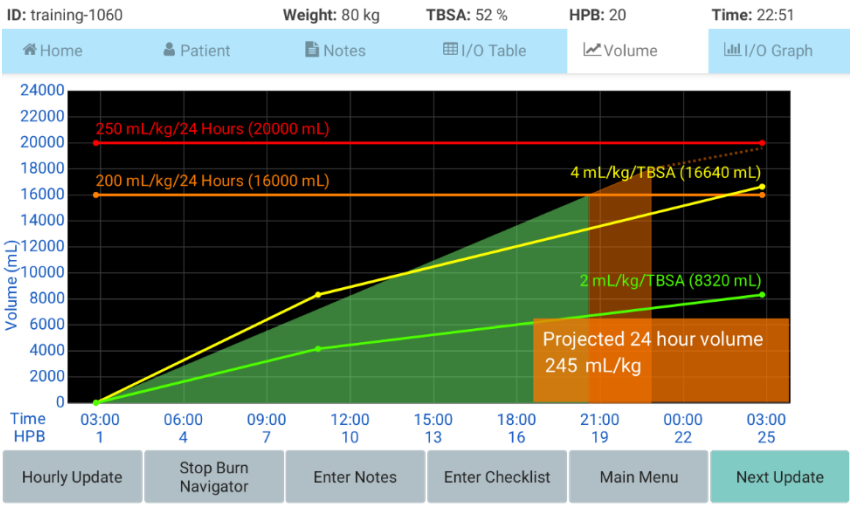
There are several safety rules included in the recommendation algorithm. For example:

- The recommendations won't change more than 40% from the last infusion rate.
- The maximum recommendation is 2,000mL/hr, or 28.6*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*weight(kg), whichever is lower) and the recommendation after that will not go above 1,500mL/hr (or 28.6*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 may recommend a rate decrease (based on the "High projection decrease" field in the Clinical Settings) 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 Notes 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!

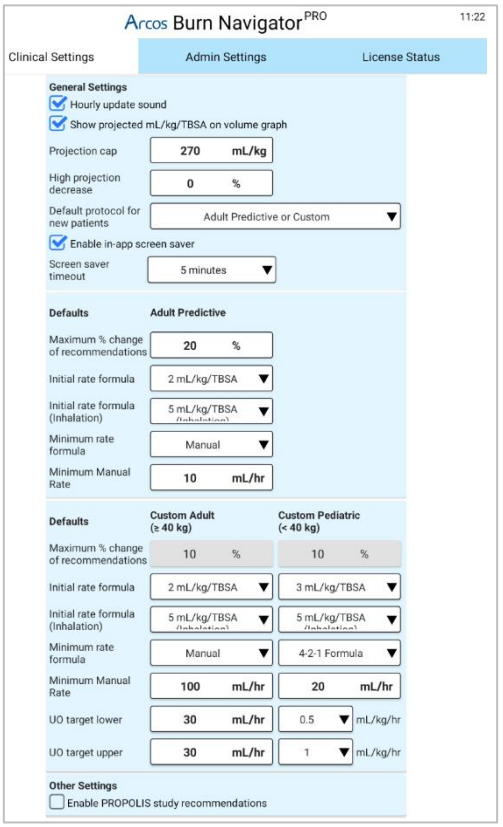
- **The Burn Navigator recommendations are not a substitute for clinical judgment. No medical decision should be based solely on the recommendations provided by the Burn Navigator.**
- **The recommendations are only as useful as the data is accurate. Use the patient assessment checklist for other indicators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

Settings

The **Settings** screen is accessible from the main menu by pressing the "Settings" button.

Clinical settings

The **Clinical settings** tab allows you to change certain default settings for resuscitations.



General settings

These settings apply to all patients.

- **Hourly update sound** — If checked, the software will play an alert sound when it is time to do an hourly fluid update.
- **Show projected mL/kg/TBSA on volume graph** — If checked, the software will display the 24-hour projected fluids on the volume graph in units of mL/kg/TBSA in addition to mL/kg. Disabling this setting will show only mL/kg.
- **Rec. increase cap** — The maximum 24 hour projected volume. Between 9 and 24 HPB, the software will not recommend increasing the rate if the calculated 24 hour projection exceeds this level. This setting applies to all active patients.
- **High projection decrease** — Between 9 and 24 HPB, the software will recommend decreasing the rate by at least this amount if the 24-hour projected volume exceeds the **Rec. increase cap**. It may be set to 0%, in which case the software may recommend keeping the rate the same. This setting applies to all active patients.
- **Default protocol for new patients** — Allows overriding the initial protocol selection in the new patient wizard.
    - ***Adult Predictive or Custom*** is the default setting, which selects the Adult Predictive algorithm for patients >= 40kg without electrical injury, and otherwise selects either Custom or Monitor Only protocols.
    - ***Custom Protocol*** will select the Custom protocol for all adult and pediatric patients. It will still select Monitor Only for patients < 10kg, < 40kg with electrical injury, or without urinary catheter.
    - ***Monitor Only*** will select Monitor Only by default for all patients.
- **Enable in-app screen saver** — Enables or disables the in-app screen saver. We recommend leaving this ON to improve battery usage.
- **Screen saver timeout** — Selects the duration of inactivity before the screen saver appears.

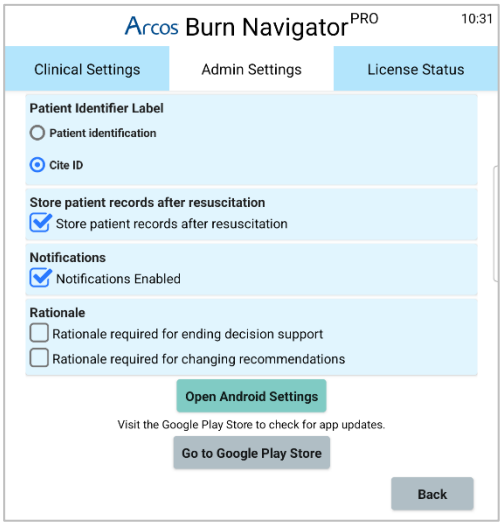
Protocol settings

These settings are specific to each of the Adult Predictive and Custom protocols. The Custom protocol has two sets of defaults, one each for adult (≥ 40 kg) and pediatric (< 40 kg) patients.

- **Max recommendation % change** — The maximum amount that the software will recommend changing the primary fluid infusion rate. This setting can be changed for the Adult Predictive protocol only, and applies to all active patients.
- **Initial rate formula** — The default initial rate formula for new patients. It can be overridden for individual patients during new patient setup.
- **Initial rate formula (Inhalation) –** The default initial rate formula when inhalation confounder is "yes".
- **Minimum rate after 8 HPB** — The default minimum rate formula for new patients. If "Manual" is chosen, the default manual rate can also be set. This setting can be overridden for individual patients via the Patient tab.
- **Custom protocol UO targets** — Sets the default urine output targets for the custom protocol. Default targets are in volume-based units for adult patients and weight-based units for pediatric patients. This setting affects new patients only, and can be overridden for individual patients during new patient setup.

Admin settings

The **Admin settings** tab contains settings related to the user interface and behavior of the software.



- **Patient identifier label** — Selects the label used for the patient identifier field in the new patient setup wizard, the patient screen, etc. The available choices are "Patient identification" (default) and "Cite ID".
- **Save patient records after resuscitation** — If unchecked, the software will not save inactive patient records after decision support has ended; instead, they will be deleted immediately.
- **Enable notifications —** If checked, the software will generate an Android system notification when an hourly fluid update is due and the screen is off or the app is in the background.
- **Rationale required when ending decision support** — If checked, the software will require a rationale to be selected when ending decision support.
- **Rationale required when changing the infusion rate** — If checked, the software will require a rationale to be entered during hourly fluid updates, when entering a new rate different from the recommended rate.

The Admin Settings tab allows you to access the managed Google Play store (where you can check for and install updates to the Burn Navigator app.)

Burn Nav Web integration

If your institution has access to Burn Navigator on the web, then the software can optionally be linked with Burn Nav Web to upload patient records and import clinical settings. ***Patient records are not automatically uploaded.***

To connect to Burn Nav Web, you will need an internet connection. Navigate to the **License Status** tab on the settings screen, press the "Sign In" button, and login using the email address and password for your Burn Nav Web user account.

If the device is already linked to an account, you will see the signed-in user email, as well as the license activation and expiration dates.

NOTE: A Burn Nav Web subscription and mobile enterprise license are required to use this feature. Sold separately; contact sales@arcosmedical.com or call +1 877 542 8025 for more information.

Use of a Burn Nav Web account is subject to our **Terms of Service** and **Privacy Policy**; visit https://arcosmedical.com for more information.

NOTE: Burn Nav Web integration is currently available only for subscribers based in the USA.

Importing Clinical Settings

When the device is linked to Burn Nav Web, the Admin Settings tab will have a new button "**Import Settings from Web**". This button is not visible if you are not signed in. Press it at any time to immediately fetch the clinical settings from your Burn Nav Web account and apply them on the device. This action overwrites your previous settings.

Handoff

The **Handoff** wizard is accessible via the "Handoff" button on the main menu.

Bluetooth Handoff

Bluetooth handoff allows to transfer patient records between two Android or iOS devices. In order to use this feature, both devices must support Bluetooth low energy, and must have installed version 6.3.0 or later of the Burn Navigator app. Bluetooth must be turned on (for security, it is off by default). Android receivers must have location access enabled.

To use Bluetooth handoff, perform the following steps.

1. On the sender device, launch the app, then select Handoff > Send to device > Bluetooth.
2. On the recipient's device, launch the app, then select Handoff > Receive from device > Bluetooth.
3. After a few seconds, the recipient will see a list of the sender's active patients.
4. Have the recipient select the patient to be transferred.
5. Wait until the transfer completes.

NOTE: A given patient record cannot be sent to the same recipient more than once. To transfer a new copy of a patient record, delete the old copy from the recipient's device first.

ALERT: Bluetooth data transfer is unencrypted. Users are expected to have appropriate security safeguards in place to protect patient data during Bluetooth handoff.

Manual Handoff

Manual handoff is intended to be used only in uncommon situations where Bluetooth communication is not feasible.

To use manual handoff, perform the following steps:

1. On the sender's device, launch the app, then select Handoff > Send to device > Manual.
2. Select the patient record to be handed off.
3. You will see a screen with a summary of the patient setup information.
4. On the recipient's device, launch the app, then select Start New Patient or Handoff > Receive from device > Manual.
5. The recipient will be taken to the new patient setup wizard. Complete the wizard using the information on the sender's screen.

NOTE: Manual handoff is essentially the same as admitting a new patient, and most details of the patient's resuscitation history will be lost, including notes, checklists, and hourly fluid updates. This data will not be recoverable on the other device.

Web Handoff

Web handoff can be used to securely upload a patient record to Arcos servers so that users can continue resuscitation using the web edition of Burn Navigator. A Burn Nav Web enterprise subscription (sold separately) is required to use web handoff.

In order to use this feature, you must have an internet connection and be signed in with a Burn Nav Web user account. Then, perform the following steps:

1. From the main menu, select Handoff > Upload to web.
2. Select the patient record to be uploaded.
3. You will be asked to confirm that the patient information is correct before uploading.
4. Choose Yes to begin the upload. An alert will be shown when the operation finishes.

ALERT: Patients uploaded to Burn Nav Web will be assigned to the "hospital" or user group of the account used to sign in on the device. The data will be available to all users in the same group.

ALERT: Each patient record can be uploaded at most once. Do not continue resuscitation on the device after uploading to the web; subsequent updates will not be visible on the web.

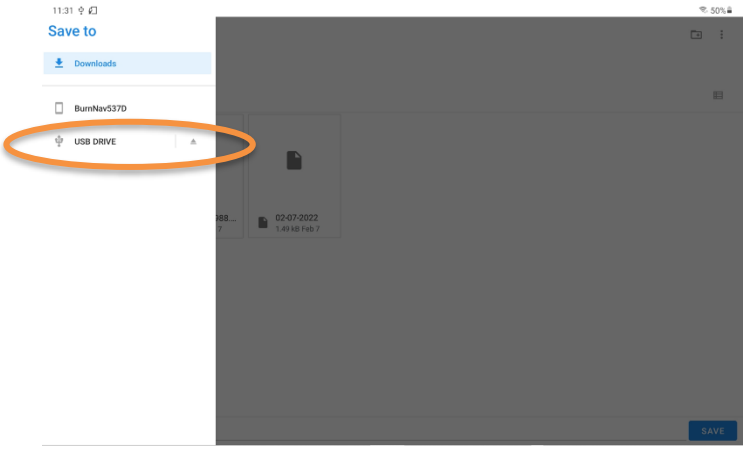
Exporting Data

Burn Navigator can export patient records as either a CSV format report or as an encrypted DAT file for processing by the Burn Nav Data Tool. The Data Tool is an application for Windows PCs available separately.

To transfer these exported files to another device, you will need a USB flash drive with either dual USB Type-A & Type-C connectors, or a USB Type-A to Type-C adapter.

To perform the export:

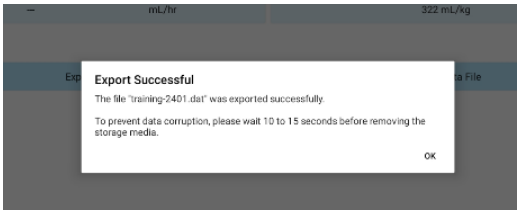
1. Insert the USB drive into the USB Type-C port on the tablet.
2. Select an active or inactive patient record from the main menu.
3. On the Home tab, select "Export CSV" or "Export Data File" depending on the type of file you want to export.
4. The system will show a "Save to" file browser. Navigate to the USB drive (see picture at right), confirm the file name, and press Save.



Note: The software will not overwrite existing files with the same name. For example, if you save "training-7914.dat" to a directory containing a file of the same name, the new file will instead be saved as "training-7914 (1).dat".

Note: If you do not see the USB drive in the file browser, check that it is correctly inserted. The tablet cover may prevent you from fully inserting some drives into the port.

5. After saving, wait 10 to 15 seconds before removing the USB drive. Removing it too quickly may result in a corrupted file.



Note: DAT files exported from Burn Nav Active devices are **not** compatible with Burn Nav H2 or RX devices.

ALERT: CSV reports are not encrypted, and DAT files, while encrypted, can be decrypted by anyone with access to the Data Tool. Use appropriate security precautions when storing patient records on portable storage media. We recommend deleting these files from the portable media after you have transferred the file to its destination.

Software Updates

Arcos will from time to time release updated versions of the Burn Navigator software in order to add new features, improve existing features, or fix problems according to feedback from customers. In most cases, updates will be downloaded automatically when the tablet is not in use and is connected to the internet.

You may also manually check for and install updated software by going to the app's Google Play store listing from the Admin Settings page.

Although updates are rigorously tested before release, there is nonetheless a risk that an update will remove or change features in a way which disrupts your use of the software, or that issues may exist which are not found during our pre-release testing.

The device's operating system and other installed software are also subject to automatic updates, which are developed and released independently by the original device manufacturer or third-party software developer. Arcos is not responsible for the content or timing of updates to non-Arcos developed software.

We will occasionally publish new versions of this User's Manual to accompany updates to the Burn Navigator software. The latest version of the Manual can be found at https://arcosmedical.com/burn-navigator/training-and-resources.

Security and Privacy Safeguards & Best Practices

The Burn Navigator should be used and handled in a manner that protects the privacy of patients. You may have an obligation to do so by law. Burn Navigator implements various technical and operational safeguards to assist in keeping data secure and reduce the likelihood and severity of any breach; however, these are not foolproof and must be coupled with other best practices.

Following is a non-exhaustive list of security features implemented by the Burn Navigator.

1. Patient data is stored on the device in an encrypted format.
2. Access to potentially insecure functions of the operating system is restricted.
3. The app does not transmit or receive any patient information over a network, except during a user-initiated handoff procedure, and only to the extent necessary to support such functions.
4. When a patient record is transferred to Burn Nav Web, it is sent over a secure HTTPS connection.
5. Burn Navigator does not require entry of any identifying patient information. The "Patient ID" label can be changed to "Cite ID" to emphasize this. The software will automatically record the dates and times of various events during resuscitation; however, dates are kept for internal purposes only and are not displayed to the user.
6. It is possible to permanently delete patient records after resuscitation has ended.
7. The device can optionally be configured to require a PIN or password to access the software.

We believe that Burn Navigator patient records, as stored on the device and displayed to users, can be treated as de-identified data, provided that no personally identifying information is entered into the Burn Navigator during resuscitation.

It is assumed that organizations will have appropriate physical access controls in place to protect the device against theft or access by unauthorized persons.

Arcos **does not** enter into a business associate agreement with you or your organization solely by virtue of your purchase and/or use of the Burn Navigator tablet.

For more information, see the in-app *HIPAA Compliance Statement*, accessible from the splash screen.

If you have security or privacy questions, please contact us at support@arcosmedical.com.

FAQ – Frequently Asked Questions

1. **Why is the first bar in the Fluids I/O graph so short?**
    a. 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 hourly recommendations?**
    a. No, additional fluids are not included in hourly recommendations. 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 different color on the Fluids I/O Graph.
    b. 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.
    c. 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. When you perform the hourly fluid update, on the "Additional Fluids" screen, enter the volume of the bolus. The bolus will show as a different color 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.

8. **Can I use Bluetooth to hand off a patient to my personal device?**
    a. Yes, this device can exchange patient data with the Burn Nav app available on the Google Play and Apple app stores.

9. **Can Burn Navigator connect to an electronic medical record (EMR) system?**
    a. At present, no.

Troubleshooting

Starting Up	
The device does not boot.	● Connect the AC adapter. ● Insert a fully charged battery. ● Remove the battery pack and the AC adapter, and then connect them again.
Cannot turn on the tablet.	• 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.

Handoff	
Unable to send or receive a patient via Bluetooth handoff.	• Ensure that Bluetooth is enabled on both devices. • Location access must be enabled on Android receiving devices in order to use Bluetooth handoff. Go to Settings > Biometrics and security > Location and ensure that master location access is ON and that Burn Nav has the location permission. • Move the devices closer together. • Move away from any sources of radio interference. • Ensure that both apps are up to date. App updates may occasionally cause incompatibility with previous app versions. • Reboot one or both devices.

Shutting Down	
The device does not shut down.	• Wait one or two minutes. It is not a malfunction. • Remove and reinsert the battery.

Display / Interface	
The screen is too dark.	• The screen may be off. Press the Power or Home buttons to turn the screen on. • The device may be shut down. Press and hold the Power button for 3-5 seconds. • Adjust the display brightness in Android settings.

Battery	
The battery does not charge, or charges very slowly.	• Check for damage to the USB connector. • Clean the USB connector. • Replace the USB cable. • Replace the AC adapter. • Replace the battery.
The battery loses charge very quickly.	• Reboot the device. • Replace the battery.

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 "Training Mode" or "New Patient" when there are 6 active patients	The maximum number of patients are being resuscitated.
User attempts to delete an inactive patient record.	PLEASE CONFIRM: Are you sure you want to delete this patient record?
A fluid update comes due, or an alert is raised, for an active patient while viewing a different patient.	Other patients on this device have pending alerts. Would you like to return to the main menu to review those patients?
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 Stop Burn Navigator 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?"
72 hours post burn has been reached	"It has been 72 hours post burn. Fluid decision support for this patient has ended."

Cause of Alert or Message	Alert or Message Text
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 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."
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 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"

Cause of Alert or Message	Alert or Message Text
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."
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 H2O, 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: • 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."

Cause of Alert or Message	Alert or Message Text
The user indicates that the patient is hypotensive, hyperglycemic, on pressors or on diuretics when the algorithm *recommends* a decrease in fluid rate	"Alert! Consult with attending physician about an appropriate fluid rate during presence of hypotension, hyperglycemia, pressors or diuretics."
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."
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.	"It is not yet time to do the hourly fluid update or the 10 minute edit window has expired. To update the pump setting, go to the Home screen and select the "Current Infusion Rate" field."
During a wireless handoff, the system time on the receiver is more than 30 minutes ahead or behind of the device that exported the patient file	Warning – Time Offset A time difference of __ minutes has been detected. Please check that your device's date and time are set correctly before proceeding. If you continue, the received patient data may be adjusted to correct for the difference. Go ahead with this transfer?
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 and a decrease is set in the High projection decrease setting.	High 24 hour volume projected! Fluid decrease recommended.

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: Samsung Electronics America, Inc.
85 Challenger Road
Ridgefield Park, NJ 07660

Wireless LAN / Bluetooth
The tablet is capable of connecting to a Wireless LAN to receive software updates, and can use Bluetooth to transfer patient data between devices.

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.

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.

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
- Visible swelling or bulging of the battery pack

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 may not be 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.

NOTE

- The battery pack may become warm during recharging or normal use. This is completely normal.
- Recharging may 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 may take longer to fully recharge, and the operating time may be shorter. Only use the computer within the allowable temperature range.
- 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 — Burn Nav Active (Product no. 1153)

Main Specifications

CPU	2 GHz, 8-core Qualcomm SDM670
Main Memory*[1,2]	4 GB RAM
Internal Storage*[1,2]	64 GB internal flash storage
External Storage*[1,2]	MicroSD card (up to 512 GB) (sold separately)
Interface	USB 3.1 Type-C connector
	10.1” TFT LCD FHD (1920x1200) w/ capacitive multitouch digitizer
Wireless communication	Wi-Fi 802.11 a/b/g/n/ac; 2.4/5 GHz; VHT80
	Bluetooth 5.0, LE up to 2 Mbits/s*[3]
	NFC
Location	GPS, Glonass, Beidou, Galileo
Hardware buttons	Side: Power, Volume Up/Down, Active
	Front: Menu, Home, Back
Charging	DC Input via USB (5.0 V / 2.1 A)
	Included AC to USB-A adapter (100-240VAC, 50/60Hz)
Battery Pack	Li-Polymer battery (7,600mAH) with adaptive fast charging
Operating Time*[4]	Approx. 15 hours
Charging Time*[5]	Approx. 3 hours
Dimensions*[6]	6.70” x 9.59” x 0.38” (170.2 x 243.5 x 9.9 mm)
Weight*[6]	1.44lbs (653g)
Installed OS*[7]	Android™
Certifications	IP68*[8], MIL-STD-810G*[9], EPEAT*[10], Energy Star*[10], RoHS*[10]

Notes

*1 1 KB = 1,024 bytes / 1 MB = 1,048,576 bytes / 1 GB = 1,073,741,824 bytes
*2 Some space is reserved for internal use by the operating system and application software.
*3 1 Mbit = 1,000,000 bits.
*4 Average time under typical load with new, fully charged battery. Varies depending on actual usage.
*5 Varies depending on usage conditions.
*6 Dimensions and weight excluding protective cover.
*7 Operations of this computer are not guaranteed except for the pre-installed OS.
*8 Water resistant up to 5 feet deep for 30 minutes.
*9 With bumper. Passed MIL-STD-810G testing against a subset of 21 specific environmental conditions, including temperature, dust, shock/vibration, and low pressure/high altitude. Device may not perform as shown in all extreme conditions.
*10 Tablet hardware certified by the original hardware supplier.

Service & Technical Support

Please report any software bugs or 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
or 877-542-8025

Shipping information will be provided.

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