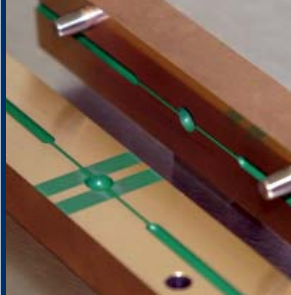


# “Clam Shell” Balloon Forming Machine

Model 2210H-CS

- Computer Interface and Data Communication
- 9” Color LCD Touch Screen Display with Tilt Adjustment
- Centralized Display of Parameters
- Multiple Temperature & Pressure Settings Per Cycle
- Electronic Output and Real Time Graphical Viewing of Forming Parameters in Lab-view or Excel
- Fast Mold Changes
- Precision Ball Screw Stretch Slides
- Pressure Profile Control During Forming Process
- Closed Loop Control of all Balloon Forming Parameters



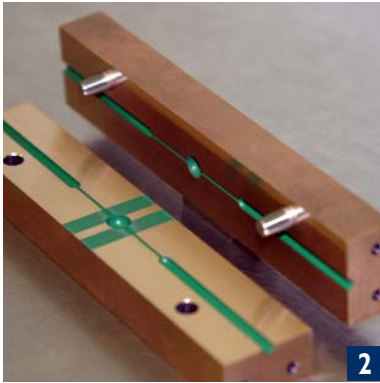
## GENERAL INFORMATION

Interface Associates’ **“Clam Shell” Balloon Forming Machine** (figure 1) is a bench-top system designed to produce a variety of high strength polymer balloons using a stretch, blow molding process. These balloons are almost exclusively used in medical procedures; such as angioplasty, stent delivery and many other dilation and occlusion applications.

The balloons are formed from precision extruded polymer tubing inside a metal mold. The forming process requires careful synchronization of heating, axial stretching and internal pressurization of the tubing. Interface Associates’ machines provide very accurate and repeatable control needed to produce high quality balloons with tight tolerances. Since the forming process is different for each balloon size and material, the machine operator must have at his disposal sufficient means to quickly set the individual parameters and arrange them in a specific sequence or program. This program is then automatically executed by the machine during balloon production.

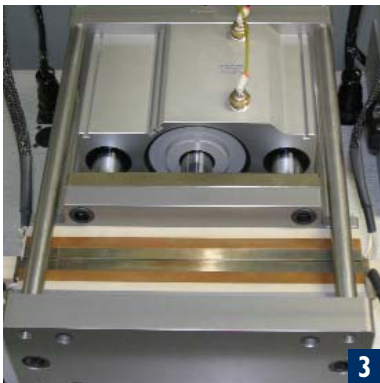
The “Clam Shell” Balloon Forming Machine, Model 2210H-CS, is closely related to our most successful product, the Computerized Balloon Forming Machine, Model 2210H. These two machines share the same chassis, computerized control system and software. The machines differ namely in the configuration of molds they are designed to work with. As the name suggests, the “Clam Shell” machine uses 2-piece radially opening molds, as opposed to 3-piece axially opening molds for the standard 2210H machine. Though there is a substantial overlap in the utility of both machines, there are certain classes of balloons that specifically require the “Clam Shell” machine features. These features are long balloons made of soft materials, soft stretchable balloons that require high neck-down and balloons made of materials that stick to the mold wall.

## “Clam Shell” Balloon Forming Machine



### MOLDS - figure 2

The balloons are formed inside a metal mold from precision extruded polymer tubing. The 2-piece mold is split into two symmetrical halves along the long axis of the balloon. This type of mold design is referred to as a “Clam Shell”. Mold opening and closing is perpendicular to the long axis of the balloon and it is controlled by a large pneumatic cylinder with precision ball bearing guides. Loading the tubing into a “Clam Shell” mold is very simple. The mold is wide open during loading, therefore threading the tubing through small openings of the mold ends is not required. This is especially beneficial when using soft and pliable polyurethane tubing to produce long balloons.



Originating the axial tubing stretch prior to mold closing will result in tubing diameter reduction. The mold halves then move together and easily close around the tubing even when the mold necks are smaller than the original un-stretched tubing O.D. At the end of the forming cycle two mold halves move apart from each other and the finished balloon is exposed. It can then be removed from the machine without any force or tugging on the balloon tails. This feature is ideal for balloons that are difficult to remove from the mold, such as long balloons or balloons made of soft materials that have a tendency to stick to the mold wall. To further alleviate the sticking problem, the mold cavity surfaces can be coated with a non-stick layer of Teflon. Unlike the conventional 3-piece mold, the “Clam Shell” mold cavity is fully exposed so the Teflon coating can be easily applied. See a separate Specification Sheet for additional details about our “Clam Shell” balloon molds.



The module that facilitates mold mounting, heating and cooling is called a “mold mount” (figure 3). Each mold half requires its own “mold mount” with its own electrical heating and water cooling connections. The “mold mount” accomplishes the following:

- a) provides sealed channel for circulation of chilled water during mold cooling
- b) provides mounting for electric cartridge heaters for mold heating
- c) allows for fast mold changes
- d) allows for fast changes from one size of “mold mount” to another

In order to accommodate a wide range of balloon sizes while maintaining efficient heating and cooling, a number of standard interchangeable “mold mounts” are available.

An optional cooling water tank and a compact water chiller can be ordered for the machine.

### AXIAL STRETCH MECHANISM

On each side of the mold closing cylinder, aligned with the balloon mold centerline, are precision ball screw slides that carry the left and right tubing clamps. The left and right ball screw slides are driven independently by powerful servomotors equipped with position feedback transducers. As the balloon tubing is axially stretched, the system has accurate information about the position and the speed of stretch. Furthermore, each stretch slide has a built-in force transducer that monitors the axial force exerted on the tubing. With such extensive information about the tubing status, the operator can perform axial stretch in multiple steps at incremental distances, varying speeds and forces, thus achieving a thinner wall thickness in the cone and neck area of the balloon.

## “Clam Shell” Balloon Forming Machine

### TUBING CHUCKS AND CLAMPS - figure 5 and 6

These devices are used to firmly grip a section of the tubing during the stretch portion of the cycle. Additionally, they must seal one end of the tube section and supply high pressure gas into it on the opposite end. The tubing chuck (figure 5) and clamp (figure 6) are installed on top of stretch slides described in the previous paragraph. Since the machine must handle a wide range of balloon sizes, Interface Associates offers a large selection of air activated chucks and clamps with interchangeable collets.

### PRESSURE CONTROL

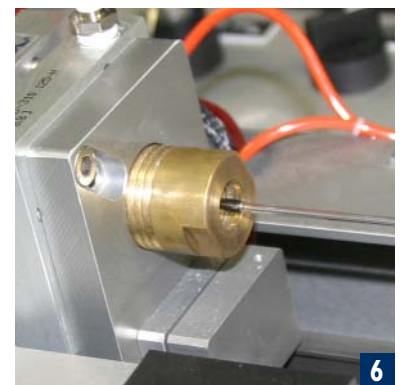
The formation of the balloon inside the metal mold is driven by high pressure gas (typically dry, pure nitrogen) that is introduced inside the stretched and heated section of the balloon tubing. The timing of tubing stretch and pressure introduction must be carefully synchronized to optimize the balloon forming process. The 2210H-CS machine uses a high speed, high pressure digital module that accurately controls the magnitude of gas pressure and gas flow into the balloon. This approach also allows for multiple pressure levels used during different parts of the balloon forming cycle.

### USER INTERFACE - figure 7 and 8

The “Clam Shell” Balloon Forming Machine utilizes an industrial grade computer to control all of its functions. It provides closed loop control of temperature, axial stretch distance and speed, stretch force and gas pressure and flow. Real time data output of all process parameters is available on a RS-232 data port. Operator inputs are through a touch-screen display panel (figure 7). The touch-screen integrates input, control and display of all machine parameters in one location. The tilt angle of the panel can be adjusted for optimum viewing clarity (figure 8). The operator can enter new parameters, manually activate individual machine functions during testing or trial runs, perform machine calibration, set limits, configure new balloon forming sequence, recall complete programs from the internal memory and up-load or down-load programs to or from an external PC computer. Multiple programs (up to 18) can be stored in the internal memory.

### DATA OUTPUT

The machines real time data output can be connected to a PC via an RS-232 cable. The individual parameters of the balloon forming process can be then viewed graphically using a program such as Visual Basics. Using empirically established criteria for the shape of the curve, the operator is then able to determine if any process adjustments are required. A complete set of balloon forming parameters for each balloon production order can be stored in an electronic format in an external data base for future recall.



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## “Clam Shell” Balloon Forming Machine

### CAPABILITIES

The machine can form balloons in shapes that are generally suitable for the stretch blow molding process in sizes from Ø1.0 to Ø26mm in diameter and 5.0 to 250mm in length. Materials such as PE, PVC, polyurethanes, polyamides (Nylon, Pebax) and PET can be processed. Due to its nearly unlimited programming capabilities, multiple temperatures and pressure levels can be used within one balloon forming cycle as well as incremental axial tubing stretch at varying speeds. These features are especially important when processing difficult-to-form balloons (large body diameter, small neck diameter, long balloon length) that require a secondary neck and cone thinning step at reduced pressure, balloon heat-setting at elevated temperature and pressure, etc.

Based on the expected range of balloon sizes, the machine is typically configured with desirable options at the time of order. Additional modules can be added as the need for new balloon sizes arise.

### SPECIFICATIONS

Power Requirements:	110 VAC, 60 hz • 220 VAC, 60 hz • 220 VAC, 50 hz *
Size:	54" L x 21" W x 20" H
Weight:	120 lbs. • 54.4 Kg
Finished Balloon Sizes:	Ø1.0 to Ø26mm by 5.0 to 250mm long
Heating Power:	Up to 3,000 Watts
Forming Pressure:	Up to 1,000 PSI (up to 6.89 MPa) Dry Nitrogen
Compressed Air:	80 - 120 PSI (.55 MPa - .83 MPa)

\* Due to many different machine configurations, wattage requirements vary