

# Functional SW Requirements

## Version 2.0

Version 1.0	June 4, 2013	Initial Release
Version 2.0	July 3, 2013	Expanded Definitions

## Referenced Documents

The following documents should be used in conjunction with this document to fully understand system and product specifications.

1. *IA Technical SW Requirements for BH VX.X.docx*.
2. *IA BLE Engr Test RX.X.docx*.

## User Characteristics and Environment

Health care professionals in acute psychiatric inpatient facilities will use the initial version of this product as a “rounding tool” to monitor patient safety. Future uses of this system will likely be in general med/surg hospitals. Unlike general med/surg hospitals, very little technology is deployed in psychiatric settings. In fact, this system will replace a paper-and-pencil system. These facilities are driven by compliance and other regulations, which are primarily communicated to staff via paper procedures. In general, staff using this product should be assumed to be non-technical with lower than average technology skills and comfort. In addition, these facilities operate continuously, 7x24 with very little IT support, especially during non-business hours. Invisalert anticipates having some type of user support but the hardware, UI and functionality of this product must be very intuitive, stable and robust.

Here are some of the key users for the system:

1. **Observers**. These are heavy users that perform the majority of scheduled patient observations. Typically, Observers are Medical Technicians or MedTechs and have some formal training but less than an RN.
2. **Nurses**. RN's are present on BH units, perform observations and supervise the MedTechs.
3. **Administrators**. Administrators are often responsible for unit or multi-unit facility operations including patient safety and staff supervision. The Admin typically also has some revenue (census or patient management), cost and/or P&L responsibility. Admin's would not be primary users of the system but would heavily use the system to monitor observation compliance and staff performance. The Admin or a high-level designee would also setup staff in the system as users and set permissions.
4. **Admissions**. Admissions staff could be RN's or high performing MedTech's. They would use the system to check-in patients by loading their photo and other key identification information.

## Project Overview.

Invisalert is developing a “rounding tool” for inpatient healthcare settings. The initial product will be specifically designed for acute inpatient behavioral health settings. The system consists of a tablet PC carried by a caregiver and a band worn by patients that contains a Bluetooth LE RFID chip. The Bluetooth chip “talks” to the tablet's RFID chip, which allows a patient-rounding schedule to be satisfied, Fig 1. The tablet PC has a “dashboard” of patients and the relevant rounding information associated with each patient. A series of screens allow the user to interact with the system. This document describes

how the user will interact with the system to round on patients and transact patients around the facility.

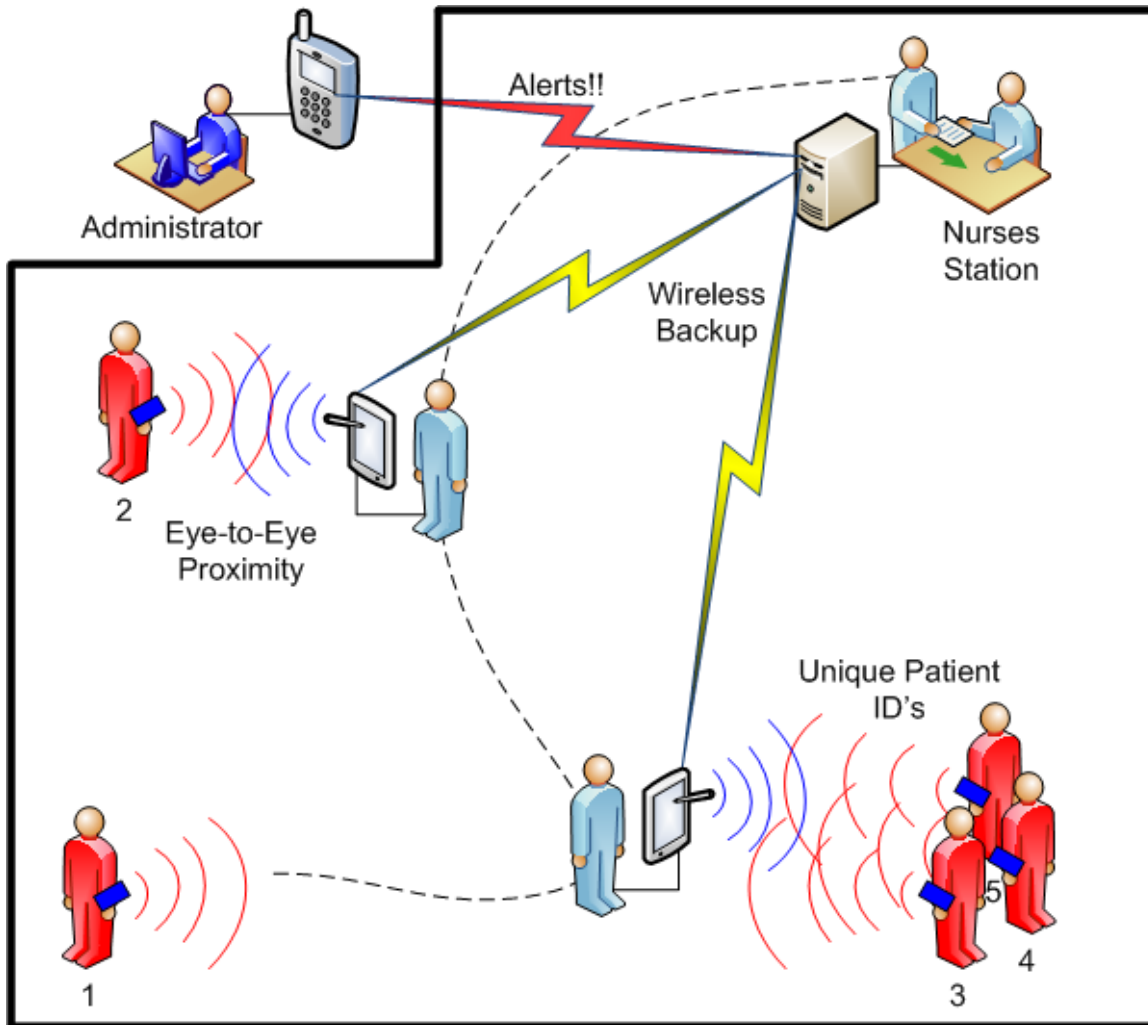


Figure 1. Invisalert "Rounding System" with tablet PC's and RFID bands on a secure unit (typically <24 patients).

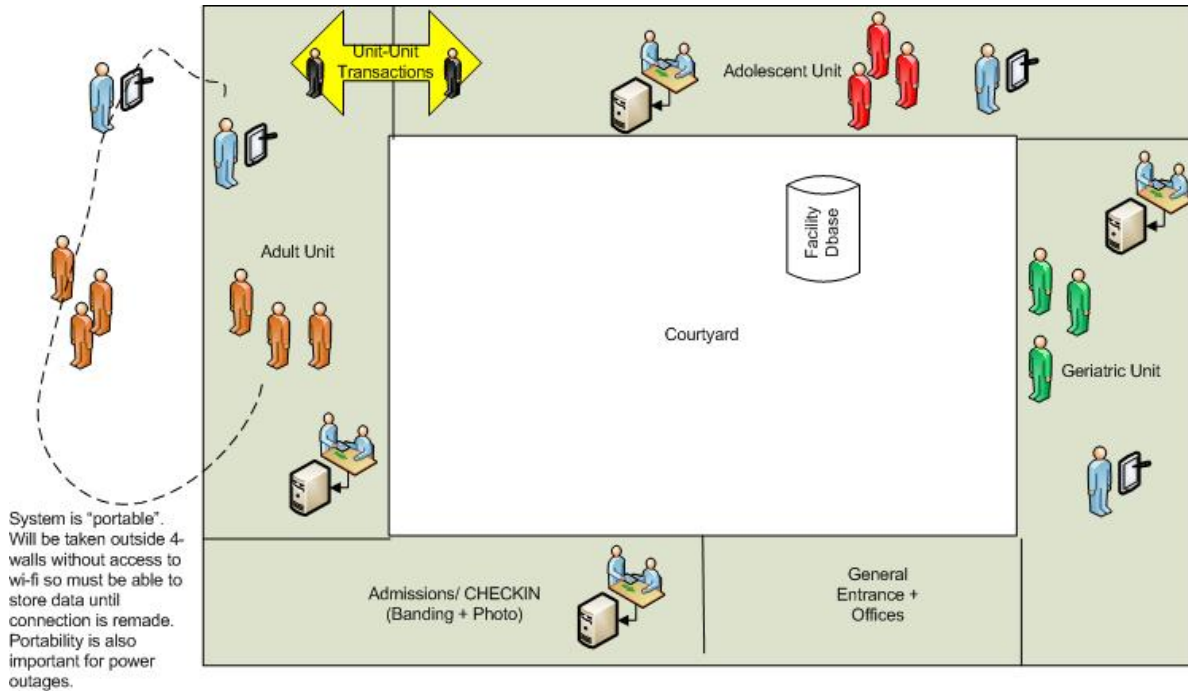


Figure 2. Invalert rounding system shown for a typical (75-100 patients) stand-alone facility with 3 different units.

**Functional Requirements (Screens).** (See Appendix for detailed UI screen definition).

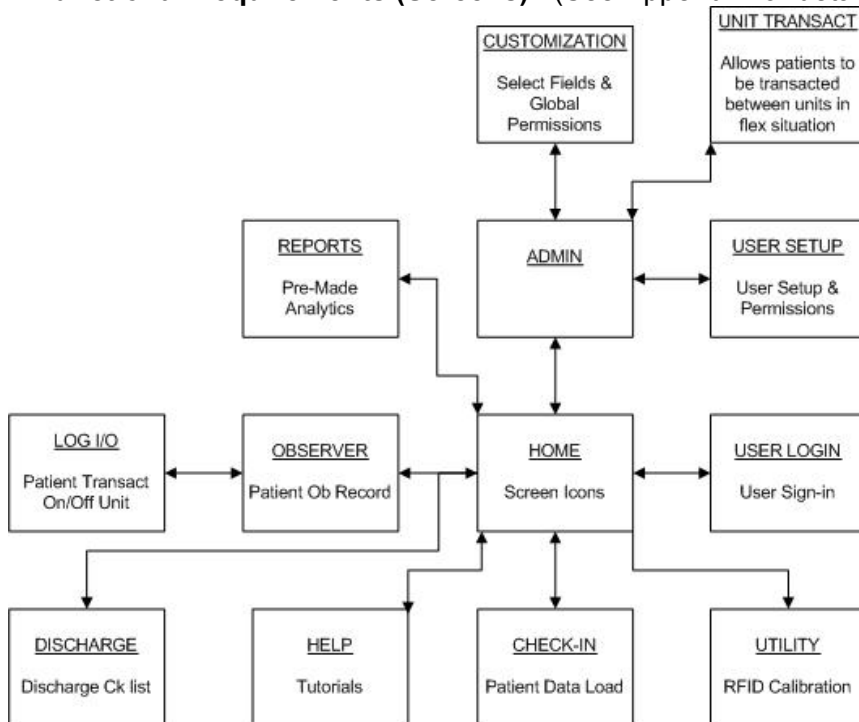


Figure 3 User screens defining the system. UTILITY screen not shown.

System Functionality (Numbers correspond to notes on screen shots in the Appendix). Where appropriate refer to the Workflow Map.

- A. **HOME** Screen. Home screen should be the landing page when you first turn-on the device.
- B. **REPORTS** Screen. A limited number of reports will be available. [Need to define the minimum type of report would be.]
- C. **HELP** Screen. [Needs definition. Help screen could have a series of icons for each page of functionality in the system. Each icon could open up screen shot video's showing mock operations with narration. Should this screen only appear on desktop's? or portable? ]
- D. **OBSERVER** Screen. The purpose of the OBSERVER screen is to facilitate patient observation using a dashboard with schedule prompts, alerts and other features supporting patient management on a behavioral health unit. Most of the information that appears on the OBSERVER screen is input from the CHECK-IN screen.
  - 1. **Notes.** The notes field can be populated from a pre-defined set of pull-downs. After every observation, this field should blank for the next observation. [Not clear if this should be set of pull-downs or simple type in notes] [#Fields TBD].
  - 2. **Location and Behavior.** These are 3-digit fields with pre-defined pull-downs. An Admin screen will used to generate pull-downs inputs. These fields should be blank at the start of each observation.
  - 3. **Proximity Indicator.** This feature should indicate to the user what the proximity setting is for the patient. UI note – This indication could be color-coded bars or some other mechanism.
  - 4. **In-Range.** This feature should indicate whether the tablet and bracelet are within range and therefore an observation can be performed. UI notes: Two indicators should be used. Text could say In-Range or Out-Range or something else. The screen should also take on a partially transparent overlay when the bracelet is out of range.
  - 5. **Low Battery.** This feature should appear when the bracelet battery advertises a low battery condition. [The BlueGiga chips have a battery life utility but we would have to write some custom firmware to get the chip to advertise its state. It is not clear if there would need to be some simple processing within the system software to interpret that low battery signal]. UI Notes: Low battery condition alert should only appear when the condition exists. It might be useful to have a progressive warning such as a light and then a blinking light.
  - 6. **Discharge.** This feature takes the user to a discharge screen for that particular patient.
  - 7. **On-Time Check Performance.** There should be some indicator to provide feedback to users as to their observation check performance. This is intended to motivate the user to be compliant with checks. Administrators will use this information for performance appraisals. [Not clear how this performance should be calculated so that it is impactful or where this calculation should be defined or if it should be modifiable]. UI Note: A visual indicator as opposed to a number might be better for feedback or perhaps both.

8. **Interval Countdown.** The interval minutes count down until an observation is made which causes the interval to reload. UI Notes: A progression of things should happen during interval countdown:
  - i. 4.00 minutes. Digits turn red.
  - ii. 1.00 minutes. Background turns red and numbers turn white.
  - iii. 0.00 minutes. Chime sounds.
  - iv. <0.00 minutes – count down continues showing negative blue digits that flash.
  - v. Alert-1. At some predefined time (ADMIN Customization screen), an alert is sent out. Up to three additional predefined alerts can follow in succession. [ *How likely is it that all the tablets on a unit will be out of wi-fi range and therefore alerts can not be sent out?*]
9. **Log I/O.** This is a navigation feature to take the user to the LOG I/O screen so a patient may be logged out of the system.
10. General UI notes for the Observer screen:
  - i. The highest priority (closest to interval expiration) patient always rolls to the top of the dash-board. Once a check has been satisfied, that patient rolls to the bottom of the patients.
  - ii. Might be useful to have a battery indicator in the software that alerts the user to battery status better than the tablet's small indicator.
  - iii. Dashboard should be scrollable.
- E. **CHECK-IN Screen.** The purpose of the CHECK-IN screen is to enter a new patient into the Invisalert software system by loading forms of identification and unique aspects of patient care and restrictions. This is also the screen where a unique RFID identifier is paired with a patient. No two active patients in the system can share the same RFID identifier. However, archived records can have duplicate RFID numbers since RFID devices will be reused.
  1. **Picture.** Picture will be taken at the ADMISSIONS desktop using a USB camera (to be specified). Picture capture process should be integrated with the software and be “bullet-proof” (When picture is taken, the file should automatically be wherever it needs to reside).
  2. **Name.** Last and first names will be typed in manually. [#Fields TBD]. [ *If a BHU is part of a larger integrated system where a patient's name and other parameters are already on bar-coded forms, would it be useful to load such parameters via bar-code reader?*].
  3. **Patient ID.** Patient ID is a unique identifier for the patient. [#Fields TBD].
  4. **Medical Record.** Medical record is a unique identifier for a particular patient's episode of care. A given patient may have multiple admissions and therefore multiple episodes of care. [#Fields TBD].
  5. **Diagnosis.** Diagnosis consists of two fields since a patient may have more than one diagnosis. [#Fields TBD].
  6. **Unit.** Unit is the name of the treatment group where the patient is located such as Adult, Child, Elderly, etc. [#Fields TBD].
  7. **Room.** Room is the name/number of the room where the patient lives while on the unit. No more than two patients share rooms so no more than two active patients can have the same room number. [#Fields TBD].

8. **Proximity.** Three options for proximity: 1:1, Close, Far. A given proximity setting defines a minimum signal strength required for the tablet to “link” with the wristband chip. The fourth button is intended to exempt the patient from a global proximity setting on the ADMIN screen. (The global proximity setting could be used to set a ‘Far’ setting at night so as not to disturb patients.) [#Fields TBD]. *[Default settings for each proximity will be determined via pre-product launch engineering studies. However, site-to-site calibration may be needed].*
  9. **Interval.** The interval is the time interval in minutes between checks. The default will be 15min. Pull-down plus manual entry up to 120min. Three digit field. This field will require specific permission for the user to change (permissions set on the ADMIN screen).
  10. **RFID.** The RFID field is for the unique Bluetooth LE identifier (MAC address) that the patient wears. The Admissions staff (see Workflow Map) will capture the MAC wirelessly using their hardware’s API. The chip advertises its MAC so it should be able to be captured by the desktop hardware and assigned to the patient. *(A hardware note: The desktop or tablet and the band to be “discovered” will have to be isolated from other bands so we can be sure the right MAC is discovered and assigned to the patient. A special utility might have to be written to discover and capture the MAC address.)* If a patient requires a replacement bracelet, the new chip identifier will be read by the Unit Admin’s desktop station. [#Fields TBD]
  11. **Prompt-1 and Interval-1.** This feature is intended to create a prompt that shows up on the OBSERVER screen dash-board for the patient. For example, a patient at risk of falls might have a prompt that reads: “Ask patient if they need bathroom”. This prompt would show up at whatever interval was pre-programmed (for example, every 1hr). The prompt would show up in the patient dash-board every hour but synchronized with the closest observation due. The prompts should be a pull-down menu only (pull-downs will be input from one of the Admin screens) [#Fields TBD] . The intervals should be a set of pull-downs. Intervals in minutes for continuous intervals 24hrs a day (3-digit fields). Up to three prompts/intervals should be programmable per patient. You should also be able to select up to two discrete times from an AM/PM clock pull-down. For example, you might want a medication prompt to be given twice a day.
- F. **LOG I/O screen.** This screen allows the user to log a patient out of the system. The patient is not being discharged but may need to travel off the locked perimeter of the unit for family meetings or therapy or hospital visits. In this case, the patient would be logged out and put in the care of a sponsor that effectively would have the patient in a 1:1. This screen logs out the patient to a sponsor and creates a prompt for their expected return. When the patient returns they will need to be logged back into the system. If the patient is overdue, no alerts are necessary but the screen does allow for the expected time back to be edited.
1. **Observation Panel.** The observation panel ports over from the Observation screen.
  2. **Log In. Log Out.** These features allow a patient to be logged in or out of the system. If the Log Out feature is selected, additional features must be filled in before log-out can occur. UI Notes: Either command should ask the user to confirm the action.



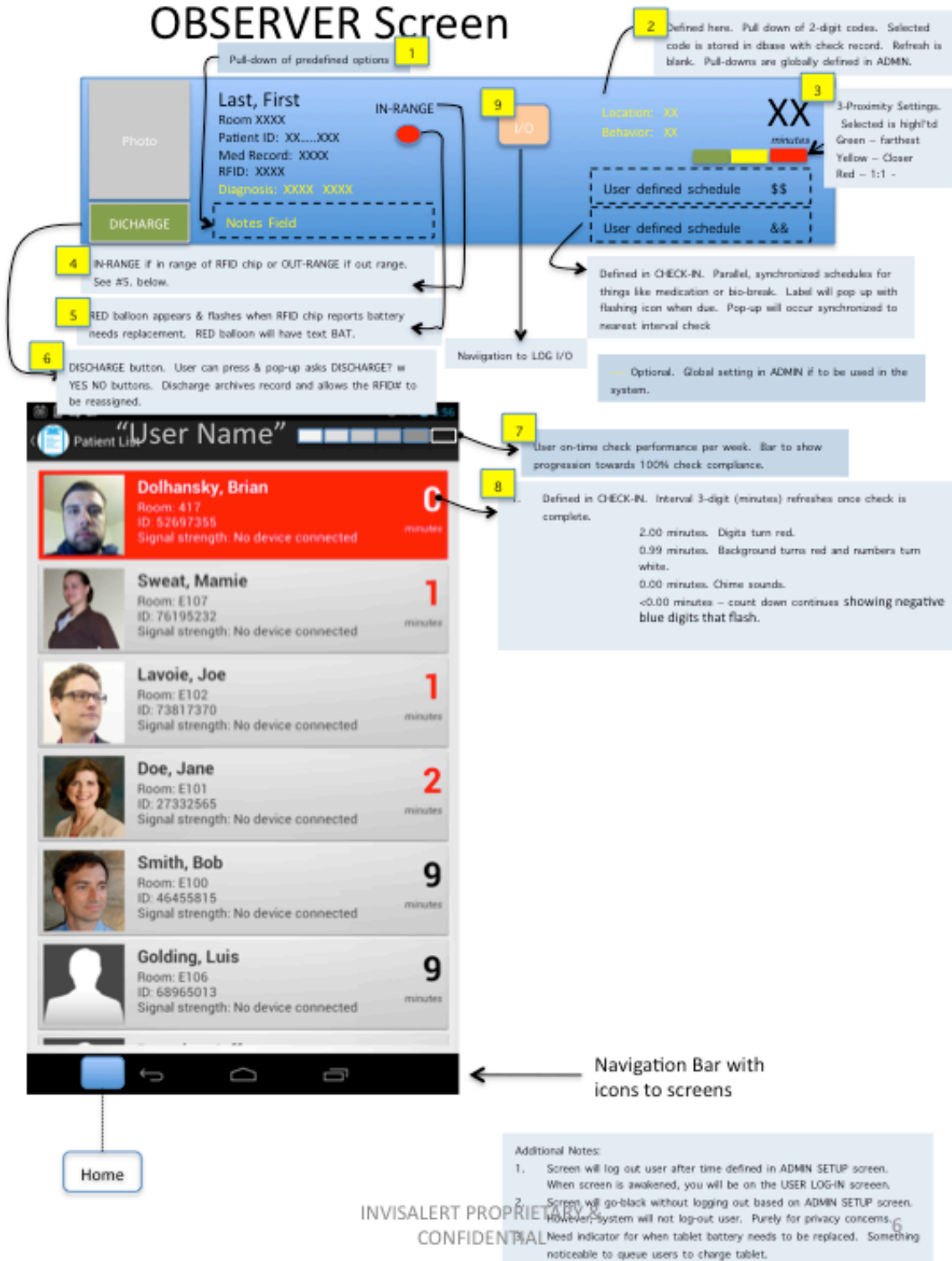
3. **Destination.** This feature allows the user to specify a destination for the patient. UI Notes: A pull-down of pre-defined destinations. [An Admin screen will have to be created to allow for all pull-downs to be populated.] [#Fields TBD]
4. **Sponsor.** This feature allows the user to assign a sponsor to the patient. The intent is that the sponsor will be responsible for the patient's care while they are out of the unit. [#Fields TBD]
5. **Log-in Return Prompt.** This feature creates a prompt (in the Observation screen – see #7) for when the patient should return. UI Notes: A pull-down AM/PM clock. [Will the patient ever be off the unit for more than 24hours?].
6. **Edit.** This feature allows the user to edit the return prompt (The patient could be delayed in their return).
7. **UI Note.** This graphic shows how the patient dashboard should look in the OBSERVER screen. The screen should have a partially transparent overlay and Log-Out and Log-In text as shown. When the estimated log-in time is hit, the log-in time digits should turn red and flash.
- G. **USER LOG-IN.** This screen allows the user to log into the system. Presumably the log-in could be a pull-down. Passwords would likely be assigned and controlled by the administrator. [#Fields TBD]
- H. **ADMIN.** This screen would likely be a navigation screen to the following functions: USER SET-UP, UNIT TRANSACTION, CUSTOMIZATION. [A fourth screen admin screen might be for populating and editing pull-downs.]
- I. **USER SET-UP.** This screen allows the administrator to load or delete users from the system and set permissions for each user depending on their role and responsibility.
  1. **Last, First.** Name input. This should be the user ID.
  2. **Employee ID.** Employees may have unique identifiers when they are hired.
  3. **Role.** Administrator would select a predefined role for the employee from a pull-down. [Most EMR's and hospital system are adopting roles-based permissions rather than individual permissions. This allows permissions to be consistent and manageable across the entire IT ecosystem. This feature should be designed with the idea that it will need to be synch'd with a system function upon integration.]
- J. **ROLES PERMISSIONS.** This screen will be used to set permissions for roles (as opposed to individuals)
  1. **Roles.** Pull down of pre-defined roles in the system [An Admin screen will have to be created to allow for all pull-downs to be populated].
  2. **Permissions.**
    - CHECK-IN function.
    - ADMIN function. Permission for all ADMIN screens and functions.
    - REPORTS. Access to all reports.
    - INTERVAL EDIT. Ability to modify the observation interval.
    - UNIT TRANSACTIONS. Ability to transact patients between units.
- K. **CUSTOMIZATION.** This screen allows the administrator to customize the system to suit practices on their particular unit.
  1. **Global Proximity.** This feature would allow all patients to have the same proximity setting for some window of the day. For example, during nighttime sleeping hours you might want a global FAR setting that was less obtrusive. You could opt particular patients out of the global setting in the CHECK-IN screen. UI Notes: This



- feature would have to be optional, pull-down for proximity setting, pull-down for clock settings.
2. **Optional Fields.** These features can be turned off here. Different facilities have different practices so some may opt out of certain features. These features are present on the OBSERVER screen but only Location and Behavior codes are input at that screen.
    - i. Location.
    - ii. Behavior.
    - iii. Diagnosis.
    - iv. Parallel Schedules.
    - v. Notes.
  3. **Alerts.** When a check is missed (interval counts down to zero), staff can be alerted via text and/or email. The first alert is initiated from a time delay which can be set from T=0 to 30 min in 1 minute increments. Up to four different people can be alerted. Each alert has a time delay which can be set from T=0 to 30 min. For example, if all four alerts were set to T=10 min, all four alerts would go off simultaneously 10min after the interval hit T=0.
- L. **UNIT TRANSACTION.** This feature allows patients to be ‘transacted’ between Units in a behavioral health facility. Some BH facilities have multiple units (ie – Adult, Adolescent, Geriatric, etc.) under one roof. Each unit is a self-contained operation. Certain states allow facilities to ‘flex’ their beds. For example, an Adult patient could be admitted to a Geriatric unit for a day or so until a bed was freed up in the Adult unit. Each Unit’s active database should only contain the patients on their particular unit. When a patient is physically moved from one unit to another, this feature would allow them to be transacted from one unit’s active dbase to another. Once a patient ‘leaves’ one unit, his record is archived and his active record is in the new unit. No patient can have an active record (present in OBSERVER dashboard) in more than one unit.
1. **Name/ID.** The patient’s name and ID are used to retrieve the patient’s record. UI Notes: The patients picture and other vitals should present once their ID is entered.
  2. **From/To:** ‘From’ is the patient’s current unit and should populate once their ID is retrieved. ‘To’ is the patient’s destination unit, which could be selected from a pull-down.
- M. **DISCHARGE.** The discharge feature allows a patient to be discharged but is intended to create several gates to ensure certain activities are done prior to the patient leaving the unit. The specific items to be checked will likely depend on each individual facility’s processes so during set-up, Invisalert would fill these in. User customizable is probably not necessary since discharge processes are not likely to change. Common to all system will be two buttons: Band Collection and Discharge. Since the bands are to be refurbished, it is important to capture them in a gated step. [*Current thinking is that bands will be disposed of rather than recycled or refurbished.*]
1. **Panel** ports over from the observation screen.
  2. **Actions.** Discharge actions.
- N. **UTILITY.** A utility screen or functionality may be needed so that the proximity settings can be customized for a particular facility and the preferences of an administrator. For example, the 1:1, Close and Far settings will be “fuzzy” due to the inherent nature of RFID (different environments can “shorten” or “lengthen” link distances depending on the amount

of reflection, absorption and shielding. Therefore, a particular administrator may prefer the feel of one setting other another.

## Appendix. UI Screens.



# CHECK-IN Screen

8

Proximity will likely be three distance settings: FAR, CLOSE, or 1:1. System will ask to confirm type of prox setting. One button will be to exempt from global prox setting on the Admin screen.

1

Picture is added at the desktop station using a web-camera or whatever is setup to take a picture at the setup station. However picture is taken, there needs to be a mechanism to pull the photo in to the CHECKIN record (simple!).

2

Name is added by typing, Last, and then First.

3

Patient ID is a unique identifier for the patient. Type in manually or via bar code reader.

4

Medical Record is a unique identifier which links the patient with an episode of care. Type in manually or via bar code.

5

Diagnosis is the patient's diagnosis. Select from pull-down menu. Two possible diagnosis per patient.

6

Unit identifier could be a name or number but will be selected from pull-down (Adult-1, Child-2, ED-3, etc).

A lot of facilities flex beds so a patient might spend a night in a geriatric unit and move the next day to an adult unit. We need a foolproof way to transact patients between units.<sup>1</sup>

7

Room number. Pull down. No more than 2 active patients can have the same room number.

9

Interval check. Pull down plus manual. Up to 120 min. Special permissions for inputting interval or editing interval. Default is automatically 15min

10

RFID #. Bar code reader entry. System should prevent # from being assigned if it is associated with another patient active in the system. Should be impossible since bar code is physically on chip assy & upon discharge, # if freed-up for reuse.

11

Prompt-1: Pull-down (can be question or statement. This something the caregiver would see at the OBSERVATION screen). Interval-1: Manual entry. This is how often the prompt appears on the observation screen. OR, you should be able to set up to two clock times per prompt. If interval, it could be 2hrs around the clock or up to discreet clock times during a 24hr day.

Up to 2 additional Prompt/intervals can be defined.

These prompts popup at the defined interval but at the closest observation interval.

The screenshot shows a mobile application interface for patient check-in. At the top, there's a header with a back arrow, a home icon, and the title 'CHECK-IN'. Below the header, there's a patient photo placeholder with an 'Add Picture' button. The main form contains several input fields: 'Name' (split into 'L: Doe' and 'F: John'), 'Patient ID' (XXXXXXXXXX), 'Medical Record' (XXXXXXXXXX), 'Diagnosis' (two XXXXXXXXXX fields), 'Unit' (XXXXXXXXXX), 'Room' (XXXXXXXXXX), 'Proximity' (radio buttons for GP Exempt, FAR, CLS, 1:1), 'Interval' (XXXXXXXXXX min), 'RFID' (XXXXXXXXXX), 'Prompt-1' (XXXXXXXXXXXXXXXXXXXX), and 'Interval-1' (XXXXXXXX min (or clock t's, up to 2)). At the bottom, there's a navigation bar with 'Home' and 'Obser' icons. Numbered callouts 1 through 11 point to specific elements: 1 points to the photo area, 2 to the Name fields, 3 to Patient ID, 4 to Medical Record, 5 to Diagnosis, 6 to Unit, 7 to Room, 9 to Interval, 10 to RFID, and 11 to Prompt-1. Callout 8 points to the Proximity radio buttons.

## Notes:

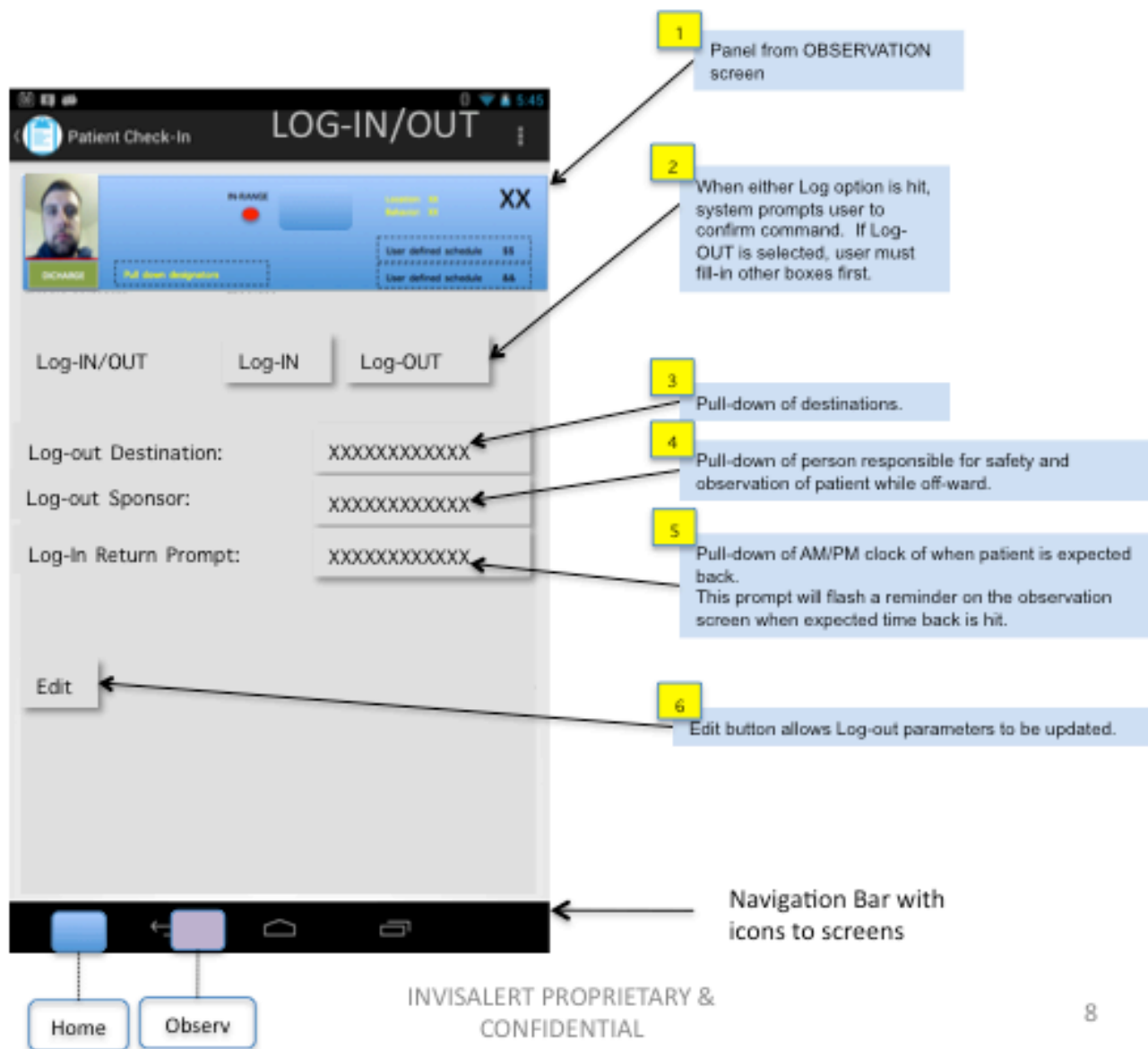
1. A 100-bed facility will typically be divided into units that are up to 24 beds and as small as 10. Each facility will have a central database containing all active (resident) patients as well as archived records. However, each unit is self contained and personnel and devices should never see patients on another unit. Some facilities can not flex beds (X beds of a given type can ONLY be used for the given type, ie Adult). However, many states allow flexing which means that a facility can admit an Adult patient to a Geriatric unit for a day or so until a bed is available on the Adult unit. In this case, the patient should show up in the Geriatric unit database but not the Adult unit until they are physically moved there. The patient will be issued a bracelet upon admission and will keep it if they move between units.
2. May want to enable ability to load some inputs via bar code in addition to manual entry. Thinking is that some facilities may have integrated EMR or other systems which automatically generate bar code patient ID, etc. prior to admission to BH facility.
3. Field lengths and formats need to be defined.

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# LOG I/O Screen



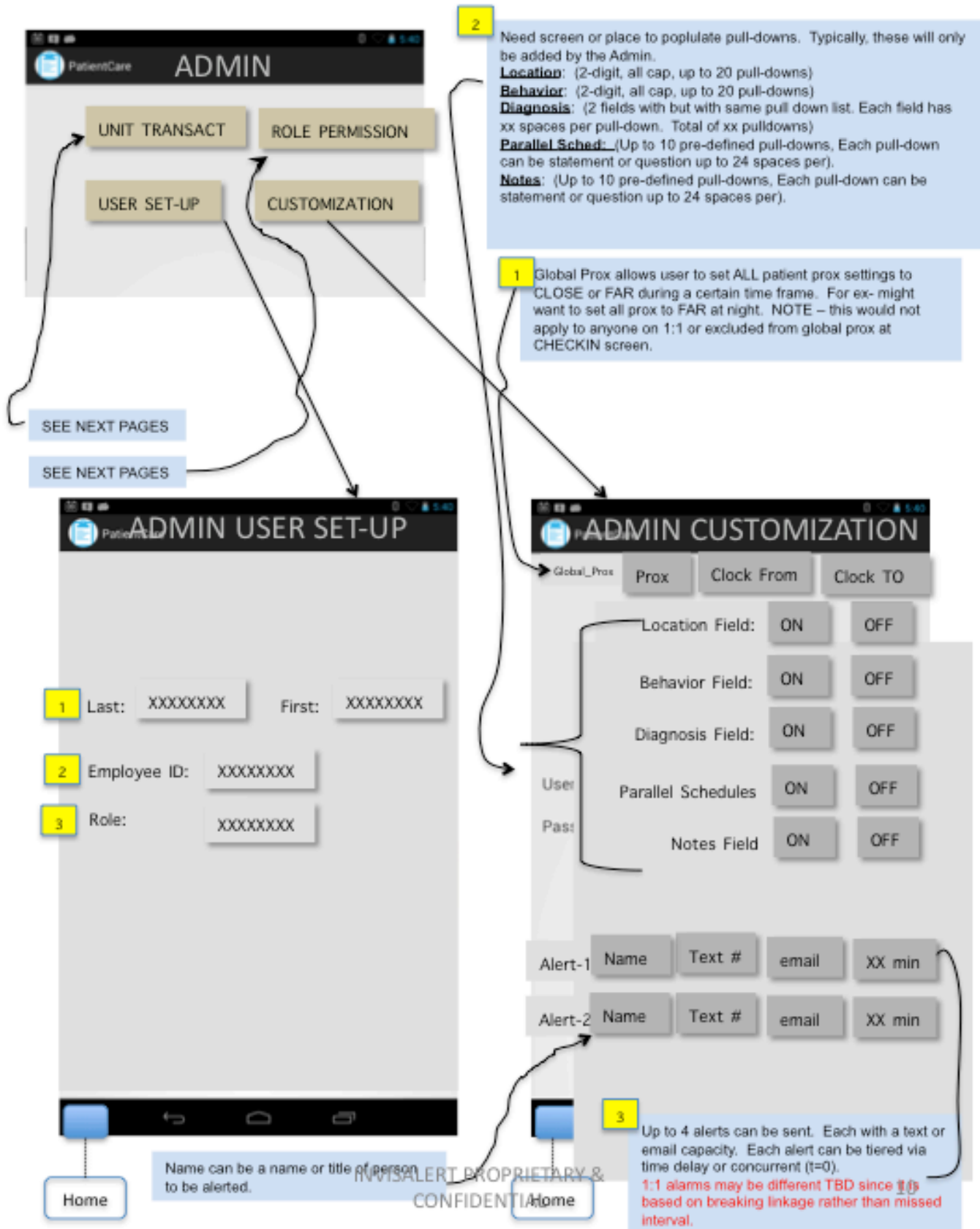
- 7 When a patient is logged out, patient panel on OBSERVATION screen has ~50% transparent grey overlay with words as shown. When time is hit that patient is expected back, red letters flash and a different chime is sounded that observation check chime every 15 minutes to alert staff to check on whereabouts of patient. Overlay disappears when patient is logged back in and observation schedule resumes.



# USER LOG-IN

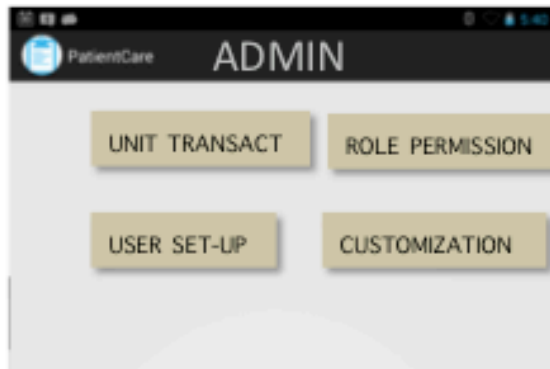


# ADMIN Screens





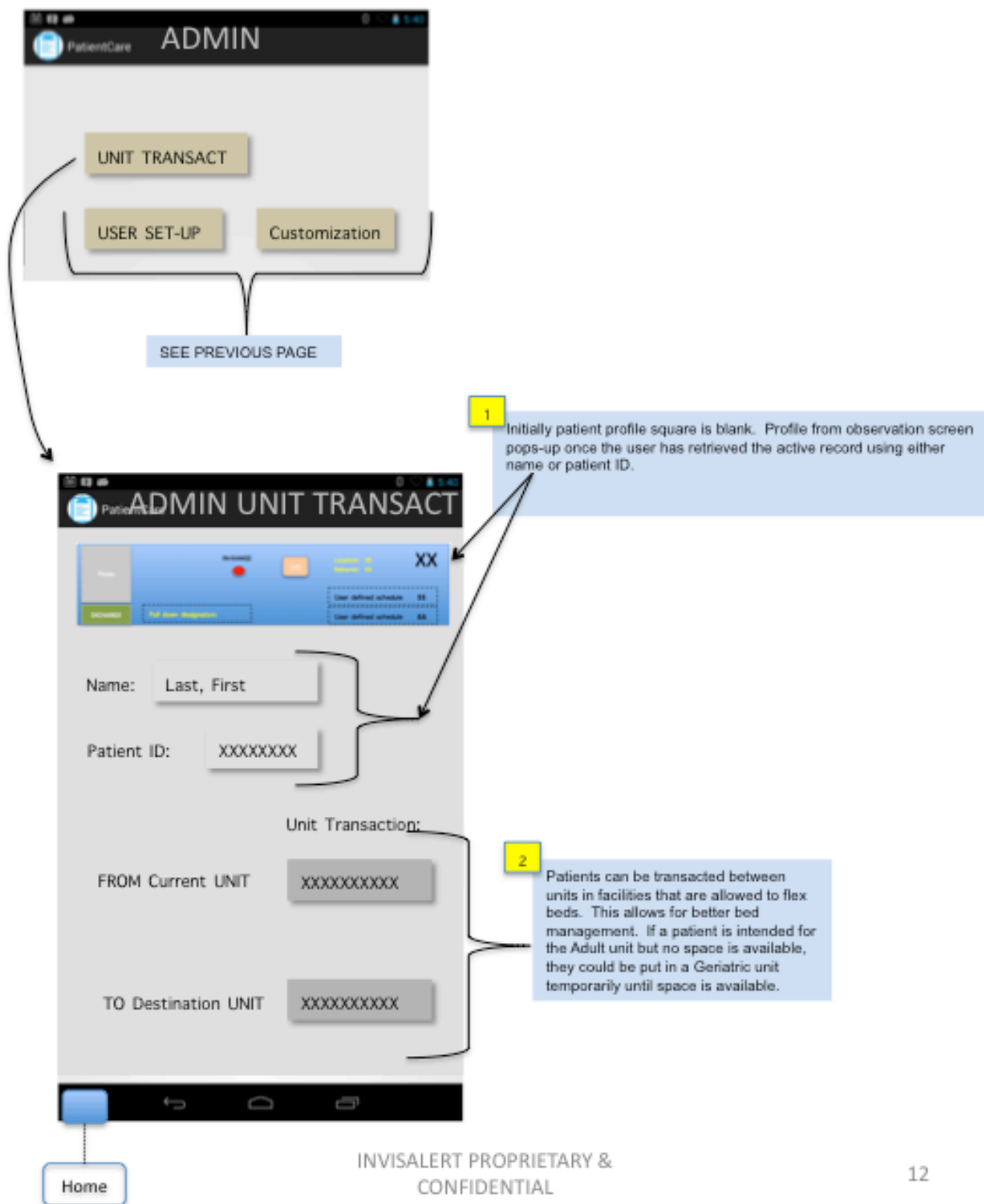
# ADMIN Screens



Home



## ADMIN Screen (cont.-)



# DISCHARGE Screen

