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CAPSULE CHECKER

Kunihiko Edamatsu
Koh'ichiroh Muneki
Takayoshi Makabe
Yoshio Sugiyama
Harunori Maruyama

I. FOREWORD

Automation of the pharmaceutical industry is remarkable, and the spread of the G.M.P. (Good Manufacturing Practice), concept, the official guidance of the Ministry of Welfare, and improved quality control through mechanization are expected. However, it appears that visual inspection will remain part of automated production processes. A typical example of such visual inspection is inspection of all the capsules by a female inspector for mashed end, bad joint, mashed, crack, and other defects generated when filling the capsules.

This capsule checker is a sister product of the tablet checker and many of its parts, such as the strobe lighting television camera system, 3-drum 2-row conveying system, and microcomputer judgement system, are identical to those of the tablet checker. However, the illumination method, digitizing, algorithm, etc. have special features attributable to the unique shape of capsules.

Because capsules are three dimensional, a multi-directional observation system was studied. But because of quantitative evaluation detection experiments with defective capsules, actual production line visual inspection conditions, cost-performance, etc., we developed this checker to be practical for even two-direction observation. The results confirmed the expected performances. The following outlines the operation, performances, algorithm, etc. of the capsule checker.

II. INSPECTION FUNCTIONS

Pharmaceutical companies visual inspect the capsules after filling and before shipment. Defective capsules are primarily produced during the capsule manufacturer's production process and the pharmaceutical company's filling process. The capsule checker inspects the exterior of filled capsules before printing.

Although capsules mainly consist of gelatin, a pigment may frequently be added to make them opaque and a dye may be added for coloring. Because of raw material procurement restrictions, only a few companies in the world make empty capsules. Because of the nature of the raw material, empty capsules must be stored in a stringently controlled environment. As shown in the manufacturing standards given in *Table 1*, the dimensions of the capsules must be strictly controlled because of their relationship with the mechanical precision of the filling machine.

Table 1 Standardized size of capsules

(Unit: mm)

Size	Axial length				Diameter			
	Before locking	Tolerance	After locking	Tolerance	Cap	Tolerance	Body	Tolerance
#0	23.8		20.8		7.67		7.36	
#1	21.7		19.0		6.96	±0.07	6.64	±0.06
#2	20.4	±0.5	17.5	±0.4	6.39		6.09	
#3	18.4		15.5		5.87		5.58	
#4	16.8		14.0		5.36	±0.06	5.08	±0.05
#5	12.5		11.0		4.94		4.69	

Although many types of defects are generated during the capsule manufacturing processes, the proportion of

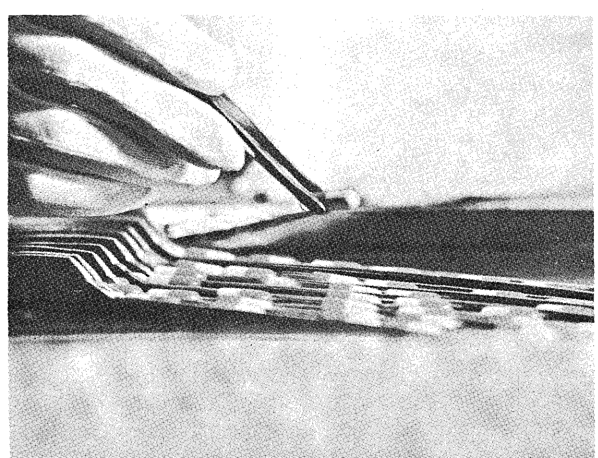
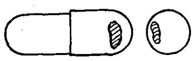
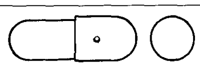
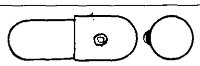
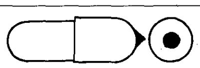
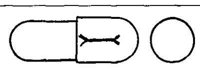
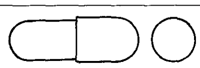
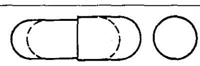
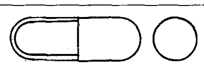
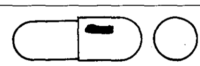
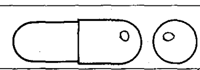
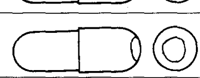
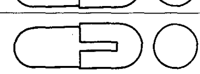


Fig. 1 Capsule inspection by human eyes

Table 2 Typical inspection items in pharmaceutical company

Appearance	Item	Contents
	Thin spot	Part of the capsule is extremely thin
	Speck	Spot of different color gelatin
	Bubble	Air bubble
	Heavy end	End of capsule is thick
	Collet pinch	Wrinkle in longitudinal direction of body
	Foreign capsule	Wrong size and color
	Long or short	Axial length is incorrect
	Double cap	Cap fits over the body
	Foreign material	Foreign matter (oil, dust, etc.) on the surface
	Hole	Hole in capsule through which the filled medicine escapes
	Crack	Cracking
	Mashed end	Part of the end of the capsule is depressed.
	Bad joint	Part of the body cut crosses and appears at the surface of the cap (including defective cutting).

defects to production run is extremely small. A female inspection removes these defective capsules by visually inspecting all the capsules.

After being filled with medicine, the capsules are visually inspected again by a female inspector as shown in *Fig. 1.* Because the capsules are circular and are inspected while being rolled mechanically, the inspector's eyes tire easily, and some inspection items become extremely difficult to detect, depending on the contents of the defect. *Table 2* lists the defect items. The most common defects produced at the pharmaceutical company are bad joint and mashed end.

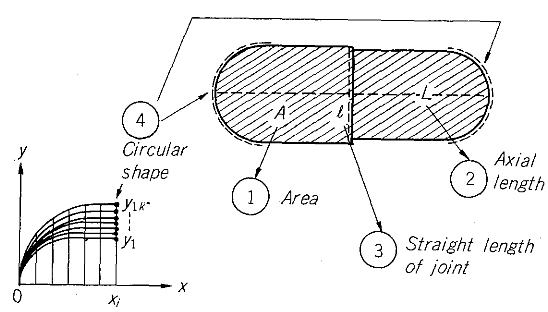


Fig. 2 Principle of defect-detection technique

III. CHECKER JUDGEMENT PRINCIPLES

The checker judges whether or not the outside of the capsule is defective from the four items, area, length, linearity, and circular shape, shown in *Fig. 2.*

1. Area

The projected area of the capsule is measured and the capsule passes when the following condition is satisfied:

$$A_{min} \leqq A \leqq A_{max}$$

Where, A_{max}: Maximum area of good capsule

A_{min}: Minimum area of good capsule

2. Length

The minimum value (X_{min}) and maximum value (X_{max}) are calculated from the left circular coordinates (X_{L_1}, X_{L_2}, ... X_{L_N}) and right circular coordinates (X_{R_1}, X_{R_2}, ... X_{R_N}). The capsule axial length L ($= X_{max} - X_{min}$) is calculated, and the capsule passes when the following condition is satisfied:

$$L_{min} \leqq L \leqq L_{max}$$

Where, L_{max}: Maximum length of good capsule

L_{min}: Minimum length of good capsule

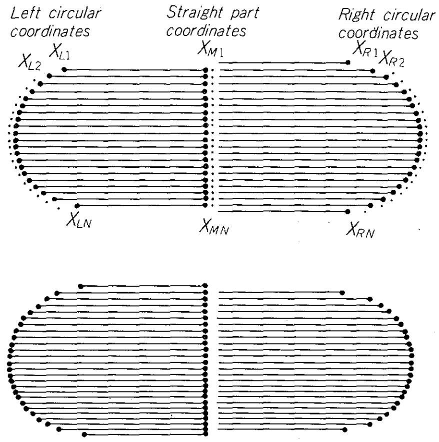


Fig. 3 Normal binary pattern

3. Linearity

The linearity of the capsule is judged from the X coordinates ($X_{M_1}, X_{M_2}, \ldots\ldots X_{M_N}$) of the joint as shown in *Fig. 3*. The capsule passes if the straight portion is normal. Since computation time is long when the linearity is judged by finding the regression equation by the least squares method, it is judged by the following method.

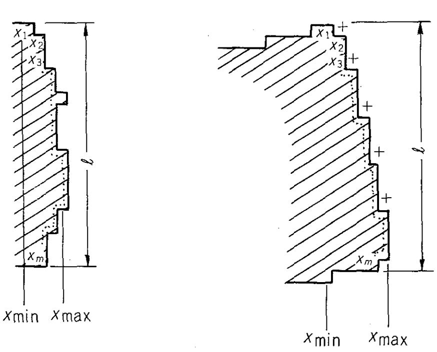
The continuous lengths $l_1, l_2, \ldots\ldots l_n$ in the Y direction at which $|X_{M_i} - X_{M_{i+1}}| \leqq \epsilon$ are calculated from the X coordinates ($X_{M_1}, X_{M_2}, \ldots\ldots X_{M_N}$) and the maximum value is made l (see *Fig. 4*). If the maximum value and minimum value of the X coordinates of $l\,(x_1, x_2, \ldots\ldots x_m)$ are made $X_{\max}$ and $X_{\min}$, when $(X_{\max} - X_{\min}) \leqq \delta$, the straight part is judged to be perpendicular and the capsule passes when the following condition is satisfied:

$l_{\min} \leqq l \leqq l_{\max}$

Where, $l_{\max}$: Maximum value of straight part of good capsule

$l_{\min}$: Minimum value of straight part of good capsule

When $(x_{\max} - x_{\min}) > \delta$, the straight part is judged to be slanted, whether or not $l\,(x_1, x_2, \ldots\ldots x_n)$ is a monotone increase (decrease) is computed and whether or not it is linear is judged from the rate of this increase (decrease).



(a) Perpendicular joint (b) Sloped joint

Fig. 4 Part of joint

4. Circular Shape

The left circular coordinates ($X_{L_1}, X_{L_2}, \ldots\ldots X_{L_N}$), right circular coordinates ($X_{R_1}, X_{R_2}, \ldots\ldots X_{R_N}$), and other data are processed, the shape of the semicircular body and cap is inspected, and whether or not the capsule passes or fails is judged.

For instance, the end coordinate, that is, the maximum value, of the right circular coordinates (X_{R_N}) is found and the 1/4 circle cap at the top and bottom shown in *Fig. 5* is calculated with this coordinate as the standard.

Next, the vertical symmetry of the 1/4 circle cap is compared against the standard curves and whether the capsule passes or fails is judged. There are "k" standard curves as shown in *Fig. 2*. The standard curve is selected with the value of the ith value of the calculated curve and comparison and judgement are performed. Whether the left circle coordinate values pass or fail is judged similarly.

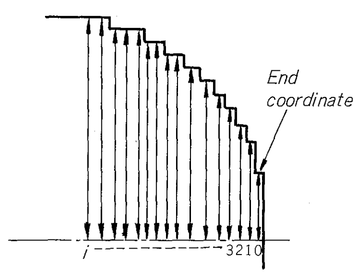


Fig. 5 Part of right circle

IV. CONSTRUCTION AND OPERATION

Fig. 6 shows an exterior view of the checker. As shown in *Fig. 7*, its configuration resembles that of the tablet checker. The capsules are observed and judged from two directions.

1. Configuration

As shown in *Fig. 7*, the checker consists of a mechanism section and a control section. These sections consist of the following:

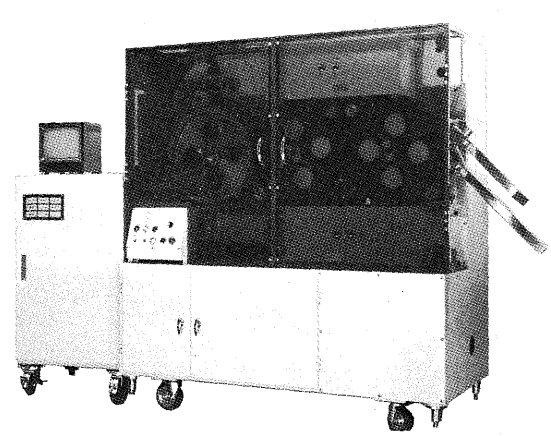


Fig. 6 Capsule checker

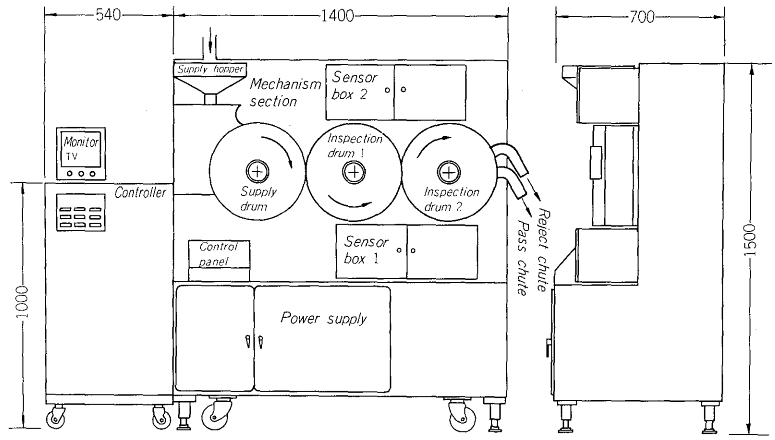


Fig. 7 Configuration of checker

1) Mechanism section
   (1) Supply hopper: Stores the uninspected capsules.
   (2) Supply drum: Arranges the capsules in two rows.
   (3) Inspection drums 1, 2: Inspect the front and rear of the capsules.
   (4) Eject section: Ejects the good and defective capsules according to the results of judgement.
   (5) Sensor box 1, 2: Contains the television camera and strobe light and photographs the capsules.
   (6) Control panel: Normal operation.
   (7) Power supply: Strobe power supply, relay panel, calendar timer, etc.
   (8) Drive system, etc.: Drive motor, vacuum blower.
2) Controller
   (1) Preprocessor: Video signal switching, binary encoding, noise cleaning, abnormal light detection.
   (2) Identification section: Arithmetic processing, judgement, control.
   (3) Mass trouble display: Various alarm display.
   (4) Auxiliary control panel: Testing, adjustment, maintenance.

2. Operation of Mechanism Section

Referring to *Fig. 7*, the supply drum arranges the capsules supplied to the hopper into two rows to facilitate observation by the television camera and transfers the capsules to inspection drum 1. When the capsules are carried into the field of view of the television camera in sensor box 1, they are sensed by the position sensor and one side (front) of the capsule is immediately observed with the light beam of the strobe. Next, the capsules are carried from inspection drum 1 to inspection drum 2 where the opposite side (rear) of the capsule is observed by the television camera in sensor box 2. The results of observation are processed by the microcomputer at the controller and pass/fail judgement is performed. The results for the two sides (front and rear) are combined, and if the capsule is good, it is ejected from the pass chute and if it is defective, it is ejected from the reject chute by air.

Moreover, the time interval of the position sensor signals is constantly measured, and if jamming (mechanical trouble) should occur, the change in this interval is detected, the drum is immediately stopped, and an alarm is

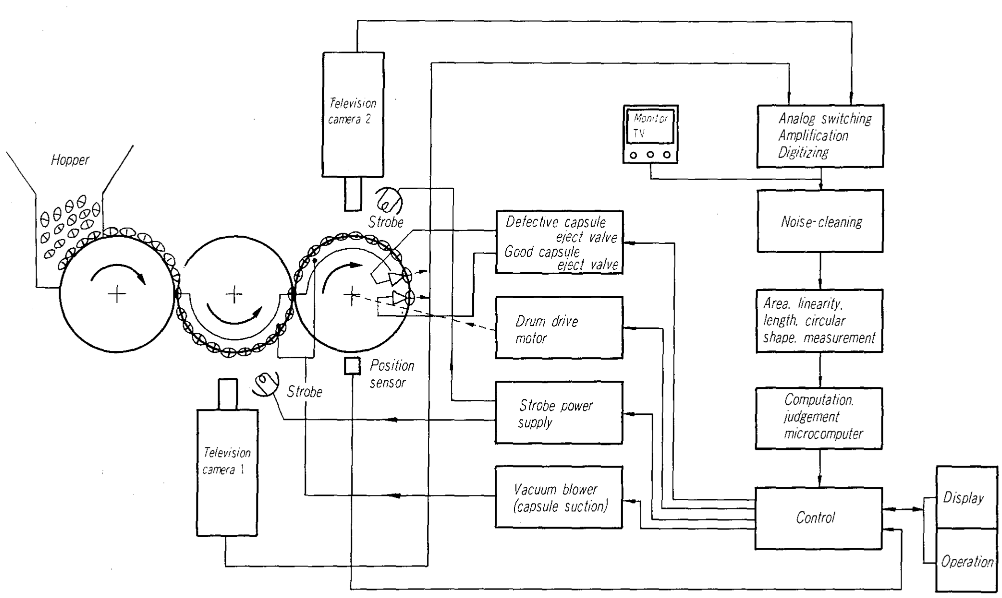


Fig. 8 Block diagram of checker

displayed at the mass trouble display.

3. Operation of Controller

Operation of the controller is described in accordance with the block diagram in *Fig. 8*.

1) Preprocessing

The video signals from television cameras 1 and 2 are binary coded by switching them with an analog switch corresponding to the time of the position sensor.

After the image signal is differentiated, it is logically processed to a defect signal. The shape signal is binary encoded by the fixed-level thresholds method. The defect binary signal and shape binary signal are combined to produce the image binary signal which is input to the two-dimensional local memory and processed.

Processing capacity is increased by observing two capsules, top and bottom, such as the binary pattern in *Fig. 3*.

2) Noise-cleaning circuit

The image binary signal is divided into 320 x 240 image elements, input to a two-dimensional local memory consisting of spiral shift registers and noise cleaning is performed by the circuit shown in *Fig. 9*.

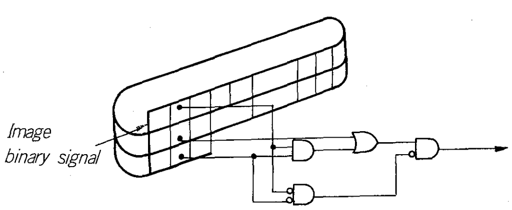


Fig. 9 Circuit of noise-cleaning

3) Data storage

The coordinate values of the end of the rise of first segment of the horizontal scan is made the left circular coordinate values ($X_{L_1}, X_{L_2}, \ldots\ldots X_{L_N}$). When there is only one segment during one horizontal scan period, the coordinate value of its falling end are stored as the right coordinate values ($X_{R_1}, X_{R_2}, \ldots\ldots X_{R_N}$) and when there are two or more segments during one horizontal scanning period, the coordinate value of the falling end of second segment is stored.

The coordinate values of the falling end of first segment are stored as the linear coordinate values ($X_{M_1}, X_{M_2}, \ldots\ldots X_{M_N}$).

These coordinates are stored directly on an RAM in DMA (Direct Memory Access) mode during the vertical scanning period (1/60 sec).

4) Microcomputer

Two 8 bit microcomputers perform pass/fail judgement from the contents of the RAM storing the data by means of the algorithm described in section **III**. The main computer controls collation of the judgement results of the front and rear sides of the capsule, output of the defect reject signal, etc. while judging the area, linearity, etc. The sub microcomputer judges the length, circular shape, etc. and posts the judged results to the main microcomputer by I/O.

The address bus and data bus are connected by a selector switch so that the contents of the RAM of the sub microcomputer can be directly read from the main microcomputer. Therefore, the main microcomputer can read the length, circle, and other data.

5) Others

The number of selected good and defective capsules can be counted and displayed. Moreover, besides display of the area, length, circle data, linearity data, defect cause, etc., they can be statistically processed and their mean value, maximum value, minimum value, standard deviation, frequency distribution, etc. can be calculated and displayed.

Table 3 Specifications of capsule checker

	Item	Contents
Inspection performance	Number of image division	320 (horizontal) x 240 (vertical)
	Resolution	0.1mm square (for 32mm x 24mm field of view)
	Processing speed	16 capsules/sec
	Detectable defects	All the defects listed in *Table 2*.
	Inspection standard	Switchable from low sensitivity to high sensitivity by changing PROM setting.
	Applicable capsules	Capsules having the dimensions given in *Table 1* by changing the drums.
	Illumination check function	Overlighting, underlighting check
	Eject	Capsules are ejected from pass and reject chute by air.
Environment	Power requirement	AC 200±15V, 50/60±1Hz, 3-phase
	Air source	5kg·G/cm²
	Temperature	15~30°C (operating)
	Humidity	30~70% (operating)
Others	Noise	80dB or less
	Drum filling rate	83% or greater
	Supply system	Outside supply

V. CHECKER SPECIFICATIONS

Table 3 gives the main specifications of the checker.

VI. FEATURES

Besides stable selection with fixed standards, this checker also features:

(1) Processing speed of 16 capsules/second.

(2) 0.1 mm square resolution (32 mm x 24 mm television camera field of view).

(3) Capsules of various dimensions can be inspected by changing the drums.

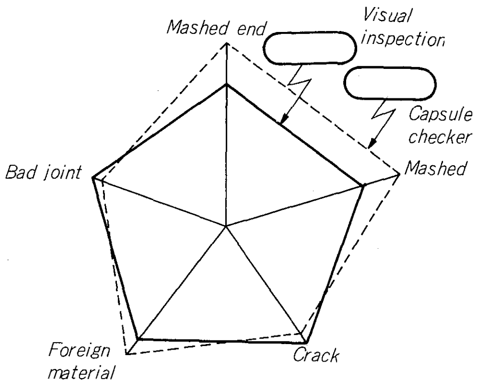


Fig. 10 An example of test results

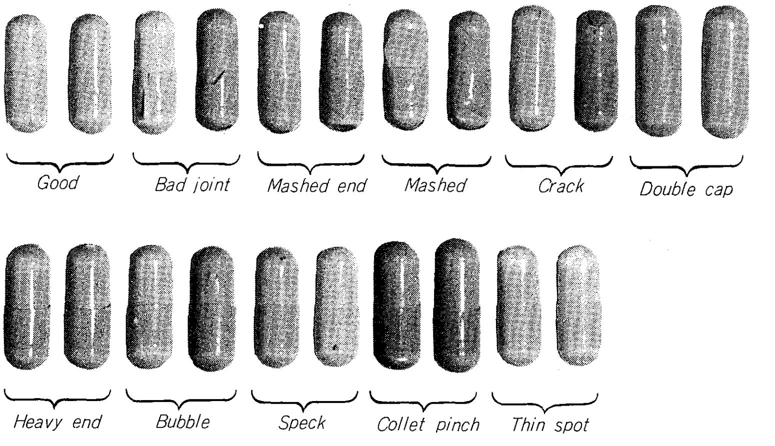


Fig. 11 An example of sample capsule

(4) Since the trouble cause is displayed and the checker is automatically stopped when trouble occurs, unmanned operation is possible.
(5) Various safety devices make it easy to handle by female workers.
(6) Judgement standard can be changed from low sensitivity to high sensitivity by changing the PROM settings.
(7) Image signal is monitored and whether or not the strobe light is suitable is judged. Strobe firing is also checked, and when abnormal, an alarm signal is generated.
(8) If jamming occurs, it is detected and the checker is automatically stopped.
(9) Since empty defective judgement is continuous when the hopper becomes empty, the checker is automatically stopped.

VII. APPLICATION EXAMPLE

This checker was used to inspect size No. 1 capsules having a cap and body of the same color (ivory white). *Fig. 10* compares the reject rate of the checker and the reject rate by visual inspection for the main defect items.

The number of defective samples was approximately 100~200 for each defect item and were taken from the same lot for both visual and checker inspection. *Fig. 11* is an example of defective samples. The results of visual inspection by a female inspector of a pharmaceutical company at the normal line speed were used.

The inspection performances of the checker were compared with the inspection performance by visual inspection as described above and can be said to be almost the same.

VIII. CONCLUSION

The judgement algorithms were studied with a computer system developed for exterior inspection and quantitative detection experiments were conducted with multi pattern recognition equipment. From the results of these studies, a speed of 16 capsules/second was obtained by speeding up the processing time by changing part of the software to hardware and doing the computations with two microcomputers, etc. The results of comparison with visual inspection on an actual line proved that the inspection performance of the checker is equal to that of a human inspection. With the cooperation of all users, we expect the application of this checker to increase in the future.

Finally, we wish to thank all those at the Production Engineering Research Laboratory of Sankyo Co., Ltd. (a big pharmaceutical company in Japan) for their guidance and cooperation in the development of this checker.