

Digistat Smart Central Quick Reference Guide

Digistat Smart Central US V5.2

DIG UD SCN QRG 0006 ENG V02

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Digistat Smart Central US version 5.2

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The Digistat Smart Central software is a Class II medical device in accordance with 21 CFR §870.2300 provided by the FDA and therefore it is to be installed, configured, maintained and used in US only.

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This document is a Quick Reference Guide to some of the main Digistat Smart Central product features and functionalities.

This is not the Digistat Smart Central product user manual, and it does not fully describe all the product's features and functionalities. See the Digistat Smart Central user manual for complete instructions on the product's features and functionalities.

1. Start-up procedure

1.1 Digistat Smart Central installation

The Digistat Smart Central product can only be installed by Ascom UMS technicians or technicians explicitly authorized by Ascom UMS. The end-user will find the system already installed and properly configured on his/her workstation.

1.2 How to run Digistat Smart Central

To run Digistat Smart Central

> Double click the **D**icon on the workstation desktop.

The following window is displayed while the system is loading (Fig 1).



Fig 1

After a few seconds, the Digistat Smart Central work area is displayed (Fig 2).





1.3 Log In procedure

To use Digistat Smart Central user login is required. I.e. the user must insert his/her credentials (user name and password). To log in, at the beginning of every work session,

> Click the **User** button indicated in Fig 3 **A**. The following screen is displayed.

		1				_						6									V							
	ISTAT	Ch	10056	e pa	tient							۴	/							2	ζ?	[]	GEN CEN	TRAL	\odot	16:5 21 N	0 OV 2017	?
								U	SERNA	ME					_	C												
								PA	SSWC	ORD						V												
Q)	W		E		R	T	Y		U		1		0		Р			Back	space		i,		7		8	9	
	A												К									I		4				
Tab)						V	B		N		м									En	ter		1				
	Loc																			Del		i		0				
												R	ECEN	т														
1	ļ	ADMIN	ASCO	М		2					3							4					5	5				
6						7					8							9										
																				6								
																				E							9	
												+ M	IORE.		đ	З LC	ск		>	CAN	CEL					~	ок	
ig 3																												

Then,

- > Insert the username in the "User Name" field (Fig 3 B).
- ▶ Insert password in the "Password" field (Fig 3 C).
- Click the **Ok** button (Fig 3 **D**).

The user is this way logged. An acronym indicating the user currently logged is displayed on the **User** button on the control bar (the acronym is "ADM" in Fig 4).



1.3.1 How to disable the automatic user log out ("User lock" functionality)

If the system remains idle for a certain time (configurable), the user is automatically logged out. To disable this functionality it is necessary, after username and password specification and before clicking **Ok**,

> Click the **Lock** button on the "Log in" screen command bar (Fig 5 A).



If the user is locked, a padlock is shown at the bottom of the user icon (Fig 6).



1.4 Log out

The user, to close a work session with Digistat Smart Central, must "log out" from the system.

To log out

Click the User button on the command bar (Fig 7 and Fig 3 A).



The user acronym disappears from the **User** button.

2. Digistat Smart Central unavailability

If, during start up, there are problems connecting with the server, Digistat Smart Central provides a specific "System recovery" window (Fig 8).

	DIGI Stat ®
	Trying to re-connect Message Center not found Database OK Digistat ¹ is a registared trademark of ASCOM UMS sr. Copyright Car you Connect and ASCOM UMS sr. Close THE SERVER IS UNAVAILABLE
Fig 9	

rig 8

The connection problem sometimes is automatically solved after a short time. If not, please contact Ascom UMS/Distributor technical assistance. See paragraph 10 for Ascom UMS/Distributor contacts.

Cases exit, rare but possible, in which it is physically impossible to use the Digistat Smart Central (due to long duration black outs, catastrophic events etc.).

The healthcare facility using Digistat Smart Central should define an emergency procedure to face this kind of events and to:

- 1) allow the hospital departments to be operative again;
- 2) restore the Digistat Smart Central availability as soon as possible.

Ascom UMS/Distributor can provide support and assistance for the emergency procedure, but the healthcare facility is responsible for the procedure definition and execution.

See paragraph 10 for the manufacturer contacts.

3. Digistat Smart Central main screen

The "Smart Central" screen displays an overview of the situation of each patient in the ward (Fig 9).



Fig 9

The screen is divided into rectangular areas, named "Bed areas" (Fig 9 **A**). Every area refers to a bed and displays information on the devices connected to the patient admitted to that bed. By default, only the data referring to alarmed beds is displayed, and only data relating to alarms is displayed. A bed is alarmed if at least one of the devices connected to the bed is alarmed. If multiple alarms occur at the same time on the same bed, the alarm with the highest priority is notified.

It is possible to display all the available data (both referring to the non-alarmed beds and referring to the non-alarmed devices on the alarmed beds) by clicking the "VALUES" button on the command bar (Fig 9 **B**).

3.1 Bed areas

Each "Bed area" displays some of the data provided by the devices connected to the patient (Fig 10). The kind of data displayed depends on the design and configuration of the device.

If the "Bed area" is light blue, as in Fig 10, it means that there is at least one low priority alarm, and no medium and/or high priority alarms, coming from the connected devices.

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If the "Bed area" is yellow, as in Fig 11, it means that there is at least one medium priority alarm, and no high priority alarms, coming from the connected devices.



Fig 11

If the "Bed area" is red, as in Fig 12, it means that at least one of the connected devices is in high priority alarm state.



Fig 12

The connected beds from which no alarms are received appear as in Fig 13. No device data is displayed as this might distract the reading of possible alarms occurring on the other beds.

2 6	⁹ Patient 2, Jim
	Q
	<u>O</u> r
(\mathbf{i})	Pump 2: Next EOI: 0h13m
Fig 13	1

To display device data on these devices, click the **Values** button on the command bar (Fig 9 **B**). The "Bed area" will appear as in Fig 14.

2 (🔗 Patient 2, Jim								
	AGW								
	P1:Amiodaron 10 ng/mL/min								
	P2:Noradrenaline 14 ng/mL/min								
	P3:								
	P4:Frusemide 12 ng/mL/min								
	CARESCAPE								
	HR ECG: 72 bpm								
	NBP: 104/71 (87) mm Hg >>>								
	More devices								
í	Pump 2: Next EOI: 0h13m								

Fig 14

Disconnected beds are displayed as in Fig 15.

1	(Antonio, Bando	
		(1)	
		Ŭ	
L			

Fig 15

3.2 The Digistat Smart Central command bar

The buttons on the command bar of the Digistat Smart Central make it possible to perform different actions.



SMART CENTRAL

The arrow buttons (Fig 16 **A**) make it possible to scroll up and down the screen when it is not possible to display all the configured "Bed areas" at the same time.

Values

When one (at least) of the non-displayed "Bed areas" is notifying an alarm, the corresponding button takes the color corresponding to the alarm priority level (blue = low; yellow = medium; red = high).

In case of multiple alarms the arrow color corresponds to the highest priority notified.

(?) Legend

An icon can be displayed in the box between the arrow buttons (Fig 17). It indicates that there is an alarm on one of the "Bed areas" currently displayed.



The **Legend** button displays a reference-window indicating the meaning of all the different icons that can be found while using the software.

The **Values** button displays all the available data (both referring to the non-alarmed beds and referring to the non-alarmed devices on the alarmed beds).

3.3 Events list

It is possible to display a detailed list of all the events occurred in a bed.

To display the events list:

Click the "Bed area" referring to the bed to be displayed (Fig 18)





The events list will be displayed on the right (Fig 19).

7 S Patient 7, Mark Male 49 y MRN: 20000007	\bigcap	Interval:	1 hour	6 hours 12 hours 1 day 7 days
 AGW P1: Amiodaron 10 ng/mL/min , 20 mL/h , 10 mcg/mL , 00:20:00 minutes P2: Noradrenaline 14 ng/mL/min , 23 mL/h , 15 mcg/mL , 00:21:00 minute P3: , 45 mL/h , 00:21:00 minutes P4: Frusemide 12 ng/mL/min , 22 mL/h , 4 mcg/mL , 00:21:00 minutes 	es	Event: Devices:	all all all	④ ● ▲ ▲ print
-₩- Carescape HR ECG: 74 bpm NBP: 128/72 (100) mm Hg SPO2 Art: 96 %		Time Device 09:55 MON 09:55 MON	# 	Description A End: ECG Sensor Warning End: Arterial Blood Pressure too high
Evita HR ECG: 73 bpm RR: 13 bpm LOW PEEP: 7 mm Hg PSF: 9 mL/s PI mean: 8 mbar PLT: 7 mbar FiQ2 Art: 59 % VTe: 374 mL		09:55 MON 09:55 MON		Arterial Blood Pressure too high ECG Sensor Warning End: ECG Sensor Warning End: Arterial Blood Pressure too high ECG Sensor Warning Arterial Blood Pressure too high Bolus; Duration= 5 sec; Type= HandFree; Rate=800 mL/h; Volume= 1.1 mL
MVe: 4862 L/min		09:52 MON 09:52 MON 09:52 MON 09:52 MON		End: ECG Sensor Warning End: Arterial Blood Pressure too high ECG Sensor Warning Arterial Blood Pressure too high
① Pump 1: Next EOI: 0h34m		09:52 INF 09:50 MON 09:50 MON 09:50 MON 09:50 MON 09:50 MON 09:54 INF 09:48 INF 09:45 MON	1 (1) 1 1 1 1 1 1 1 1 1 1 1 1 1	Bolus; Duration= 5 sec; Type= HandFree; Rate= 800 mL/h; Volume= 1.1 mL End: ECG Sensor Warning End: Arterial Blood Pressure too high ECG Sensor Warning Arterial Blood Pressure too high Bolus; Duration= 5 sec; Type= HandFree; Rate= 800 mL/h; Volume= 1.1 mL End: Arterial Blood Pressure too high
SMART CENTRAL)	00.4E MON	VALUES	EVENTS



3.4 Dashboard configuration

If the Digistat Smart Central is configured as a "Dashboard" Smart Central, some additional functionalities are available. These are the "Vital Signs" and "Charts" functionalities. Both functionalities are accessible from the "Events list" (Fig 20 **A**).



3.4.1 Vital Signs

> Click the Vital Signs button to activate the "Vital Signs" functionality (Fig 21 A).



"Vital signs" makes it possible to display in a table some selected patient parameters (Fig 22). The displayed parameters are defined by configuration. In the table they are grouped by acquisition device.

Alarms and events	Vit	tal signs		Charts	3 4
Range:1	1 hour all	6 hours	12 hours	1 day	7 days
Interval:	1 min	5 mins	15 mins	30 mins	1 hour
Devices:	all 💉	* -11- 6 ¹ 3	i	🍯 pH	8 Å
ALL PARAMETE	ERS		18	13:19	^
💉 AGW (AGWSER	IAL-5)				
СН				10	
💉 Alaris CC (1255	i)				
VolumeRate		mL/h		45	
InfusedVolume		mL	83.988	3184.	788
VTBI		mL	8	603	
PumpPressure		mm Hg	2	109	
PumpTimeRema	in	S		20	
PumpTimeRema	in		:20:00	00:21	:00
DeltaInfusedVolu	ume	mL	300	0.800	
💉 Alaris CC (1295	i)				
DrugConc		mcg/mL		10	T
∎ Fig 22					

3.4.2 Charts

> Click the Charts button to activate the "Charts" functionality (Fig 23 A).



Fig 23

"Charts" makes it possible to display different charts drawn from the acquired parameters. The charts show the configured parameters as trends. The number of charts, their contents and names are defined by configuration.

3.5 Notification area

A notification area is displayed on the right of the "Smart Central" screen, reporting various notifications sent by the connected devices (Fig 24 **A**).



Fig 24

The notification area can be, by configuration:

- Always visible
- Automatically displayed when a new notification comes
- Only visible after user click on the notifications button on the Control Bar (Fig 24 B).

The different messages are displayed in chronological order (most recent on top) and by criticality (High priority alarms on top, then medium priority, then low priority).

Each notification is characterized by the colour corresponding to the priority level (red for high priority, yellow for medium priority, blue for low priority).

4. Alarms notification (summary)

By default, the Digistat Smart Central screen displays the device data on a bed only if there is an alarm notification coming from at least one of the devices connected to that bed.

In a condition of "No notifications" the "Smart Central" screen would appear as in Fig 25, where five connected "Beds" are displayed and no devices on any of the beds is in alarm state.

1 (¹) Patient 1, Care	2 🔗 Patient 2, Jim	3 🔗 Patient 3, Joe						
Ċ	I	I						
	(i) Pump 2: Next EOI: 0h13m	(i) Pump 3: Next EOI: 1h20m						
4 🔗 Patient 4, Rose	5 🔗 Patient 5, Ellen	6 🔗 Patient 6, Bill						
I	9	6						
(i) Pump 1: Next EOI: 0h55m	(i) Pump 2: Next EOI: 2h01m	(i) Pump 3: Next EOI: 1h05m						
SMART CENTRAL								

Fig 25

Each time an alarm occurs on one of the devices, the data relating to the bed to which the device is connected is displayed. In Fig 26, for instance, bed 3 is notifying a high priority alarm. A short text specifying the kind of alarm occurring is displayed on the "Bed area".

1 () Patient 1, Care	2 🔗 Patient 2, Jim	3 👗 Patient 3, Joe
		- Carescape
		🔺 Arterial Blood Pressure too high;
		ECG Sensor Warning
	•	
(1)	67	
\bigcirc	0	
	(i) Pump 2: Next EOI: 0h13m	
4 🔗 Patient 4, Rose	5 🔗 Patient 5, Ellen	6 🔗 Patient 6, Bill
	0	0
67	(5)	(6)
0	0	0
Pump 1: Next EOI: 0h55m	Pump 2: Next EOI: 2h01m	(i) Pump 3: Next EOI: 1h05m
		· · · · · · · · · · · · · · · · · · ·
SMART CENTRAL	V (?) LEGEND OVALUES	

Fig 26

In addition, a sound notification is provided. Three different sounds exist, one for each alarm priority level. In case of multiple alarms, the sound corresponding to the one with highest priority is provided.

The occurrence of alarms is also notified on the command bar by the arrow-buttons indicated in Fig 27, Fig 28 and Fig 29.

SMART CENTRAL	\sim	Legend	Values	
Fig 27				
SMART CENTRAL	\sim	(?) Legend	Values	
Fig 28				
119 20				
SMART CENTRAL		Legend	Values	
Fig 29				

An icon can be displayed between the arrow buttons (Fig 30). It indicates that there is an alarm on one of the "Bed areas" currently displayed.



A visual feature on the upper bar on each "Bed area" keeps temporarily track of the last alarm notified after the "Bed area" has changed to a different priority level alarm (or no alarm). This makes it possible to be aware of alarms occurring and rapidly passing.

When the state of a "Bed area" changes to a lower level alarm (or no alarm), the color relating to the previous alarm (Fig 31) remains on the heading bar for a certain configurable time.

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	0	0
0	0	0
(i) Pump 3: Next EOI: 1h05m	(i) Pump 1: Next EOI: 0h55m	

4.1 Alarms notification on Control Bar

Alarms are also notified on the Control Bar, so that they are always visible.

		Ø				
	Choose patient		а адм	CENTRAL	() 17:41 21 NOV 2017	?
Fig 32						

The button color depends on the alarm priority level (cyan=low; yellow=medium; red=high). For high and medium priority alarms, the button flashes.

Click the button to display the notification area (Fig 32 A)

The notification disappears when the alarm conditions no longer exist.

5. Sound Check procedure

When Smart Central is started, it provides a specific sound indicating that the sound notification of alarms is working properly.

If the sound is not provided the user can perform a "Sound Check" procedure. To perform the "Sound Check" procedure

Click the Menu button on Control Bar (Fig 33)



The following menu is displayed (Fig 34).

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MAIN	MENU		×					
曝	CLINICAL CONFIGURATION	छ	SYSTEM CONFIGURATION					
X		Ģ	MODULES CONFIGURATION					
RIII	PATIENT REPORTS		SYSTEM REPORTS					
ĭ	STATISTICS	P	CHANGE PASSWORD					
(QUIT	ñ	ABOUT					
\times	× CLOSE							

Fig 34

Click on Modules Configuration (Fig 34 A)

The following menu opens (Fig 35).

MOD	JLES CONFIG	URA	TION		\times
Ģ	DAS Ports	A	₽ ġ	SOUND CHECK	
Γø	SmartCentral Maintenance Log	g			
\times		CL	.OSE		

Fig 35

Click on Sound Check (Fig 35 A)

A pop-up window opens, asking whether a sound is heard or not from speakers.

If a sound is heard, then click **Yes**. The pop-up window disappears and nothing else happens (meaning that the Digistat Smart Central is working correctly).

If no sound is heard, then click **No**. The pop-up window disappears and a notification is displayed on the Control Bar, meaning that an error occurred while checking the sound notification system.

6. Patients management

To access the Patients management functionalities

- DIGIST Choose patient... 1 🔗 Patient 1, Care 2 🔗 Patient 2, Jim 3 🔗 Patient 3, Joe *.*G. (i) Pump 1: Next EOI: 00h06m Pump 2: Next EOI: 00h03m (i) Pump 2: Next EOI: 00h01m 4 D Patient 4, Rose 🔗 Patient 5, Ellen 6 🔗 Patient 6, Bill 5 Heart Rate High Θ S Pump 5: Next EOI: 00h02m (i) Pump 3: Next EOI: 00h03m (i) Pump 1: Next EOI: 00h00m SMART CENTRAL • 💿 Valu
- Click the Patient button on Control Bar (Fig 36 A).

Fig 36

The screen displayed after clicking this button depends on the chosen configuration. If the list of admitted patients (Fig 37) is not displayed by default, to display the list of admitted patients:

> Click the In Bed button on the command bar (Fig 37 A)

The list of beds configured in the domain is this way displayed (Fig 37 B).

Ξ		Choose patier	1t			<u>R</u> adm	CENTRAL	C 2:56 AM 23 NOV 2017	()
¢	PA	TIENTS	1 1	Patient 1 Care 22/11/2017 07:57					
	PA SE	TIENTS	2 100	Patient 2 Jim 22/11/2017 07:57					
			3 ICU	Patient 3 Joe 22/11/2017 07:57					
		B	4 10	Patient 4 Rose 22/11/2017 07:57					
			5 10	Patient 5 Ellen 22/11/2017 07:57					
			6 100	Patient 6 Bill 22/11/2017 07:57					
			7 100	Patient 7 Mark 22/11/2017 07:57					
			8	Patient 8 Aaron 22/11/2017 07:57					
			9	Patient 9 Blake 22/11/2017 07:57					
			10	<u>A</u>					
	ANO	NYMOUS		IN BED	ADT				
	PATIENT EX	PLORER 🕂 M	IEW/AD	MIT 🖉 EDIT				NONE ×	CLOSE



The rectangular buttons on the screen (Fig 37 **A**) represent the beds configured in the workstation domain (usually the beds of a specific ward). If a patient is admitted to a bed, the patient name is displayed on the area (Fig 38 **A**). Below the patient name the admission date is displayed. Buttons with no name correspond to empty beds (Fig 38 **B**).



Fig 38

Click one of the buttons to select the corresponding patient

The name of the selected patient is then displayed on the **Patient** button on Control Bar (Fig 39).



After clicking one button the current situation of the selected patient on the Smart Central (i.e. the corresponding "Bed area") is displayed in full-screen mode.

Some configurations make it possible to admit patients from the healthcare facility ADT, to create new patients and to operate on "anonymous" patients when patient personal data is not available. Refer to the Digistat Smart Central user manual for a description of these functionalities.

7. Digistat Mobile

7.1 Login

To login to Digistat Mobile

> Touch Login on the lower-right corner of the "Applications list" screen (Fig 40 A or Fig 41 A)



Fig 40

The following screen will be displayed (Fig 42 or Fig 43)



- Insert username and password (Fig 42 A or Fig 43 A).
- > Touch the Login button (Fig 42 B or Fig 43 B)

7.2 General Notifications

Digistat Mobile provides short notifications when the application is not active as well (Fig 44 **A**). The highest level notification indicates the overall alarm level of the Digistat Mobile application. Actually are implemented three levels of severity for the notifications, each of them corresponding to a different color (red = high priority – yellow = medium priority – cyan = low priority); in addition a purely informative notification is foreseen just as reminder for the user (purple).

For each module a row in the notification area is foreseen. Any change in the notifications is performed within the row related to the module triggering notification change.



Fig 44

- Swipe the notification to make it disappear.
- > Touch the notification to directly access the relevant patient (see an example in Fig 45).

If the alarm notification from a module is related to one patient, then by touching it the alarmed patient tab is displayed; moreover, if the alarm notification is raised for more than one patient, by touching it the list of alarmed patient is displayed.

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At any time, on any device, the LED color reflects the higher priority alarm.

In the case of sound notifications, the Product ever plays the notification with higher priority; if a notification is being executed and a new alarm has to be raised, then the Product restarts the notification with higher priority. Notifications with low priority level don't have any sound associated.

In case of service stop, a notification is provided to the user: it has the highest level of severity and it's not swipable.

In case of disconnection, the Product mobile client attempts to reconnect to the Product server. If this attempt fails, a not-swipable system notification is provided to the user, according to the following two different options:

- **Android previous than 8.0**. One notification, non swipable, highest priority level. The user can mute it by pushing the **Mute** button;
- Android 8.0 and later. Two notifications, one non swipable without sound or LED color, the second one swipable with the highest priority level, reporting useful information about the cause of the disconnection. Moreover, the second notification will not be shown anymore since the user pushes the **Mute** button.

7.3 Sound Check procedure

The Sound Check Procedure makes it possible to verify if the sound and vibration notification of alarms is working properly.

To perform the "Sound Check" procedure

> On the home screen of the Digistat Mobile Application, touch the \equiv icon on the topleft corner of the screen (Fig 46 **A**)



Fig 46

The following menu will be displayed (Fig 47).



Fig 47

> Touch the **Audio test** option (Fig 47 **A**).

A test notification/sound will be this way provided (Fig 48 A).



7.4 Check System procedure

The Check System menu item checks if the device running the product is properly configured and operating (i.e. all the authorizations required by Digistat Mobile application to work properly were correctly provide, if the battery health is good, etc). Moreover, the proper firmware version of the device is also checked.

To perform the Check System

> Activate the main screen of Digistat Mobile application (Fig 49).



Fig 49

> Touch the \equiv icon on the top-left corner of the screen (Fig 49 A)

The following menu will be displayed (Fig 50).

	(f=f)	DIGISTAT Mobile Copyright © Ascom UMS	■ 2:21 8	PM Q	
	•	Audio test			
A	X	Check system			
	\$	Settings			
	(mm) (mm)	Configuration			
	2	99% 50ms			
	i	About			

Fig 50

> Touch the **Check System** option (Fig 50 **A**).

A test notification will be this way provided, showing a reference to the missing authorizations (Fig 51). Please provide the requested authorization.

Android
SmartCentral Mobile
System status problem Permissions Permission android.permission.CAMERA disabled
Notifications Notifications disabled CANCEL APP SETTINGS
 1
< ● ■ Fig 51

In addition to the above mentioned checks, the Check System raises an alert message to the user if the timestamp of Mobile client differs from the one of Mobile server. If the user touches the alarm notification related to timestamp not synchronized, then triggers the redirection to Android Settings.

7.5 Check Application Whitelist Procedure

Because on some devices (i.e. Android 6.0 and later, thus NOT on Myco1 / 2) an aggressive battery optimization policy is in place, foreground services might be frozen: this may also occur to Digistat applications. The Check Application Whitelist procedure is in charge to verify that Digistat Applications are in the battery optimization whitelist:

Since this check has a negative result, a message is raised to the user suggesting to insert Digistat in the battery optimization whitelist.

The Check Application Whitelist procedure is performed in the following cases:

- During the Check System Procedure;
- > Each time the Main Screen of Mobile Application is displayed.

7.6 Patients search functionalities

The Product implements several patients search tools. These tools can be accessed from the Patients List screen.

To access the search functionalities:

Touch the icon indicated in Fig 52 A for devices without Myco/Unite integration or in Fig 53 A for devices with Myco/Unite integration.





Fig 52

The following screen will open (Fig 54).



Fig 54

Three search options are available:

- 1. textual search (insert patient data, then click Search)
- 2. barcode scan (touch the icon and then scan the patient's barcode)

3. NFC code scan (position the device close to the patient's Tag).

7.7 Patients Assignment Functionality

Patient's assignment makes it possible for a user to select one or more patients and create a group of patients who are under his charge. The name of this group in the Digistat Mobile application is "My Patients".

Since the user assigns himself some patients, the following notifications can be displayed on the handheld device:

- a) The notifications related to the patients assigned (i.e. in the group "My patients");
- b) The notifications related to the patients assigned (i.e. in the group "My patients") and those related to the patients that no one has explicitly taken in charge;
- c) The notifications related to the patients assigned (i.e. in the group "My patients"), those related to the patients that no one has explicitly taken in charge and those related to other patients if the devices which had them in charge "lose" them (for any reason, low Wi-Fi signal for instance).



To select the list of patients a user assigns himself and forming "My patients" list, on Digistat Mobile Central screen,

> Touch the \bigcirc icon (Fig 55 A).

The following screen will be displayed (Fig 56 - "Setup My Patients").





A patient can be selected/deselected by touching the corresponding "tile". Each tile corresponds to a bed. In addition, the user can select or deselect all the patients by checking the box on the top right corner (Fig 57 **D**).





The icons on the right of the patient names (Fig 57 A) have the following meanings:

 $^{\odot}$ - Patient is part of "My patients" of another user. It is still possible to select the patient. If two users select the same patient, the patient will be grouped under "My patients" for both users.

Real Patient is not monitored. I.e. another user has him/her in charge, but at the moment, due (for example) to Wi-Fi connection failure, no one is monitoring him/her.

No icon means that no one has the patient in their "My patients" list, so the patient is not monitored.

The filters indicated in Fig 57 **B** make it possible to display:

- All patients;
- Only the assigned patients;
- Only the patients that are not monitored.

The <-- icon indicated in Fig 57 C makes it possible to go back to "My Patients" list screen.

7.8 Single Patient Selection

To select a single patient:

Touch the icon indicated in Fig 52 A for devices without Myco/Unite integration or in Fig 53 A for devices with Myco/Unite integration. The following screen will appear (Fig 58 A):



> Touch the "**DOMAIN**" tab. The following window shall appear (Fig 59)



In Fig 59 all the patients are listed, without regard to their domain. The label on the top right corner of each tile highlights the domain of the patients (Fig 59 **A**).

One single patient can be selected by touching the tile corresponding to his/her bed. Just for example:

> Touch the tile indicated in Fig 59 **B**. User confirmation is required (Fig 60).



Fig 60

> Touch **Ok** to confirm. After confirmation, the following screen is displayed.

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Patient data are on top of the page (Fig 61 **A**). All the data in all the Digistat Mobile modules are now filtered by patient (i.e. all and only the selected patient alarms/notifications are displayed).

> Touch the symbol indicated in Fig 61 **B** to deselect the patient.

8. Smart Central Mobile Application

8.1 Application start-up

To start the Smart Central Mobile application

> Touch the corresponding row on the handheld device screen.



The Smart Central screen, shown in Fig 64, opens.



8.2 "Smart Central" screen

The "Smart Central" screen displays a schematic summary of the status of the medical devices connected to each bed configured in the specific handheld device (Fig 64).

The numbered squares displayed on screen represent the beds configured in the handheld device (Fig 64 **A**). The squares visible on a single screen form the "domain" of beds covered by the handheld device. The "domain" is defined by configuration.

The number displayed inside the square indicates the bed number. On each square, the status of the connected medical devices is indicated in graphic form by the background color and the related icon:

ICU 10	All the medical devices connected to the bed are on hold.
icu 6 <i>Ç</i> ə	There is at least one connected medical device running.
3	At least one of the connected medical devices is sending a low priority alarm.
ICU 2 	At least one of the connected medical devices is sending a medium priority alarm.
ICU 4	At least one of the connected medical devices is sending a high priority alarm.

8.3 Medical devices list

Touch one of the squares on the "Smart Central" screen to display the list of medical devices connected to the bed (Fig 65).

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Android	ADM 📉 😎 11:29
← SmartCentral Mob	íle ‡⊟
5 John Born 1947-02-15, Age Sex Male, ID 2000000	70 y 4
ALL DEVICES	ALARMED (0)
- \- PICCO <i>H</i> R ECG: 70 {beat}/m	in
RR: 29 {breath}/min	
Alaris GH Amiodaron 10 ng/ml 20 mL/h	./min
 Alaris GP Noradrenaline 14 ng, 23 mL/h 	/mL/min
Alaris CC 45 mL/h	
Alaris GP Midazolam 17 ng/ml 10 mL/h	_/min
Fig 65	

8.4 Alarms history

Each "device card" can be touched to access the list of all the alarms provided by the medical device (Fig 66).

Androi	d 🖌	- 🏷 😎 12:09
÷	SmartCentra	al Mobile
55	John Born 1947-02 Sex Male, ID 2	15, Age 70 y 20000004
	PICCO	
- ₽	HR: 74 {beat}, ARTs: 102 mm ARTd: 76 mm ARTm: 89 mm SPO2 Art: 99	/min n[Hg] [Hg] %
×	12:06:33 05/09/2017 En	d: ECG Sensor Warning
×	12:06:33 05/09/2017 En	d: Arterial Blood Pressure too high
۲	12:06:30 05/09/2017 AE	IP too high
	12:06:27 05/09/2017 AE	IP too high
	12:06:24 05/09/2017 AE	IP too high
۴	12:06:21 05/09/2017 AE	IP too high
	12:06:18 05/09/2017 AE	IP too high
٨	12:06:15 05/09/2017 AE	IP too high
	12:06:12 05/09/2017 EC	G Sensor
	12:06:12 05/09/2017 AE	IP too high
×	12:05:27 05/09/2017 En	d: Arterial Blood Pressure too high
Fig	66	

For each alarm, a short description and the time of occurrence are provided. For each alarm are displayed the beginning time and end time (black cross on the icon \times).

9. Digistat Smart Central IFU

The Digistat Smart Central instructions for use (IFU) are provided with the product. They can be displayed in digital format within the Digistat Smart Central product. To access the instructions for use

> Click the Help button on the command bar (Fig 67)

	Choose patient	<u>ب</u> ۲	GENERAL CENTRAL	3 17:16 21 NOV 2017	?	
Fig 67						

A screen opens, making it possible to access:

- 1) the relevant user manuals;
- 2) possible quick reference guides referring to specific procedures.

The on line documentation is in PDF format.

9.1 On line manuals

The Digistat Smart Central user manuals can also be downloaded from a dedicated site on the internet.

Every Digistat Smart Central customer can access a protected area on which all the existing versions of the relevant manuals are present. The user can this way check if an updated version of his/her manuals exists. Ascom UMS/Distributor inform their customers in case of updates impacting safety issues and provide in these cases the updated user manuals.

The area can only be accessed after user authentication. Each customer has a username and password that they must insert to access the protected area. These credentials are provided when Digistat Smart Central is installed together with the product labelling.

Each manual is identified by a specific code having this form:

"DIG DD [Product name] IU NNNN ENG Version MM"

For instance

"DIG DD IU 0001 ENG <u>V01</u>"

The final digits of the code ("V01") are the ones the progressively increase in case of updated versions of the same manual.

New versions of a document are released in case of updates of the former document (after, for instance, detection and correction of minor errors, typos, omissions etc... both in the Product and in the document).

In case of new versions of the Product a new manual is released (not a new version of an existing manual). In these cases the document code changes (in the example the document code is "0001", underlined below).

"DIG DD IU <u>0001</u> V01"

The new document is provided to the customer together with the Product update.

The document code can be read on the frontispiece and in the footer of each page. The relevant Product version is indicated on the frontispiece.

The Product version currently installed is indicated in the "About box" (see paragraph 9.1.2 for instructions on how to display the "About box").

The Product version is indicated by a number, for instance "3.0.1". The first two digits indicate new releases and major system updates. The last digit indicates minor updates and bug corrections. A user manual refers to all the Product versions sharing the first two digits. It is valid if it is the latest version published on the ftp site.

In case of loss of username and/or password please contact the Product Distributor technical assistance by phone, fax or e-mail to get new credentials.

9.1.1 How to download the manuals

The user manuals can be downloaded on the dedicated Ascom site using any browser (eg. IExplorer, Chrome, Firefox).

To download the manuals, type the following address on your web browser address bar:

Host URL: https://confluence.ascom-ws.com

It is now required to enter username and password to access the User Manuals list.

Username – User name provided by the local distributor **Password** – Password provided by the local distributor

Select Digistat and then Digistat Smart Central (NA).

Select here the Product version. The relevant manuals are there available in PDF format.

9.1.2 How to display the Digistat Smart Central about box

To display the Digistat Smart Central about box

Click the Menu button on the Control Bar (Fig 68 A)

(A)		
E DIGISTAT Choose patient	요 ? GENERAL 317:16 CENTRAL 317:16	
Fig. 68		

A menu containing different options opens (Fig 69).

MAIN MENU \times			
曝	CLINICAL CONFIGURATION	ক্ট	SYSTEM CONFIGURATION
X	SYSTEM ADMINISTRATION	□. ¢	MODULES CONFIGURATION
	PATIENT REPORTS		SYSTEM REPORTS
ň	STATISTICS	P	CHANGE PASSWORD
\bigcirc	ουιτ 🔥	ĩ	ABOUT
× CLOSE			
Fig 69			

> Click, on the menu, the **About** button (Fig 69 A).

The Digistat Smart Central about box opens (in Fig 70 an example).



9.2 Printed IFU

The customer can request a printed version of the user manuals of the purchased products. Ascom UMS will provide the requested manuals as soon as possible.

The request must be forwarded to the technical assistance. See paragraph 10 for the list of Ascom UMS contacts.

10. Manufacturer and Distributor Contacts

For any issue, please refer first to the Distributor who installed the Product.

Distributed in the U.S. by

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