

Approved by
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Clinical trial protocol of RTM-01-RES

(Moscow)

Basis: Permission of ГБМУ # 161/7/2/6245 of 26.11.98

In the Radiological Centre of the Burdenko Major Military Hospital from 17 October to 21 December 2000 the clinical trial of the RTM-01-RES was conducted.

The purpose of the trial was to evaluate the possibility to use the RTM-01-RES diagnostic system to detect breast cancer and select risk patients in the military hospitals. During the trial 51 women were examined.

All patients underwent independent CBE, ultrasound, mammography and RTM-Diagnosis. Final diagnoses were based on the pathologoanatomic investigation. The patients can be divided into the following disease groups:

Table 1

Disease	Number of Patients	Coincidence of Diagnoses	RTM-Diagnosis
Breast cancer	16	13	3 - risk group
Fibroadenoma	6	4	2 - thermogram has features of breast cancer
Proliferative Fibroadenoma	1	1	-
Mastopathy	26	23	3 – risk group
Cyst	2	1	1 – the thermogram has features of breast cancer
Total:	51		

It should be noted that RTM-Diagnosis missed no cancer.

Conclusion: RTM-01-RES is recommended to be used for screening, diagnosis of breast diseases and monitoring the treatment in hospitals and health centres of the Ministry of Defence.

Signed by K.A.Teterin

Chief radiologist and Head of the Radiological Centre of the Burdenko Major Clinical Hospital

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