

GUIDE

Setting up NCIS in an Aseptic Compounding Unit

1. Background

NCIS.Med offers functionality for both gravimetric¹ and volumetric preparation. For volumetric preparation there is also the option of using guided (on-screen) preparation or paper worksheets.

This document gives options for equipment that may be used by Pharmacy Aseptic Compounding Units (ACUs) to make best use of the NCIS solution based on their desired workflow.

2. Preparation Equipment

Table 1 lists the equipment that needs to be considered when setting up an ACU for preparation using NCIS. The exact location of equipment will be dependent on the ACUs chosen workflow, for example label printers may only be required in the isolator if gravimetric verification is being used.

Equipment	Required In		
	Isolator	Isolator Room	Prep Room
Screens	✓	✓	✓
Barcode Scanner	✓	✓	✓
Keyboard	✗	✓	✓
Mini-keyboard/keypad	✓	✗	✗
Fixings, power points, network ports	✓	✓	✓
Laser printer	✗	✗	✓
Label printer	✓	✓	✓
Scales (gravimetric only)	✓	✗	✗
Camera (gravimetric only)	✓	✗	✗

Table 1: ACU NCIS Equipment

A PC, tablet or other suitable device running Windows™ must be available to control and display the software. One PC or tablet per workspace is required as it will act as the workstation for that workspace and ensure the operator has full control over the preparation process.

The hardware can be provided in numerous variants such as:

- Portable PC in a box
- Desktop PC
- Laptop
- Tablet PC

The solution chosen will depend on many factors such as:

- Where is it best to situate the hardware:
 - Inside the isolator
 - Inside the cleanroom
 - Outside the cleanroom
- How many connection points are present in the isolator including the mix and type
- Sterility considerations within the isolator chamber and cleanroom environment

¹ Gravimetric preparation in NCIS refers to gravimetric verification of production volumes

2.1. Hardware Connections

Table 2 lists the hardware connections that need to be considered:

Equipment	Connections Required	
	Power Socket	USB Port
Scales	✓	✓
Barcode Scanner	✗	✓
Camera	✗	✓
Keyboard/keypad	✗	✓
Labelling Printers	✓	✓
PC/Tablet	✓	✗

Table 2: Hardware connections required

2.2. Hardware Requirements

Table 3 lists the latest recommendation/ requirements for the hardware components

Display	18.5in WXGA (1366 x 768. Wide-screen (aspect ratio 16:9) Large viewing angle (170 degrees/160 degrees hor/ver typical)
CPU	Intel Celeron Processor J1900 System-on-Chip (SoC) 2.0 GHz Quad-core with Burst up to 2.42 GHz
Storage capacity	2.5inch Storage bay Standard 32 GB SSD installed
System memory	1 slot DDR3L 1333 SO_DIMM socket, Support up to 8GB capacity Standard 2 GB installed

Table 3: ACU Hardware requirements for NCIS

The below lists the latest recommended barcode scanners for use with NCIS:

- Datalogic Matrix 210 (not Matrix210n)
- Datalogic Gryphon 4400 or 4500 Series
- Zebra/Motorola - Symbol LS4208
- Zebra/Motorola - Symbol LS3508
- Zebra DS8108

The latest recommended printers for use with BD CATO are the Zebra ZD 420 and ZD 421

2.2.1. Scales

For connecting the scale (for gravimetric preparation), a free COM port or a free USB port with USB/serial adapter is required.

With gravimetric preparation, an electronic scale is placed inside the safety cabinet. The following requirements apply:

- The scale either has a serial interface or the signal can be converted to a serial signal on a COM port of the operating system (adapters, etc.)
- It is essential that the scale has a weighing range of at least 2000g and a sensitivity of 0.01g over the weighing range
- The underlying scale protocol can be interpreted by BD Cato™. This applies to scales of the manufacturers Mettler-Toledo, Sartorius (international product only), and AED.
- For scale protocols that do not provide accuracy, the accuracy has to be configured manually in the scale's datasheet or in consultation with the manufacturer. The accuracy setting in the BD Cato™ scale configuration does not increase the accuracy of the weighing results.

BD has tested the following models and confirms compatibility with BD Cato™:

- Mettler XSR 4002S
- Mettler XS 4002S/M manufactured after November 2005 (International product only)

Further details on the setup and configuration of these specific devices should be following and is available from BD CATO and in the BD Cato Installation Plan document

Using different scale models or integrated weighing modules are permissible only after consulting with a BD representative.

Please note that the display of BD Cato™ only serves as a repetition of the determined weighing results of the scale. BD Cato™ does not itself determine weights

A USB/serial adapter is required if no COM port is available on the client computer when using the Mettler XS 4002 S/M scale and the scale therefore shall be connected via USB port.

It is essential that the scale signal in the operating system is represented by a COM port that can be configured in BD Cato™.

2.3. Isolator Design

The following should be considered when specifying an isolator that will best accommodate NCIS:

- Position of equipment in and on the isolator. For example if the engine for air flow is in the back of the isolator, it needs to be considered in case of integrating screens into the back-wall. Usually this can be discussed with the company that provides the isolator.
- Ideally mount as much equipment externally so that it can be easily modified and serviced. It will also reduce the surface area to clean and reduce the contamination risk in the critical areas.
 - Barcode scanners may also be able to be mounted externally as long as the focal length allows reading of the barcode and the operator is easily able to use it.
 - Some isolator manufacturers can also offer touch screens built into the isolator.
- Be careful not to introduce dead zones in the critical working areas. Test with a smoke gun following hardware installation to ensure airflows are not compromised and move equipment around if needed
- The PC should be as close as possible to the isolator, due to the necessary hardware connections & the signal.
- Integrated screens at the side wall of the isolator have been used, provided there is adequate space for transfer hatches.
- The stability of scales in the isolator needs to be considered due to vibration and airflow disturbance, the use of a marble plinth may be necessary. It should be noted that some isolators vibrate so intensely that scales cannot be used.
- Some sites have employed a recess in the working area of the isolator which the scale fits into.
- In the past it has been acknowledged that the surface area available to the operator can be greatly reduced especially with both a scales and keyboard in the working zones of the isolator. This is especially relevant when opening and closing transfer hatch doors. This should be considered when specifying the size of the work area, also consider the use of rails and mounted bins for storage.
 - The CATO mini keyboard can be mounted on the back wall of the isolator however it requires a mounting bracket to be built during manufacture or retrofitted to the isolator. Consider the reach of the operator if using this option.

3. Specific ACU Scenarios

3.1. Two glove isolator with space for screen inside or behind isolator

This is the preferred setup. It allows for a proper unidirectional workflow and no duplication of hardware is necessary.

The recommendation in this case would be to integrate the screen into the back wall of the isolator, either built into the wall or mounted behind. The minimum depth of the isolator working space should be 52cm to allow sufficient workspace for the operator and hardware

An integrated touchscreen into the isolator must be flush with the isolator back wall. One disadvantage of this is that maintenance of the screen will impact the isolator as it would need to be decommissioned to allow access to the screen.

Mounting the screen behind Perspex at the back of the isolator allows for appropriate sterility and airflow and essential maintenance is possible. A keyboard will be required within the isolator to allow the operator to manage the gravimetric or guided volumetric steps.

Please note: Ergonomic issues may arise should there be a deviation from a standard position of the screen (i.e. in front of the user).

Figure 1 represents a possible setup for a single operator.

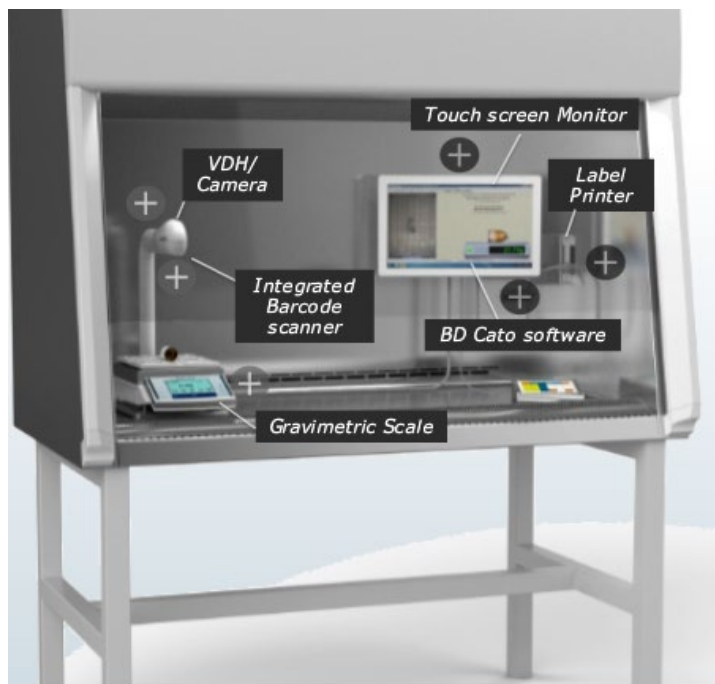


Figure 1: System Setup for single user

3.2. Two glove isolator with no screen space

While this is possible, for ergonomic reasons it is not recommended to install the screen outside the isolator. The operator's seated position over an extended period of time needs to be considered while designing the isolator layout if a screen is to be utilised outside an isolator.

Please note that for gravimetric preparation, a screen is always necessary.

For volumetric preparation there is the option to either prepare following the guided volumetric preparation, where a screen is necessary, or the quick volumetric preparation without step by step processing.

3.3. Four glove isolator (2 operators) with space for 2 screens inside or behind isolator

The screens should each be integrated near each corner of the isolator and not near the middle area, to allow the operator enough space and their own working area. The same considerations as 3.1 are relevant here.

Installations of this kind have found it advantageous to have storage within the isolator (for example small shelves).

3.4. Four glove isolator (2 operators) with space for 1 screen behind isolator

This setup would be disadvantageous in terms of efficiency as only one operator can prepare gravimetrically at a time. Any deviation from a standard position of the screen (i.e., not directly in front of the operator) may have ergonomic issues.

3.5. Four glove isolator with no screen space

While this is possible for ergonomic reasons it is not recommended to install the screen outside the isolator. The sitting position over an extended period of time needs to be considered while designing the isolator setup if a screen is to be utilised outside an isolator.

Please note that for gravimetric preparation, a screen is always necessary. For volumetric preparation there is the option to either prepare following the guided volumetric preparation, where a screen is necessary, or the quick volumetric preparation without step-by-step process