

Building Safety into Isolator Controls Systems

As isolators become more customized to meet the requirements of specific Pharmaceutical processes, the controls systems have been challenged to provide more safety and flexibility. A process may require the isolator to have inflatable gaskets and provide oxygen monitoring. To meet the challenges, Walker Barrier Systems has designed a controls system that provides:

Automated start up sequence

- It is important to have an automated start up sequence to be certain that the isolator is sealed and in leak tight. This will assure the operators safety.
- Door seal test and pressure decay test is automatically performed before the isolator goes into “run” mode.

The screenshot displays the Walker Barrier Systems HMI interface. At the top, there is a status bar with the following information: **SHUTDOWN**, **LOGOUT**, **LOGIN**, **ALARMS**, and the **WALKER BARRIER SYSTEMS** logo. Below the status bar, the user information is displayed: **User Name: ssssssssssss**, **ParCS: Offline**, **2/12/2008**, **User Level: ssssssssssss**, **Login Type: Local**, and **9:35:11 AM**. The main interface is divided into four sections: **Operator: Mode Start**, **Maintenance: Mode Start**, **Supervisor: Mode Parameters**, and **Administrator: Configuration**. Each section contains a grid of buttons for various functions. A red **X** icon is visible in the bottom right corner of the interface.

Operator: Mode Start				Maintenance: Mode Start	
Run Room Air	Run Nitrogen	Run Clean	Shut Down	Blower Tuning	Maintenance
Door Seal Test	Pressure Decay Test	Ammonia Leak Test	Ammonia Aerate		

Supervisor: Mode Parameters				Administrator: Configuration	
General	Room Air	Nitrogen	Clean	Local Password Setup	HMI Config
Door Seal Test	Ammonia Leak Test	Ammonia Aerate	Pressure Decay Test		

PARAMETERS-DOOR SEAL TEST

Test Time: MIN



PARAMETERS-PRESSURE DECAY TEST

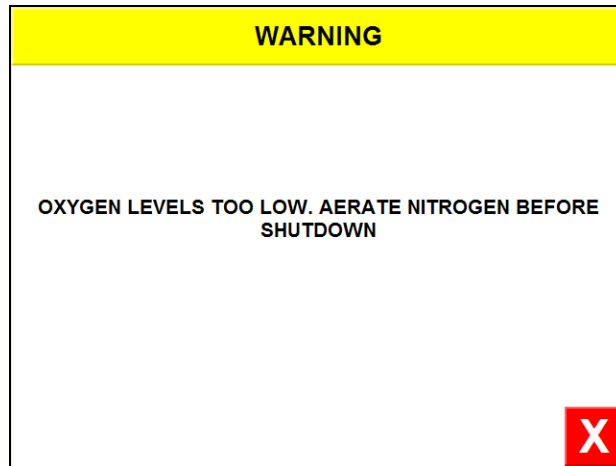
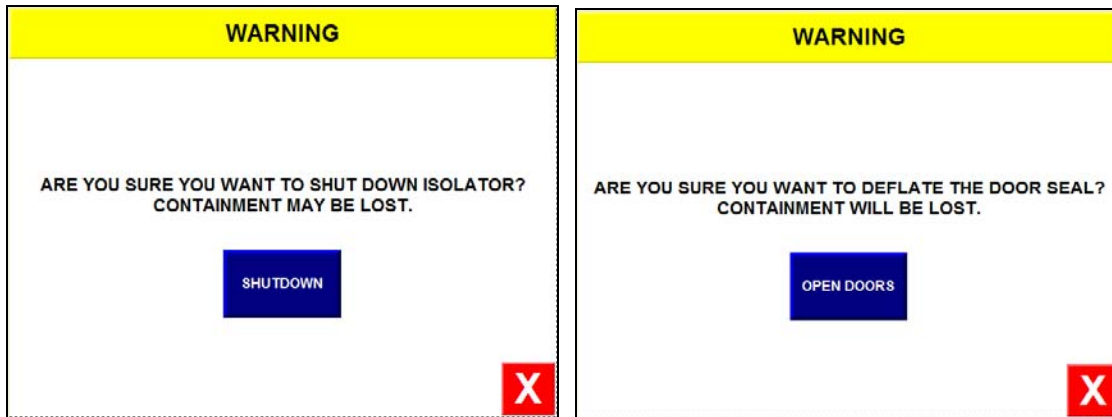
Chamber Pressure:	<input type="text" value="N.NN"/>	"WC
Nitrogen Valve:	<input type="text" value="NNN"/>	%
Pressurize Time:	<input type="text" value="NNN"/>	MIN
Settle Time:	<input type="text" value="NNN"/>	MIN
Minimum Test Start Pressure:	<input type="text" value="N.NN"/>	"WC
Test Time:	<input type="text" value="NNN"/>	MIN
Allowable Pressure Drop:	<input type="text" value="N.NN"/>	"WC
Allowable Temperature Change:	<input type="text" value="NN.N"/>	deg. F
Low Chamber Pressure Alarm:	<input type="text" value="N.NN"/>	"WC
High Chamber Pressure Alarm:	<input type="text" value="N.NN"/>	"WC



Oxygen Monitoring

- A visual indication is provided when environmental conditions (RH and O2 levels for example) are met.
- The isolator cannot be shutdown until a safe O2 level within the isolator has been reached.
- This protects the operator from opening an isolator and breathing air that has low oxygen levels.

- Shutdown warnings are given to remind the operator that certain unsafe conditions may still exist.

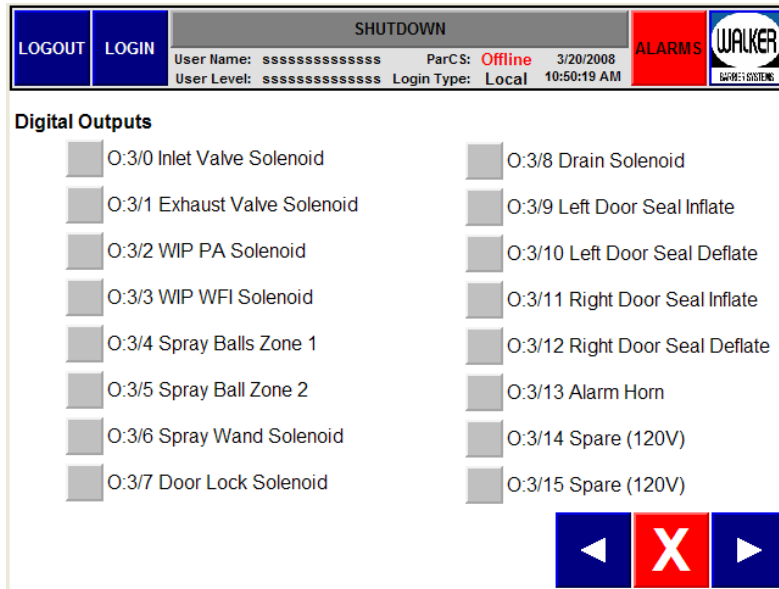


- If the operator requests a mode that is not allowed, they will be prompted to return to the status screen. This will help prevent any errors that may result in an unsafe condition.
- Other prompts may be added such as a close door screen which appears when the operator requests a mode that requires the door to be closed.

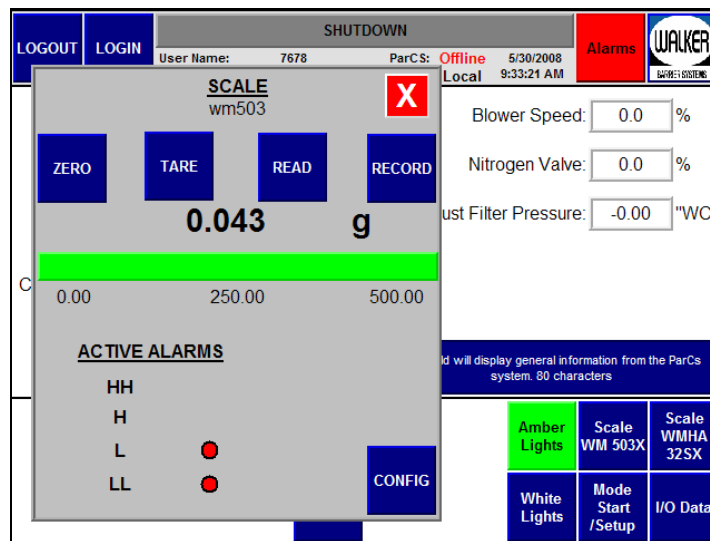
Password Protection

- Password protection provides security against unauthorized use of the isolator. This prevents individuals who have not been properly trained in the process or use of the isolator from creating an unsafe condition.
- Unique username and password combinations with automatic logout times are developed for trained operator, supervisor and maintenance use.

- From the maintenance mode I/O's can be validated on the isolator HMI screen without any additional equipment.



Finally, weigh scales are often integrated into isolators. To simplify operations, especially when weighing in a relative humidity or oxygen controlled environment, the scale can be operated from the local isolator HMI screen. This eliminates the need for multiple displays.



These sophisticated controls systems are supported by GAMP documentation from Walker Barrier Systems.